Health & Population Department
PROVINCIAL QUALITY CONTROL BOARD, PUNJAB.

289 Meeting of PQCB

Date: 27-03-2025

Time: 11:00 AM

Venue

COMMITTEE ROOM OF DIRECTORATE GENERAL HEALTH SERVICES, PUNJAB, 24-COOPER ROAD, LAHORE.

TABLE OF CONTENTS

- MSS-177698,177699/2023 (Case Id: 0000130021)
- **Case No. 9**
- MSS-178849,178850/2023 (Case Id: 0000131002)
- **Case No. 10**
- MSS-176662/2023 (Case Id: 0000129149)
- **Case No. 11**
- PQCB/MSS-185879/2024 (Case Id: 0000138166)
- **Case No. 12**
- PQCB/MSS-193304/2024 (Case Id: 0000146420)
- **Case No. 13**
- PQCB/MSS-212454-212455/2024 (Case Id: 0000174150)
- **Case No. 14**
- PQCB/SM-03-04/2021 (Case Id: 0000162221)
- **Case No. 15**
- PQCB/R-687/2021 (Case Id: 0000060331)
- **Case No. 16**
- PQCB/R-686/2021 (Case Id: 0000060330)
- **Case No. 17**
- R-490/2023 (Case Id: 0000102445)
- **Case No. 18**
- MSS-191440/2024 (Case Id: 0000144395)
- **Case No. 19**
- 167981 (Case Id: 0000119667)
- **Case No. 20**
- R-511/2023 (Case Id: 0000114248)
- **Case No. 21**
- PQCB/R-477/2021 (Case Id: 0000054328)
- **Case No. 22**
- PQCB/MSS-207336/2024 (Case Id: 0000167919)

- **Case No. 23**
- SM-18-08/2023 (Case Id: 0000073591)
- **Case No. 24**
- 200223/2024 (Case Id: 0000156457)
- **Case No. 25**
- MSS-183004/2024 (Case Id: 0000135103)
- **Case No. 26**
- SM-15-07/2021 (Case Id: 0000187866)
- **Case No. 27**
- PQCB/R-383/2021 (Case Id: 0000061197)
- **Case No. 28**
- MSS-171486/2023 (Case Id: 0000123287)
- **Case No. 29**
- PQCB/R-800/2021 (Case Id: 0000057442)
- **Case No. 30**
- PQCB/MSS-171054/2023 (Case Id: 0000122781)
- **Case No. 31**
- PQCB/MSS-174268/2023 (Case Id: 0000126480)

ITEM No. 1

REGULAR CASES

Case No. 1

PQCB/ MSS-192925, 192926/2024

Tehsil and District Bahawalnagar

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Managing Director, M. Muzammil Nazar 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil and District Bahawalnagar, reported that: -

i. He, on 22-02-2024, inspected the premises of Main Medicine Store, O/o Chief Executive Officer (DHA), Bahawalnagar, took three different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug samples to Drug Testing Laboratory, Bahawalpur.
ii. The subject drug samples, sent vide memo no. 192925 and 192926, dated: 23-02-2024, after test/analysis were declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Bahawalpur**, as detailed below:

Sr #	**Name of drug**	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**
1	Suspension Parapol Paediatric Suspension 120ml [Paracetamol 120mg/5ml. 120ml] **Mfg. date: 11-2023** **Exp. Date: 11-2025** **Reg # 002772**	179-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-20101000088/DTL Dated: 07.06.2024
	Specs Applied: USP 2024/Others/In house			

COMPOSITION: Each 5ml contains:

Paracetamol USP…. 120mg

PHYSICAL CHARACTERISTICS:

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles,** filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.***

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9

Determined: 5.4 @ 23.4ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml

Determined 122.50 mg/5ml (102.08%)

Limit 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol: Limit: NMT 0.1% Determined: Not Detected	**Diethylene Glycol:** Limit: NMT 0.1% Determined: Not Detected
Propylene Glycol Determined: 10.815%	

Note: The extension is granted via PQCB order no. **PQCB/TEX-BWP-38/2024** Dated 21-05-2024

RESULT: The Sample is declared as **"SUB-STANDARD"** on basis of Physical Characteristics.

2	Suspension Parapol Paediatric Suspension 120ml [Paracetamol 120mg/5ml. 120ml] **Mfg. date: 11-2023** **Exp. Date: 11-2025** **Reg # 002772**	178-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-20101000087/DTL Dated: 07.06.2024

SPECIFICATION: USP 2024/Others/In House

COMPOSITION: Each 5ml contains:

Paracetamol USP…. 120mg

PHYSICAL CHARACTERISTICS:

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles,** filled in an amber plastic bottle, sealed with a white screw cap, further **packed** in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."***

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9

Determined: 5.4 @ 23.6ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml

Determined 123.97 mg/5ml (103.31%)

Limit 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**

Limit: NMT 0.1% Determined: Not Detected	Stated: NMT 0.1% Determined: Not Detected
Propylene Glycol Determined: 9.33%	

Note: The extension is granted via PQCB order no. **PQCB/TEX-BWP-38/2024** Dated 21-05-2024

RESULT: The Sample is declared as **"SUB-STANDARD"** on basis of Physical Characteristics.

iii. Store Keeper, Main Medicine Store, O/o Chief Executive Officer (DHA), Bahawalnagar, provided invoice/ warranty No. 000649 dated 13-02-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi., as a proof of its purchase

iv. Warrantor portions of drug samples were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. Copies of test/analysis reports were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug samples from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its **42nd Committee meeting** held on **30-07-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request for retesting.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/ Sale of Substandard Drug**
b. **Issuance of false warranty**

3. Show cause/Personal hearing Notice notice(s) issued to the accused persons(s) dated 11-11-2024.
4. The firm submitted review petition against 42nd committee meeting orders dated 30-07-2024 vide letter no. Nil dated Nil (Received on 06-11-2024).

GROUNDS OF REVIEW PETITION:

SUBJECT: REVIEW PETITION UNDER CLAUSE 2 OF PART VIII OF THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We M/S Lisko Pakistan (Pvt) Ltd Petitioner Company" would like to submit instant review petition before the learned Provincial Quality Control Board. Puniab against the order of committee PQCB dated 20-09-2024 (the "impugned Decision") in which request of re-testing from NIH, Islamabad has been turned down (orders attached) for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspector of Drugs, BAHAWALNAGAR (the "Respondent Drug Inspector") has been directed to expedite Investigation so that permission for prosecution can be granted.

There are several grave infirmities and ambiguities in DTL reports "Impugned reports" issued by government analyst of DTL Bahawalpur and also in decision "Impugned Order by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, It is pertinent to highlight the fresh grounds that have arisen in the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. Committee PQCB has turned down request for retesting from NIH, Islamabad with the statement which itself contains several ambiguities and infirmities “the committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate the formulation with respect to bitter in taste and propvlene glvcol concentration hence unanimously decided to turn down the retesting request of the firm"

A) Government analyst has not declared samples substandard on the basis of concentration of propylene glvcol rather it has been declared substandard on the basis of physical characteristics (Bitter taste and absence of solid particles as per USP <1151>). Once appeal for retesting has been submitted against impugned Reports and errors are being highlighted by the firm, committee PQCB can only Scrutinize grounds on the basis of which samples have been declared substandard but cannot introduce new grounds or raise additional issues in DTL report by their own if they were not shown as noncompliant by the government analyst In the initial report. Drug act 1976 and other existing laws have clearly defined duties and limitations of both government analyst and PQCB. Members of committee PQCB initiated discussion i.e. toxicity due to propylene glycol, role of propylene glycol to solubilizing Paracetamol without having conclusive evidences and turned down appeal for retesting by relying on this premise. Therefore, all discussion in impugned order related to propylene glycol is unlawful and illegal and cannot be relied as ground on the basis of which appeal has been turned down.

B) It is pertinent to highlight that in our previous meetings of committee PQCB, when we requested to kindly evaluate our sample, committee members PQCB was of the opinion that product sample cannot be evaluated & tested in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIH Islamabad for conclusive report.. However, opinion of the committee PQCB regarding the same product has suddenly been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product, samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions.

C) Firm's representative never agreed with the findings of government analyst (bitter in taste and free from any dispersed solid particles) rather firm's representative always claimed that Parapol suspension ensure a palatable profile that supports patient compliance and also claimed presence of dispersed solid particles in Parapol suspension. However, firm's stance has been improperly and incompletely stated in the "impugned order"

D) Firm's claim regarding presence of dispersed particles and palatable taste profile can only be verified if samples will be sent to NIH, Islamabad for the conclusive and fair report. However, same has not been done and appeal for retesting has been turned down in slipshod manner without verifying firm's claim and arguments.

2. It is pertinent to highlight that since October 2023, our product "Parapol suspension" has been subjected to targeted victimization, with test results from various DTLs influenced by external factors. This interference has led samples of Parapol suspension being improperly classified as substandard based on invalid, impermissible, and non-pharmacopeial grounds despite of the fact that there being no quality issue and product complied in all applicable USP tests. The targeted Victimization and unfair treatment by Punjab DTLs toward Parapol is further evidenced by an incident involving the Drug Testing Laboratory in Bahawalpur. On 09-03-2024, DTL Bahawalpur, initially declared Batch No. 178-24 and 179-24 of Parapol suspension as standard quality and uploaded the corresponding reports on their portal. However, these standard reports were subsequently removed due to external pressures, and substandard reports for the same batches were uploaded Several months later. This suspicious & doubtful act of DTL Bahawalpur emphasizes the need for an unbiased and fair analysis, which only NIH Islamabad, as an appellate laboratory, can provide for reassessment of the Samples. Furthermore, is also important to highlight that committee PQCB did not give satisfactory reasons and grounds on the basis of which honorable committee members of PQCB showed reliance and trust on the Sub-standard" reports by the government analyst while same batches were declared “standard" on 9-3- 2024 by DTL Bahawalpur.

3. It is very important to highlight and note that government analyst maliciously used reference of WHO working document (QAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely impermissible and hence makes report invalid. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining

the concentration of propylene glycol.

4. The government analyst has stated that the samples of Parapol suspension are “bitter in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

5. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited "USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. Samples of Parapol suspension were declared substandard based solely on personal observation (bitter taste) without conducting chemical analysis for accurate and instrument based identification of sweetener in the composition

6. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house / others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on ' In- house/other specifications' renders the report invalid and inaccurate

7. The government analyst has wrongfully claimed the products to be a "liquid" and free from any dispersed solid particles despite the same being a suspension. Government analyst has quoted reference of USP general chapters <l151> for showing non-compliance. However, it is important to highlight that USP general chapters <1151> on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to classify product as suspension, solution or syrup. Same has been confirmed in letters by NIH Islamabad dated 6-6-2024 and 29-8-2024 to POCB as below:

i) Letter dated 6th June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any Such test on the basis of which the samples are declared sub-standard by DTLs of Punjab"

ii) Letter dated 29th August 2024 "It is once again informed that USP monograph for Acetaminophen oral Suspension have different tests including test from the general chapters ie performance test (uniformity of dosage units 905, deliverable? Volume - 698, impurities 4- Aminophenol in Acetaminophen containing Drug Products, 277). Specific test (p 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the and The USP samples were declared substandard by DTLs Punjab General Chapter <I151> on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply". The foregoing infirmity makes the report invalid and baseless.

8. "It is pertinent to note that the esteemed Punjab Quality Control Board (PQCB) previously investigated the matter regarding the presence or absence of particles in Parapol suspension by constituting a special committee comprising five pharmaceutical experts, including two respected members from PQCB. The honorable members of this special committee conducted a thorough examination of the samples and reached conclusions in our favor, affirming our claim that Parapol qualifies as a 'suspension.' The committee's findings explicitly stated that Parapol is a 'biphasic liquid-like suspension' with a translucent appearance due to the presence of visible particles (a copy of the expert committee's findings is attached).

However, contrary to this initial finding, the same committee members, who were previously convinced of the presence of solid particles in Parapol suspension, subsequently disregarded these findings. They participated in the disputed decision "impugned order" that denied our request for retesting and upheld the remarks of the government analyst, who asserted that Parapol suspension is free from dispersed particles and does not comply with USP <1151>.

9. Government analyst has mentioned in form 7 «S.No# 6 that “USP 2024 / In-House / Others" has been applied. However, it is pertinent to highlight that neither USP 2024 nor method of analysis (In-House) of Parapol suspension provided by the firm

gives any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension / solution / syrup. Therefore, Product Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

10. Since Parapol suspension was being declared of standard quality by DTL Bahawalpur till 10-10-2023 this proves that till this date, as per analysts of DTL Bahawalpur, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Bahawalpur must have received a revised and new method of analysis from the firm after 10-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 10-10-2023 which proves malice intention and act of victimization by government analyst.

11. In continuation of Point no# 1, in which few flaws and inaccuracies in the impugned order made by the committee PQCB were highlighted, we would further like to add more infirmities in the order in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. It is to be noted that point of discussion regarding toxicity and side effects of higher concentrations of propylene glycol is inapplicable and inappropriate when government analyst categorically admitted in committee meetings that method applied to determine exact concentration of propylene glycol is not as per WHO reference document rather it has been derived from it. Firm's claim of addition of less than 1% propvlene glycol has been completely overlooked in the impugned order and no scrutiny was carried out by the committee PQCB to verify firm's claim. Firm stated in every committee meeting before honorable board that we are supplying same product with the same formulation across Pakistan for decades and millions of children have safely consumed this product to alleviate pain and fever without any reported clinical toxicity. Despite this, the PQCB committee exhibited an unfair approach by relying on the impugned results of the government analyst, who determined the concentration of propylene glycol using a non-reliable and non-pharmacopeial method.

b. On what basis and in what capacity did Mr. Ijaz Alvi, Director of DTL Rawalpindi, present his views regarding the toxicity of propylene glycol before the committee, given that the impugned reports pertain exclusively to DTL Multan? It is to be noted that Mr liaz Alvi is not part of committee PQCB and firm has no faith on him as he is part of malicious campaign against our product. This raises concerns about the impartiality of the Process and suggests a coordinated effort by all DTLS of Punjab to unfairly target the product 'Parapol' without relying on legal facts and objective findings.

c. How and on what grounds committee members got convinced by views of Director, DTL Rawalpindi and Government Analyst, DTL Bahawalpur in which they were trying to establish a view that firm has solubilized paracetamol in propylene glycol without counter verifying it with firm’s claim?. Firm has already provided list of excipients with quantities before the committee POCB in which it was mention that firm added propylene glycol less than 1% in the formulation of Parapol Suspension only with the purpose as stabilizer and as preservative. Firm's representative comprehensively explained that it is practically impossible to solubilize paracetamol in an amount of propylene glycol and water that has been used in the formulation of Parapol suspension. Nevertheless, the PQCB Committee chose to accept the unverified personal opinions of the individuals mentioned and issued a biased decision without validating the firm’s assertions.

d. Question i.e. testing of propylene glycol in finished product duly raised by the committee members is inaccurate, as firm is not bound to test excipients in finished form neither does tested by any DTL of Pakistan. Firm is always well aware of the fact that how much amount of any excipient is being added in formulation and as per GMP guidelines, all excipients are being consumed once passed initially from quality control department. Moreover, Specs claimed for Parapol suspension is USP and firm carries out all applicable test as per USP which specifically provide testing of API in a finished product only. Despite of the fact, committee POCB turned down our appeal for retesting to prevent us from the right of justice.

e. The quality of propylene glycol as a raw material, along with its associated standards, cannot be questioned or used as grounds for denying the request for re-testing. The impugned DTL reports themselves acknowledge compliance with the WHO reference document and confirm the absence of impurities such as EG and DEG, which demonstrates that the quality of the propylene glycol used was fully compliant and without any issues. Furthermore, under the latest DRAP guidelines, propylene glycol cannot be released for use unless tested by federal laboratories. The firm has consistently stated in all meetings that the propylene glycol used in the batches of Parapol suspension was tested and approved by the Central Drug Laboratory (CDL) in Karachi prior to its consumption.

Additionally, we would like to highlight grounds comprehensively which have already been discussed in difference committee meeting that further supports our stance in said case:

1. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:
"It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 {Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976}"

In this regard, committee POCB was duty bound to consider the foregoing facts whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

2. The malafide intentions of the Government Analysts and Director DTL Bahawalpur are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 76 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

3. Since, product “"Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe /instruct to conduct test for determination of the taste of the products or test to classify product as syrup solution or suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopeial testing.

4. It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc.) of the "finished form" of the drug. In this context, the Products, like all other drugs, underwent a comprehensive manufacturing process wherein in addition to the active pharmaceutical ingredient; several other excipients were also added. Additionally, tests are prescribed in the specifications to ascertain the quality of a "finished form of drug". Thus, only tests that could have been performed by the government analyst were those prescribed in the USP and any additional information sought in relation to the excipients and or other ingredients or any testing carried out on the basis of the same is illegal and unlawful.

5. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the Samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the Substandard drugs". However, in our case, government analyst has shown her malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

6. Section 3(z) of the Drugs Act, 1976 defines the term specifications as.

(i) such specifications as may be prescribed;

(ii) or when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:-

(1) the Pakistan Pharmacopoeia;

(2) the International Pharmacopoeia;

(3) the European Pharmacopoeia;

(4) the United States Pharmacopoeia;

(5) the British Pharmacopoeia;

(6) the British Pharmaceutical Codex;

(7) the United States National Formulary; and

(8) Such other publication as may be prescribed:

In terms of the legislative scheme envisioned under the Drugs Act, 1976, more particularly, Section 3(zz) a drug shall only be deemed as substandard if it does not comply with the applicable specifications. Essentially, such determination can only be made if the drug fails to comply with the tests "prescribed" under the applicable specifications. The monograph of a drug provided under the applicable specifications lists down the requisite tests that need to be conducted in order to determine whether the drug is of standard quality. It is a matter of fact that the Drugs Act does not permit analysts to carry out inapplicable tests or tests, which have not been listed down in the applicable specifications. However, in context of the present case, the Government Analysts have malafidely declared the batches of the Product as substandard on the basis of their bitter taste & absence of solid particles without there being any criteria or test to determine the same. The foregoing action clearly constitutes a violation of the Drugs Act, 1976 as well as Rule 16 of The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal

Government Analysts) Rule 1976.

In the light of above highlighted facts and infirmities, it can be concluded that committee PQCB has failed to scrutinize the case properly as it has overlooked above evidences and factual findings. The illegalities floating on the record of the case and as mentioned in above grounds have been completely overlooked and no heed has been paid to the wrongdoings of the government analyst who has declared the Products to be of substandard quality on a completely wrongful premise. t was mandatory upon this committee PQCB to properly scrutinize the subject especially in this case when samples comply with the stated specification chemically and physically and adjudicate upon the same. However, no such exercise has been carried out in the present case. Furthermore, it is to be noted that our firm petitioner Company" and its officials have not contravened the provisions of the Drug Laws and the rules made thereunder rather they are committed to ensure compliance thereof. PQCB passed an impugned order (turning down request for retesting) which completely disregard not just of the principles of fair trial and due process envisioned under Article 10-A and Article 4 of the Constitution but also disregard of the scheme of law envisioned under the Drugs Act, 1976 as-well as the fundamental rights of the Petitioner Company enshrined under the Constitution of Islamic Republic of Pakistan, 1973.

On the premise of foregoing submission and grounds highlighted above, it is mandatory and essential for the learned Board to review its decision. We reserves the right to agitate additional grounds at the time of arguments if needed. We as “Petitioners" are seeking the setting aside of the Impugned Decision in terms of clause 2 of Part VIII of the PQCB Regulations and pray as below:

PRAYER

In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:

i. Set aside the Impugned Order in which committee PQCB turned down appeal for re-testing and directed Provincial Inspector of and Drugs, BAHAWALNAGAR, to expedite investigation submission of final report.

ii. Pass an order for the samples of Suspension Parapol Batch No. 178- 24 and Batch No. 179-24 to be sent to the National Institute of Health, Islamabad and allow retesting of samples for the conclusive report.

iii. Direct the government analyst of the Drug Testing Laboratory, Bahawalpur to bring the method and protocols of the test employed to determine the taste of the Suspension and test to determine presence or absence of particles in suspension.

iv. Share transparent findings, causes and measures against the incident in which DTL Bahawalpur issued standard report for Batch No. 178-24 and Batch No. 179-24 and reports were removed later on and sub-standard reports were issued for same batches.

v. Permanently restrain the Provincial Inspector of Drugs, BAHAWALNAGAR from taking any adverse and/or coercive action against our firm “Petitioner Company" and against our officials based on the Impugned order / decision.

We hope that learned board will allow us to avail right of fair trial and accept above mentioned prayer.

5. Personal Hearing notice(s) issued to accused person(s) dated 01-01-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, vice-chairperson PQCB. Ms. Taiba Aslam Secretary DQCB Bahawalnagar attended the meeting online via zoom link and Mr. Muhammad Yahya Provincial Inspector of drugs Tehsil & District Bahawalnagar was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeial test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary individual to individual basis and there will be no toxicity or adverse effects due to bitter taste
ii. We are confident that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension”.
iii. As far as declaring our samples substandard declaring them to be “free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iv. He further added that although the DTL has quantified Propylene Glycol in the test report but failed to mention the limit and to specify whether it complies or not with any official monograph.
v. He further reiterated firm’s request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting.

7. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 178-24 & 179-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Bahawalpur on the basis of physical description as “ Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles**” further reporting that “As per USP <1151> Pharmaceutical Dosage Forms; “*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*” while in actual the sample is clear viscous solution”. Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 14-06-2024 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was turn down in 42

nd Committee meeting of the Board held on 30-07-2024. Whereas, the re-submitted retesting request by the firm in its review petition received on 06-11-2024 cannot be accepted and hence, is turned down and previous decision taken in 42nd Committee meeting dated 30-07-2024 is upheld. Regarding firm's review petition against retesting orders and the plea to send their subject batches to NIH for retesting, the Board observed that in 279th meeting held on 24-04-2024, the Board sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976.

8. However, Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

9. While perusing the case record, the Board remarked that the samples in question were declared substandard on the basis of physical description as per General Chapter <1151> of the USP and bitter taste of suspension by the Government Analyst DTL Bahawalpur. The firm claims the product as "Suspension" on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Bahawalpur. Furthermore, regarding bitter taste of the suspension, the Board was of the view that the product has been developed for pediatrics use and bitter taste of suspension as reported by the DTL in the subject reports, will result in non-compliance and reluctance to take medication by children.

10. The Board further observed that the DTL also determined the percentage of Propylene Glycol as 10.815% w/v & 9.33% w/v in the batches under consideration by applying WHO Working Document QAS/23.922/rev3 Dated 31 October 2023.

Acceptable Dietary Intake of Propylene Glycol				
EMA		**50mg/kg/day**		
WHO		**25mg/kg/day**		
Batch No.	**PG Determined (as per DTL Report)**	**PG Content mg/kg/day (Calculated as per EMA Guidelines, keeping in view firm's own label recommended dose for a child weighing 10kg, 15kg & 18kg respectively)**		
		PG (mg/kg/day) (30mL Dose)	**PG (mg/kg/day) (60mL Dose)**	**PG (mg/kg/day) (120mL Dose)**
178-24	10.815%	336.13	448.17	746.96
179-24	9.33%	289.95	386.60	644.33

The Board further observed that as per guidelines of European Medicine Agency published vide No. EMA/CHMP/704195/2013 dated 09.10.2017, propylene glycol is estimated to be one-third as intoxicating as ethanol, with administration of large volumes being associated with adverse effects most commonly on the central nervous system, especially in neonates and children. Other adverse reactions reported through generally isolated, include: ototoxicity, cardiovascular effects; seizures; and hyperosmolarity and lactic acidosis, both of which occur most frequently in patients with renal impairment. Adverse effects are more likely to occur following consumption of large quantities of propylene glycol or on administration to neonates, children under 4 years of age, pregnant women, and patients with hepatic or renal failure. Adverse events may also occur in patients treated with disulfiram or metronidazole. Keeping in view all aspects of case, the Board after due deliberation and detailed discussion, unanimously decided to **pend the case**.

11. Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025.

Case is placed before the board for decision.

Summary:

Mfg. date: 11-2023

Exp. date: 11-2025

Date of sampling: 22-02-2024

Sent to DTL (Form-6): 23-02-2024

Date of receipt in DTL: 26-02-2024

Issuance date of DTL Report: 07-06-2024

Time Extension: Granted in 38th Committee meeting dated 21-05-2024

1st DI Communication with firm on dated: 15-06-2024

Retesting Request of Firm: Firm requested for retesting request dated 14-06-2024 from online DTL portal

Fate of Retesting Request: Turn down in 42nd meeting dated 30-07-2024

Permission of Show cause notice: 286-M dated 30-10-2024

Investigation report received: 07-10-2024

Show cause/Personal Hearing notice dated: 11-11-2024

Reply of the firm: NA

History of the firm (2021 onwards)

Firm: 110 cases

Product: 87 cases

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/ MSS-192925, 192926/2024

Tehsil and District Bahawalnagar

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Managing Director, M. Muzammil Nazar 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil and District Bahawalnagar, reported that: -

i. He, on 22-02-2024, inspected the premises of Main Medicine Store, O/o Chief Executive Officer (DHA), Bahawalnagar, took three different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug samples to Drug Testing Laboratory, Bahawalpur.
ii. The subject drug samples, sent vide memo no. 192925 and 192926, dated: 23-02-2024, after test/analysis were declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Bahawalpur**, as detailed below:

Sr #	Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date
1	Suspension Parapol Paediatric Suspension 120ml [Paracetamol 120mg/5ml. 120ml] **Mfg. date: 11-2023** **Exp. Date: 11-2025** **Reg # 002772**	179-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-20101000088/DTL Dated: 07.06.2024
	Specs Applied: USP 2024/Others/In house **COMPOSITION:** Each 5ml contains: **Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:**			

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles,** filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.***

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9

Determined: 5.4 @ 23.4ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml

Determined 122.50 mg/5ml (102.08%)

Limit 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol: Limit: NMT 0.1% Determined: Not Detected	**Diethylene Glycol:** Limit: NMT 0.1% Determined: Not Detected
Propylene Glycol Determined: 10.815%	

Note: The extension is granted via PQCB order no. **PQCB/TEX-BWP-38/2024** Dated 21-05-2024

RESULT: The Sample is declared as **"SUB-STANDARD"** on basis of Physical Characteristics.

2	Suspension Parapol Paediatric Suspension 120ml [Paracetamol 120mg/5ml. 120ml]	178-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-20101000087/DTL Dated: 07.06.2024

Mfg. date: 11-2023 **Exp. Date: 11-2025** **Reg # 002772**			

SPECIFICATION: USP 2024/Others/In House

COMPOSITION: Each 5ml contains:

Paracetamol USP…. 120mg

PHYSICAL CHARACTERISTICS:

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles,** filled in an amber plastic bottle, sealed with a white screw cap, further **packed** in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."***

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9

Determined: 5.4 @ 23.6ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml

Determined 123.97 mg/5ml (103.31%)

Limit 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Limit: NMT 0.1%	Stated: NMT 0.1%
Determined: Not Detected	Determined: Not Detected

Propylene Glycol

Determined: 9.33%

Note: The extension is granted via PQCB order no. **PQCB/TEX-BWP-38/2024** Dated 21-05-2024

RESULT: The Sample is declared as **"SUB-STANDARD"** on basis of Physical Characteristics.

iii. Store Keeper, Main Medicine Store, O/o Chief Executive Officer (DHA), Bahawalnagar, provided invoice/ warranty No. 000649 dated 13-02-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi., as a proof of its purchase

iv. Warrantor portions of drug samples were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. Copies of test/analysis reports were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug samples from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its **42nd Committee meeting** held on **30-07-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request for retesting.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/ Sale of Substandard Drug**
b. **Issuance of false warranty**

3. Show cause/Personal hearing Notice notice(s) issued to the accused persons(s) dated 11-11-2024.

4. The firm submitted review petition against 42nd committee meeting orders dated 30-07-2024 vide letter no. Nil dated Nil (Received on 06-11-2024).

GROUNDS OF REVIEW PETITION:

SUBJECT: REVIEW PETITION UNDER CLAUSE 2 OF PART VIII OF THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We M/S Lisko Pakistan (Pvt) Ltd Petitioner Company" would like to submit instant review petition before the learned Provincial Quality Control Board. Puniab against the order of committee PQCB dated 20-09-2024 (the "impugned Decision") in which request of re-testing from NIH, Islamabad has been turned down (orders attached) for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspector of Drugs, BAHAWALNAGAR (the "Respondent Drug Inspector") has been directed to expedite Investigation so that permission for prosecution can be granted.

There are several grave infirmities and ambiguities in DTL reports "Impugned reports" issued by government analyst of DTL Bahawalpur and also in decision "Impugned Order by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, It is pertinent to highlight the fresh grounds that have arisen in the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. Committee PQCB has turned down request for retesting from NIH, Islamabad with the statement which itself contains several ambiguities and infirmities "the committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate the formulation with respect to bitter in taste and propvlene glvcol concentration hence unanimously decided to turn down the retesting request of the firm"

A) Government analyst has not declared samples substandard on the basis of concentration of propylene glvcol rather it has been declared substandard on the basis of physical characteristics (Bitter taste and absence of solid particles as per USP <1151>). Once appeal for retesting has been submitted against impugned Reports and errors are being highlighted by the firm, committee PQCB can only Scrutinize grounds on the basis of which samples have been declared substandard but cannot introduce new grounds or raise additional issues in DTL report by their own if they were not shown as noncompliant by the government analyst In the initial report. Drug act 1976 and other existing laws have clearly defined duties and limitations of both government analyst and PQCB. Members of committee PQCB initiated discussion i.e. toxicity due to propylene glycol, role of propylene glycol to solubilizing Paracetamol without having conclusive evidences and turned down appeal for retesting by relying on this premise. Therefore, all discussion in impugned order related to propylene glycol is unlawful and illegal and cannot be relied as ground on the basis of which appeal has been turned down.

B) It is pertinent to highlight that in our previous meetings of committee PQCB, when we requested to kindly evaluate our sample, committee members PQCB was of the opinion that product sample cannot be evaluated & tested in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIH Islamabad for conclusive report.. However, opinion of the committee PQCB regarding the same product has suddenly been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product, samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions.

C) Firm's representative never agreed with the findings of government analyst (bitter in taste and free from any dispersed solid particles) rather firm's representative always claimed that Parapol suspension ensure a palatable profile that supports patient compliance and also claimed presence of dispersed solid particles in Parapol suspension. However, firm's stance has been improperly and incompletely stated in the "impugned order"

D) Firm's claim regarding presence of dispersed particles and palatable taste profile can only be verified if samples will be sent to NIH, Islamabad for the conclusive and fair report. However, same has not been done and appeal for retesting has been turned down in slipshod manner without verifying firm's claim and arguments.

2. It is pertinent to highlight that since October 2023, our product "Parapol suspension" has been subjected to targeted victimization, with test results from various DTLs influenced by external factors. This interference has led samples of Parapol suspension being improperly classified as substandard based on invalid, impermissible, and non-pharmacopeial grounds despite of the fact that there being no quality issue and product complied in all applicable USP tests. The targeted Victimization and unfair treatment by Punjab DTLs toward Parapol is further evidenced by an incident involving the Drug Testing Laboratory in Bahawalpur. On 09-03-2024, DTL Bahawalpur, initially declared Batch No. 178-24 and 179-24 of Parapol suspension as standard quality and uploaded the corresponding reports on their portal. However, these standard reports were subsequently removed due to external pressures, and substandard reports for the same batches were uploaded Several months later. This suspicious & doubtful act of DTL Bahawalpur emphasizes the need for an unbiased and fair analysis, which only NIH Islamabad, as an appellate laboratory, can provide for reassessment of the Samples. Furthermore, is also important to highlight that committee PQCB did not give satisfactory reasons and grounds on the basis of which honorable committee members of PQCB showed reliance and trust on the Sub-standard" reports by the government analyst while same batches were declared “standard" on 9-3- 2024 by DTL Bahawalpur.

3. It is very important to highlight and note that government analyst maliciously used reference of WHO working document (QAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely impermissible and hence makes report invalid. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining the concentration of propylene glycol.

4. The government analyst has stated that the samples of Parapol suspension are “bitter in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no

validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

5. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited "USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. Samples of Parapol suspension were declared substandard based solely on personal observation (bitter taste) without conducting chemical analysis for accurate and instrument based identification of sweetener in the composition

6. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house / others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on ' In- house/other specifications' renders the report invalid and inaccurate

7. The government analyst has wrongfully claimed the products to be a "liquid" and free from any dispersed solid particles despite the same being a suspension. Government analyst has quoted reference of USP general chapters <l151> for showing non-compliance. However, it is important to highlight that USP general chapters <1151> on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to classify product as suspension, solution or syrup. Same has been confirmed in letters by NIH Islamabad dated 6-6-2024 and 29-8-2024 to POCB as below:

i) Letter dated 6th June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any Such test on the basis of which the samples are declared sub-standard by DTLs of Punjab"

ii) Letter dated 29th August 2024 "It is once again informed that USP monograph for Acetaminophen oral Suspension have different tests including test from the general chapters ie performance test (uniformity of dosage units 905, deliverable? Volume - 698, impurities 4- Aminophenol in Acetaminophen containing Drug Products, 277). Specific test (p 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the and The USP samples were declared substandard by DTLs Punjab General Chapter <I151> on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply". The foregoing infirmity makes the report invalid and baseless.

8. "It is pertinent to note that the esteemed Punjab Quality Control Board (PQCB) previously investigated the matter regarding the presence or absence of particles in Parapol suspension by constituting a special committee comprising five pharmaceutical experts, including two respected members from PQCB. The honorable members of this special committee conducted a thorough examination of the samples and reached conclusions in our favor, affirming our claim that Parapol qualifies as a 'suspension.' The committee's findings explicitly stated that Parapol is a 'biphasic liquid-like suspension' with a translucent appearance due to the presence of visible particles (a copy of the expert committee's findings is attached).

However, contrary to this initial finding, the same committee members, who were previously convinced of the presence of solid particles in Parapol suspension, subsequently disregarded these findings. They participated in the disputed decision "impugned order" that denied our request for retesting and upheld the remarks of the government analyst, who asserted that Parapol suspension is free from dispersed particles and does not comply with USP <1151>.

9. Government analyst has mentioned in form 7 «S.No# 6 that “USP 2024 / In-House / Others" has been applied. However, it is pertinent to highlight that neither USP 2024 nor method of analysis (In-House) of Parapol suspension provided by the firm gives any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension / solution / syrup. Therefore, Product Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

10. Since Parapol suspension was being declared of standard quality by DTL Bahawalpur till 10-10-2023 this proves that till

this date, as per analysts of DTL Bahawalpur, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Bahawalpur must have received a revised and new method of analysis from the firm after 10-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 10-10-2023 which proves malice intention and act of victimization by government analyst.

11. In continuation of Point no# 1, in which few flaws and inaccuracies in the impugned order made by the committee PQCB were highlighted, we would further like to add more infirmities in the order in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. It is to be noted that point of discussion regarding toxicity and side effects of higher concentrations of propylene glycol is inapplicable and inappropriate when government analyst categorically admitted in committee meetings that method applied to determine exact concentration of propylene glycol is not as per WHO reference document rather it has been derived from it. Firm's claim of addition of less than 1% propvlene glycol has been completely overlooked in the impugned order and no scrutiny was carried out by the committee PQCB to verify firm's claim. Firm stated in every committee meeting before honorable board that we are supplying same product with the same formulation across Pakistan for decades and millions of children have safely consumed this product to alleviate pain and fever without any reported clinical toxicity. Despite this, the PQCB committee exhibited an unfair approach by relying on the impugned results of the government analyst, who determined the concentration of propylene glycol using a non-reliable and non-pharmacopeial method.

b. On what basis and in what capacity did Mr. Ijaz Alvi, Director of DTL Rawalpindi, present his views regarding the toxicity of propylene glycol before the committee, given that the impugned reports pertain exclusively to DTL Multan? It is to be noted that Mr liaz Alvi is not part of committee PQCB and firm has no faith on him as he is part of malicious campaign against our product. This raises concerns about the impartiality of the Process and suggests a coordinated effort by all DTLS of Punjab to unfairly target the product 'Parapol' without relying on legal facts and objective findings.

c. How and on what grounds committee members got convinced by views of Director, DTL Rawalpindi and Government Analyst, DTL Bahawalpur in which they were trying to establish a view that firm has solubilized paracetamol in propylene glycol without counter verifying it with firm’s claim?. Firm has already provided list of excipients with quantities before the committee POCB in which it was mention that firm added propylene glycol less than 1% in the formulation of Parapol Suspension only with the purpose as stabilizer and as preservative. Firm's representative comprehensively explained that it is practically impossible to solubilize paracetamol in an amount of propylene glycol and water that has been used in the formulation of Parapol suspension. Nevertheless, the PQCB Committee chose to accept the unverified personal opinions of the individuals mentioned and issued a biased decision without validating the firm’s assertions.

d. Question i.e. testing of propylene glycol in finished product duly raised by the committee members is inaccurate, as firm is not bound to test excipients in finished form neither does tested by any DTL of Pakistan. Firm is always well aware of the fact that how much amount of any excipient is being added in formulation and as per GMP guidelines, all excipients are being consumed once passed initially from quality control department. Moreover, Specs claimed for Parapol suspension is USP and firm carries out all applicable test as per USP which specifically provide testing of API in a finished product only. Despite of the fact, committee POCB turned down our appeal for retesting to prevent us from the right of justice.

e. The quality of propylene glycol as a raw material, along with its associated standards, cannot be questioned or used as grounds for denying the request for re-testing. The impugned DTL reports themselves acknowledge compliance with the WHO reference document and confirm the absence of impurities such as EG and DEG, which demonstrates that the quality of the propylene glycol used was fully compliant and without any issues. Furthermore, under the latest DRAP guidelines, propylene glycol cannot be released for use unless tested by federal laboratories. The firm has consistently stated in all meetings that the propylene glycol used in the batches of Parapol suspension was tested and approved by the Central Drug Laboratory (CDL) in Karachi prior to its consumption.

Additionally, we would like to highlight grounds comprehensively which have already been discussed in difference committee meeting that further supports our stance in said case:

1. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and

unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:
"It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 {Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976}"

In this regard, committee POCB was duty bound to consider the foregoing facts whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

2. The malafide intentions of the Government Analysts and Director DTL Bahawalpur are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 76 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

3. Since, product “"Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe /instruct to conduct test for determination of the taste of the products or test to classify product as syrup solution or suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopeial testing.

4. It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc.) of the "finished form" of the drug. In this context, the Products, like all other drugs, underwent a comprehensive manufacturing process wherein in addition to the active pharmaceutical ingredient; several other excipients were also added. Additionally, tests are prescribed in the specifications to ascertain the quality of a "finished form of drug". Thus, only tests that could have been performed by the government analyst were those prescribed in the USP and any additional information sought in relation to the excipients and or other ingredients or any testing carried out on the basis of the same is illegal and unlawful.

5. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the Samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the Substandard drugs". However, in our case, government analyst has shown her malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

6. Section 3(z) of the Drugs Act, 1976 defines the term specifications as.

(i) such specifications as may be prescribed;

(ii) or when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:-

(1) the Pakistan Pharmacopoeia;

(2) the International Pharmacopoeia;

(3) the European Pharmacopoeia;

(4) the United States Pharmacopoeia;

(5) the British Pharmacopoeia;

(6) the British Pharmaceutical Codex;

(7) the United States National Formulary; and

(8) Such other publication as may be prescribed:

In terms of the legislative scheme envisioned under the Drugs Act, 1976, more particularly, Section 3(zz) a drug shall only be deemed as substandard if it does not comply with the applicable specifications. Essentially, such determination can only be made if the drug fails to comply with the tests "prescribed" under the applicable specifications. The monograph of a drug provided under the applicable specifications lists down the requisite tests that need to be conducted in order to determine whether the drug is of standard quality. It is a matter of fact that the Drugs Act does not permit analysts to carry out inapplicable tests or tests, which have not been listed down in the applicable specifications. However, in context of the present case, the Government Analysts have malafidely declared the batches of the Product as substandard on the basis of their bitter taste & absence of solid particles without there being any criteria or test to determine the same. The foregoing action clearly constitutes a violation of the Drugs Act, 1976 as well as Rule 16 of The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal

Government Analysts) Rule 1976.

In the light of above highlighted facts and infirmities, it can be concluded that committee PQCB has failed to scrutinize the case properly as it has overlooked above evidences and factual findings. The illegalities floating on the record of the case and as mentioned in above grounds have been completely overlooked and no heed has been paid to the wrongdoings of the government analyst who has declared the Products to be of substandard quality on a completely wrongful premise. t was mandatory upon this committee PQCB to properly scrutinize the subject especially in this case when samples comply with the stated specification chemically and physically and adjudicate upon the same. However, no such exercise has been carried out in the present case. Furthermore, it is to be noted that our firm petitioner Company" and its officials have not contravened the provisions of the Drug Laws and the rules made thereunder rather they are committed to ensure compliance thereof. PQCB passed an impugned order (turning down request for retesting) which completely disregard not just of the principles of fair trial and due process envisioned under Article 10-A and Article 4 of the Constitution but also disregard of the scheme of law envisioned under the Drugs Act, 1976 as-well as the fundamental rights of the Petitioner Company enshrined under the Constitution of Islamic Republic of Pakistan, 1973.

On the premise of foregoing submission and grounds highlighted above, it is mandatory and essential for the learned Board to review its decision. We reserves the right to agitate additional grounds at the time of arguments if needed. We as “Petitioners" are seeking the setting aside of the Impugned Decision in terms of clause 2 of Part VIII of the PQCB Regulations and pray as below:

PRAYER

In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:

i. Set aside the Impugned Order in which committee PQCB turned down appeal for re-testing and directed Provincial Inspector of and Drugs, BAHAWALNAGAR, to expedite investigation submission of final report.

ii. Pass an order for the samples of Suspension Parapol Batch No. 178- 24 and Batch No. 179-24 to be sent to the National Institute of Health, Islamabad and allow retesting of samples for the conclusive report.

iii. Direct the government analyst of the Drug Testing Laboratory, Bahawalpur to bring the method and protocols of the test employed to determine the taste of the Suspension and test to determine presence or absence of particles in suspension.

iv. Share transparent findings, causes and measures against the incident in which DTL Bahawalpur issued standard report for Batch No. 178-24 and Batch No. 179-24 and reports were removed later on and sub-standard reports were issued for same batches.

v. Permanently restrain the Provincial Inspector of Drugs, BAHAWALNAGAR from taking any adverse and/or coercive

action against our firm “Petitioner Company" and against our officials based on the Impugned order / decision.

We hope that learned board will allow us to avail right of fair trial and accept above mentioned prayer.

5. Personal Hearing notice(s) issued to accused person(s) dated 01-01-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, vice-chairperson PQCB. Ms. Taiba Aslam Secretary DQCB Bahawalnagar attended the meeting online via zoom link and Mr. Muhammad Yahya Provincial Inspector of drugs Tehsil & District Bahawalnagar was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeial test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary individual to individual basis and there will be no toxicity or adverse effects due to bitter taste
ii. We are confident that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension”.
iii. As far as declaring our samples substandard declaring them to be “free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iv. He further added that although the DTL has quantified Propylene Glycol in the test report but failed to mention the limit and to specify whether it complies or not with any official monograph.
v. He further reiterated firm’s request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting.

7. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 178-24 & 179-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Bahawalpur on the basis of physical description as “ Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles**” further reporting that “As per USP <1151> Pharmaceutical Dosage Forms; “*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*” while in actual the sample is clear viscous solution”. Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 14-06-2024 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was turn down in 42nd Committee meeting of the Board held on 30-07-2024. Whereas, the re-submitted retesting request by the firm in its review petition received on 06-11-2024 cannot be accepted and hence, is turned down and previous decision taken in 42nd Committee meeting dated 30-07-2024 is upheld. Regarding firm’s review petition against retesting orders and the plea to send their subject batches to NIH for retesting, the Board observed that in 279th meeting held on 24-04-2024, the Board sent

forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976.

8. However, Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

9. While perusing the case record, the Board remarked that the samples in question were declared substandard on the basis of physical description as per General Chapter <1151> of the USP and bitter taste of suspension by the Government Analyst DTL Bahawalpur. The firm claims the product as “Suspension” on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Bahawalpur. Furthermore, regarding bitter taste of the suspension, the Board was of the view that the product has been developed for pediatrics use and bitter taste of suspension as reported by the DTL in the subject reports, will result in non-compliance and reluctance to take medication by children.

10. The Board further observed that the DTL also determined the percentage of Propylene Glycol as 10.815% w/v & 9.33% w/v in the batches under consideration by applying WHO Working Document QAS/23.922/rev3 Dated 31 October 2023.

Acceptable Dietary Intake of Propylene Glycol				
EMA		**50mg/kg/day**		
WHO		**25mg/kg/day**		
Batch No.	**PG Determined (as per DTL Report)**	**PG Content mg/kg/day (Calculated as per EMA Guidelines, keeping in view firm's own label recommended dose for a child weighing 10kg, 15kg & 18kg respectively)**		
		PG (mg/kg/day) (30mL Dose)	**PG (mg/kg/day) (60mL Dose)**	**PG (mg/kg/day) (120mL Dose)**
178-24	10.815%	336.13	448.17	746.96
179-24	9.33%	289.95	386.60	644.33

The Board further observed that as per guidelines of European Medicine Agency published vide No. EMA/CHMP/704195/2013 dated 09.10.2017, propylene glycol is estimated to be one-third as intoxicating as ethanol, with administration of large volumes being associated with adverse effects most commonly on the central nervous system, especially in neonates and children. Other adverse reactions reported through

generally isolated, include: ototoxicity, cardiovascular effects; seizures; and hyperosmolarity and lactic acidosis, both of which occur most frequently in patients with renal impairment. Adverse effects are more likely to occur following consumption of large quantities of propylene glycol or on administration to neonates, children under 4 years of age, pregnant women, and patients with hepatic or renal failure. Adverse events may also occur in patients treated with disulfiram or metronidazole. Keeping in view all aspects of case, the Board after due deliberation and detailed discussion, unanimously decided to **pend the case**.

11. Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025.

Case is placed before the board for decision.

Summary:

Mfg. date: 11-2023

Exp. date: 11-2025

Date of sampling: 22-02-2024

Sent to DTL (Form-6): 23-02-2024

Date of receipt in DTL: 26-02-2024

Issuance date of DTL Report: 07-06-2024

Time Extension: Granted in 38th Committee meeting dated 21-05-2024

1st DI Communication with firm on dated: 15-06-2024

Retesting Request of Firm: Firm requested for retesting request dated 14-06-2024 from online DTL portal

Fate of Retesting Request: Turn down in 42nd meeting dated 30-07-2024

Permission of Show cause notice: 286-M dated 30-10-2024

Investigation report received: 07-10-2024

Show cause/Personal Hearing notice dated: 11-11-2024

Reply of the firm: NA

History of the firm (2021 onwards)

Firm: 110 cases

Product: 87 cases

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 2

PQCB/MSS-197407/ 2024

CEO DHA Bahawalpur

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Managing Director, Muzammil Nazar 2. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, o/o CEO DHA Bahawalpur, reported that: -

i. She, on 24-04-2024, inspected the premises of Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, took 03 different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 197407 dated 24-04-2024,
ii. Following drug sample, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Bahawalpur**, as detailed below:

Name of Drug	Batch	Manufacturer	TRA No. and Date
Suspension Parapol Paediatric Suspension120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. date: 11-2023** **Exp. date: 11-2025** **Reg.No. 002772**	184-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	TRA 01-10097008319 /DTL 14-06-2024

Specs Applied: USP 2024/Others/In house

COMPOSITION: Each 5ml contains: **Paracetamol USP…. 120mg**

PHYSICAL CHARACTERISTICS:

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles,** filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms ***"A suspension is a biphasic***

preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9 Determined: 5.4 at 24.6ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml **Determined** 125.81 mg/5ml (104.84%) **Limit** 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Limit: NMT 0.1%	Limit: NMT 0.1%
Determined: Not Detected	Determined: Not Detected
Propylene Glycol	
Determined: 11.20%	

RESULT: The Sample is declared as **"SUB-STANDARD"** on basis of Physical Characteristics.

iii. Store Keeper, Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, provided invoice/ warranty No. 000776 dated 27-03-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi., as a proof of its purchase

iv. Warrantor portion of drug sample was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. Copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug samples from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its **283rd Special meeting** held on **20-08-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request

for retesting.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/ Sale of Substandard Drug**
b. **Issuance of false warranty**

3. Show cause/Personal hearing Notice notice(s) issued to the accused persons(s) dated 01-01-2025.
4. The firm submitted review petition against the orders of 283rd special meeting dated 20-08-2024 vide letter no. Nil dated Nil (Received on 06-11-2024).

GROUNDS OF REVIEW PETITION:

SUBJECT: REVIEW PETITION UNDER CLAUSE 2 OF PART VIII OF THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We M/S Lisko Pakistan (Pvt) Ltd Petitioner Company" would like to submit instant review petition before the learned Provincial Quality Control Board, Puniab against the order of committee PQCB dated 14-10-2024 (the "impugned Decision") in which request of re-testing from NIH, Islamabad has been turned down orders attached) for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspector of Drugs, CEO DHA BAHAWALPUR (the "Respondent Drug Inspector") has been directed to expedite Investigation so that permission for prosecution can be granted.

There are several grave infirmities and ambiguities in DTL reports "Impugned reports" issued by government analyst of DTL Bahawalpur and also in decision "Impugned Order by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, It is pertinent to highlight the fresh grounds that have arisen in the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. Committee PQCB has turned down request for retesting from NIH, Islamabad with the statement which itself contains several ambiguities and infirmities “the committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate the formulation with respect to physical characteristics (i.e bitter in taste and free from any dispersed solid particles) hence unanimously decided to turn down the retesting request of the firm"

A) It is pertinent to highlight that in our previous meetings of committee PQCB, when we requested to kindly evaluate our sample, committee members PQCB was of the opinion that product sample cannot be evaluated & tested in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIH Islamabad for conclusive report.. However, opinion of the committee PQCB regarding the same product has suddenly been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product, samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions.

B) Firm's representative never agreed with the findings of government analyst (bitter in taste and free from any dispersed solid particles) rather firm's representative always claimed that Parapol suspension ensure a palatable profile that supports patient compliance and also claimed presence of dispersed solid particles in Parapol suspension. However, firm's stance has been improperly and incompletely stated in the "impugned order"

C) Firm's claim regarding presence of dispersed particles and palatable taste profile can only be verified if samples will be sent to NIH, Islamabad for the conclusive and fair report. However, same has not been done and appeal for retesting has been turned down in slipshod manner without verifying firm's claim and arguments.

2. It is pertinent to highlight that since October 2023, our product "Parapol suspension" has been subjected to targeted victimization, with test results from various DTLs influenced by external factors. This interference has led samples of Parapol suspension being improperly classified as substandard based on invalid, impermissible, and non-pharmacopeial grounds despite of the fact that there being no quality issue and product complied in all applicable USP tests. The targeted

Victimization and unfair treatment by Punjab DTLS toward Parapol is further evidenced by an incident involving the Drug Testing Laboratory in Bahawalpur. On 09-03-2024, DTL Bahawalpur, initially declared Batch No. 178-24 and 179-24 of Parapol suspension as standard quality and uploaded the corresponding reports on their portal. However, these standard reports were subsequently removed due to external pressures, and substandard reports for the same batches were uploaded Several months later. This suspicious & doubtful act of DTL Bahawalpur emphasizes the need for an unbiased and fair analysis, which only NIH 1Slamabad, as an appellate laboratory, can provide for reassessment of the Samples. Furthermore, is also important to highlight that committee PQCB did not give satisfactory reasons and grounds on the basis of which honorable committee members of PQCB showed reliance and trust on the Sub-standard" reports by the government analyst while same batches were declared “standard" on 9-3- 2024 by DTL Bahawalpur.

3. The government analyst has stated that the samples of Parapol suspension are “bitter in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

4. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited "USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. Samples of Parapol suspension were declared substandard based solely on personal observation (bitter taste) without conducting chemical analysis for accurate and instrument based identification of sweetener in the composition.

5. It is very important to highlight and note that government analyst maliciously used reference of WHO working document (OAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely impermissible and hence makes report invalid. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining the concentration of propylene glycol.

6. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house / others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on ' In-house/other specifications' renders the report invalid and inaccurate

7. The government analyst has wrongfully claimed the products to be a "liquid" and free from any dispersed solid particles despite the same being a suspension. Government analyst has quoted reference of USP general chapters <l151> for showing non-compliance. However, it is important to highlight that USP general chapters <1151> on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to classify product as suspension, solution or syrup. Same has been confirmed in letters by NIH Islamabad dated 6-6-2024 and 29-8-2024 to POCB as below:

i) Letter dated 6" June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral Suspension have different tests including test from the general chapters ie performance test (uniformity of dosage units 905, deliverable? Volume - 698, impurities 4- Aminophenol in Acetaminophen containing Drug Products, 277). Specific test (p 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the and The USP samples were declared substandard by DTLs Punjab General Chapter <I151> on the basis of which the samples were

declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply". The foregoing infirmity makes the report invalid and baseless.

8. "It is pertinent to note that the esteemed Punjab Quality Control Board (PQCB) previously investigated the matter regarding the presence or absence of particles in Parapol suspension by constituting a special committee comprising five pharmaceutical experts, including two respected members from PQCB. The honorable members of this special committee conducted a thorough examination of the samples and reached conclusions in our favor, affirming our claim that Parapol qualifies as a 'suspension.' The committee's findings explicitly stated that Parapol is a 'biphasic liquid-like suspension' with a translucent appearance due to the presence of visible particles (a copy of the expert committee's findings is attached).

However, contrary to this initial finding, the same committee members, who were previously convinced of the presence of solid particles in Parapol suspension, subsequently disregarded these findings. They participated in the disputed decision "impugned order" that denied our request for retesting and upheld the remarks of the government analyst, who asserted that Parapol suspension is free from dispersed particles and does not comply with USP <1151>.
9. Government analyst has mentioned in form 7 «S.No# 6 that “USP 2024 / In-House / Others" has been applied. However, it is pertinent to highlight that neither USP 2024 nor method of analysis (In-House) of Parapol suspension provided by the firm gives any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension / solution / syrup. Therefore, Product Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

10. Since Parapol suspension was being declared of standard quality by DTL Bahawalpur till 10-10-2023 this proves that till this date, as per analysts of DTL Bahawalpur, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Bahawalpur must have received a revised and new method of analysis from the firm after 10-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 10-10-2023 which proves malice intention and act of victimization by government analyst.

Additionally, we would like to highlight grounds comprehensively which have already been discussed in difference committee meeting that further supports our stance in said case:

1. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:
"It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 {Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976}"

In this regard, committee POCB was duty bound to consider the foregoing c Wst 2allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

2. The malafide intentions of the Government Analysts and Director DTL Bahawalpur are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 76 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

3. Since, product “"Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe /instruct to conduct test for determination of the taste of the products or test to classify product as syrup solution or suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopeial testing.

4. It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc.) of the "finished form" of the drug. In this context, the Products, like all other drugs, underwent a comprehensive manufacturing process wherein in addition to the active pharmaceutical ingredient; several other excipients were also added. Additionally, tests are prescribed in the specifications to ascertain the quality of a "finished form of drug". Thus, only tests that could have been performed by the government analyst were those prescribed in the USP and any additional information sought in relation to the excipients and or other ingredients or any testing carried out on the basis of the same is illegal and unlawful.

5. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the Samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the Substandard drugs". However, in our case, government analyst has shown her malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

6. Section 3(z) of the Drugs Act, 1976 defines the term specifications as.

(i) such specifications as may be prescribed;

(ii) or when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:-

(1) the Pakistan Pharmacopoeia;

(2) the International Pharmacopoeia;

(3) the European Pharmacopoeia;

(4) the United States Pharmacopoeia;

(5) the British Pharmacopoeia;

(6) the British Pharmaceutical Codex;

(7) the United States National Formulary; and

(8) Such other publication as may be prescribed:

In terms of the legislative scheme envisioned under the Drugs Act, 1976, more particularly, Section 3(zz) a drug shall only be deemed as substandard if it does not comply with the applicable specifications. Essentially, such determination can only be made if the drug fails to comply with the tests "prescribed" under the applicable specifications. The monograph of a drug provided under the applicable specifications lists down the requisite tests that need to be conducted in order to determine whether the drug is of standard quality. It is a matter of fact that the Drugs Act does not permit analysts to carry out inapplicable tests or tests, which have not been listed down in the applicable specifications. However, in context of the present case, the Government Analysts have malafidely declared the batches of the Product as substandard on the basis of their bitter taste & absence of solid particles without there being any criteria or test to determine the same. The foregoing action clearly constitutes a violation of the Drugs Act, 1976 as well as Rule 16 of The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal

Government Analysts) Rule 1976.

In the light of above highlighted facts and infirmities, it can be concluded that committee PQCB has failed to scrutinize the case properly as it has overlooked above evidences and factual findings. The illegalities floating on the record of the case and as mentioned in above grounds have been completely overlooked and no heed has been paid to the wrongdoings of the government analyst who has declared the Products to be of substandard quality on a completely wrongful premise. t was mandatory upon this committee PQCB to properly scrutinize the subject especially in this case when samples comply with the

stated specification chemically and physically and adjudicate upon the same. However, no such exercise has been carried out in the present case. Furthermore, it is to be noted that our firm petitioner Company" and its officials have not contravened the provisions of the Drug Laws and the rules made thereunder rather they are committed to ensure compliance thereof. PQCB passed an impugned order (turning down request for retesting) which completely disregard not just of the principles of fair trial and due process envisioned under Article 10-A and Article 4 of the Constitution but also disregard of the scheme of law envisioned under the Drugs Act, 1976 as-well as the fundamental rights of the Petitioner Company enshrined under the Constitution of Islamic Republic of Pakistan, 1973.

On the premise of foregoing submission and grounds highlighted above, it is mandatory and essential for the learned Board to review its decision. We reserves the right to agitate additional grounds at the time of arguments if needed. We as “Petitioners" are seeking the setting aside of the Impugned Decision in terms of clause 2 of Part VIII of the PQCB Regulations and pray as below:

PRAYER

In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:

i. Set aside the Impugned Order in which committee PQCB turned down appeal for re-testing and directed Provincial Inspector of and Drugs, CEO DHA BAHAWALPUR, to expedite investigation submission of final report.

ii. Pass an order for the samples of Suspension Parapol Batch No. 184- 24, 185-24 and Batch No. 186-24 to be sent to the National Institute of Health, Islamabad and allow retesting of samples for the conclusive report.

iii. Direct the government analyst of the Drug Testing Laboratory, Bahawalpur to bring the method and protocols of the test employed to determine the taste of the Suspension and test to determine presence or absence of particles in suspension.

iv. Permanently restrain the Provincial Inspector of Drugs, CEO DHA BAHAWALPUR from taking any adverse and/or coercive action against our firm “Petitioner Company" and against our officials based on the Impugned order / decision.

We hope that learned board will allow us to avail right of fair trial and accept above mentioned prayer.

5. Show cause/ Personal Hearing notice(s) issued to accused person(s) dated 01-01-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, vice-chairperson PQCB. Ms. Taiba Aslam Secretary DQCB Bahawalnagar attended the meeting online via zoom link and Mr. Muhammad Yahya Provincial Inspector of drugs Tehsil & District Bahawalnagar was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeial test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary individual to individual basis and there will be no toxicity or adverse effects due to bitter taste
ii. We are confident that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension”.

iii. As far as declaring our samples substandard declaring them to be “free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iv. He further added that although the DTL has quantified Propylene Glycol in the test report but failed to mention the limit and to specify whether it complies or not with any official monograph.
v. He further reiterated firm’s request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting.

7. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 184-24, 185-24 & 186-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Bahawalpur on the basis of physical description as “Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles**” further reporting that “As per USP <1151> Pharmaceutical Dosage Forms; “*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*” while in actual the sample is clear viscous solution”. Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 14-06-2024 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was turn down in 283rd Special meeting of the Board held on 20-08-2024. Regarding firm’s review petition against retesting orders and the plea to send their subject batches to NIH for retesting, the Board observed that in 279th meeting held on 24-04-2024, the Board sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976. Hence, the re-submitted retesting request by the firm in its review petition received on 06-11-2024 cannot be accepted and hence, is **turned down** and previous decision taken in 283rd Special meeting of the Board held on 20-08-2024 is **upheld**.

8. Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

9. While perusing the case record, the Board remarked that the samples in question were declared substandard on the basis of physical description as per General Chapter <1151> of the USP and bitter taste of suspension by the Government Analyst DTL Bahawalpur. The firm claims the product as “Suspension” on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Bahawalpur. Furthermore, regarding bitter taste of the suspension, the Board was of the view that the product has been developed for pediatrics use and bitter taste of suspension as reported by the DTL in the subject reports, will result in non-compliance and reluctance to take medication by children.

10. The Board further observed that the DTL also determined the percentage of Propylene Glycol as 10.815% w/v & 9.33% w/v in the batches under consideration by applying WHO Working Document QAS/23.922/rev3 Dated 31 October 2023.

Acceptable Dietary Intake of Propylene Glycol

EMA		**50mg/kg/day**		
WHO		**25mg/kg/day**		
Batch No.	**PG Determined (as per DTL Report)**	**PG Content mg/kg/day (Calculated as per EMA Guidelines, keeping in view firm's own label recommended dose for a child weighing 10kg, 15kg & 18kg respectively)**		
		PG (mg/kg/day) (30mL Dose)	**PG (mg/kg/day) (60mL Dose)**	**PG (mg/kg/day) (120mL Dose)**
184-24	11.20%	348.10	464.13	773.55
185-24	11.54%	358.66	478.22	797.03
186-24	11.33%	352.14	469.52	782.53

The Board further observed that as per guidelines of European Medicine Agency published vide No. EMA/CHMP/704195/2013 dated 09.10.2017, propylene glycol is estimated to be one-third as intoxicating as ethanol, with administration of large volumes being associated with adverse effects most commonly on the central nervous system, especially in neonates and children. Other adverse reactions reported through generally isolated, include: ototoxicity, cardiovascular effects; seizures; and hyperosmolarity and lactic acidosis, both of which occur most frequently in patients with renal impairment. Adverse effects are more likely to occur following consumption of large quantities of propylene glycol or on administration to neonates, children under 4 years of age, pregnant women, and patients with hepatic or renal failure. Adverse events may also occur in patients treated with disulfiram or metronidazole. Keeping in view all aspects of case, the Board after due deliberation and detailed discussion, unanimously decided to **pend the case**.

11. Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025.

Summary of the case:

- **Mfg. date: 11-2023**
- **Exp. Date: 11-2025**
- **Sampling date (Form 4): 24-04-2024**
- **Sent to DTL (Form 6): 24-04-2024**
- **Date of receipt in DTL: 25-04-2024**
- **DTL Report Date (Form 7): 14-06-2024**
- **DI 1st intimation to firm: 15-06-2024**
- **Retesting request if any: 21-06-2024**
- **Fate of Retesting: Turned down in 283rd special meeting dated 20-08-2024**
- **Investigation report Dated: 12-08-2024**
- **Permission of SCN: 287-M dated 08-01-2025 (Post-Facto)**
- **SCN Issued: 01-01-2025**
- **Reply of the firm: NA**
- **History (2021 onwards): Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-197407/ 2024

CEO DHA Bahawalpur

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Managing Director, Muzammil Nazar 2. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, o/o CEO DHA Bahawalpur, reported that: -

i. She, on 24-04-2024, inspected the premises of Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, took 03 different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 197407 dated 24-04-2024,
ii. Following drug sample, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Bahawalpur**, as detailed below:

Name of Drug	Batch	Manufacturer	TRA No. and Date
Suspension Parapol Paediatric Suspension120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. date: 11-2023** **Exp. date: 11-2025** **Reg.No. 002772**	184-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	TRA 01-10097008319 /DTL 14-06-2024
Specs Applied: USP 2024/Others/In house **COMPOSITION:** Each 5ml contains: **Paracetamol USP…. 120mg**			

PHYSICAL CHARACTERISTICS:

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles,** filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms ***"A suspension is a biphasic***

preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9 Determined: 5.4 at 24.6ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml **Determined** 125.81 mg/5ml (104.84%) **Limit** 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Limit: NMT 0.1%	Limit: NMT 0.1%
Determined: Not Detected	Determined: Not Detected
Propylene Glycol	
Determined: 11.20%	

RESULT: The Sample is declared as **"SUB-STANDARD"** on basis of Physical Characteristics.

iii. Store Keeper, Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, provided invoice/ warranty No. 000776 dated 27-03-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi., as a proof of its purchase

iv. Warrantor portion of drug sample was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. Copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned

drug samples from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its **283rd Special meeting** held on **20-08-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request for retesting.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/ Sale of Substandard Drug**
b. **Issuance of false warranty**

3. Show cause/Personal hearing Notice notice(s) issued to the accused persons(s) dated 01-01-2025.
4. The firm submitted review petition against the orders of 283rd special meeting dated 20-08-2024 vide letter no. Nil dated Nil (Received on 06-11-2024).

GROUNDS OF REVIEW PETITION:

SUBJECT: REVIEW PETITION UNDER CLAUSE 2 OF PART VIII OF THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We M/S Lisko Pakistan (Pvt) Ltd Petitioner Company" would like to submit instant review petition before the learned Provincial Quality Control Board, Puniab against the order of committee PQCB dated 14-10-2024 (the "impugned Decision") in which request of re-testing from NIH, Islamabad has been turned down orders attached) for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspector of Drugs, CEO DHA BAHAWALPUR (the "Respondent Drug Inspector") has been directed to expedite Investigation so that permission for prosecution can be granted.

There are several grave infirmities and ambiguities in DTL reports "Impugned reports" issued by government analyst of DTL Bahawalpur and also in decision "Impugned Order by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, It is pertinent to highlight the fresh grounds that have arisen in the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. Committee PQCB has turned down request for retesting from NIH, Islamabad with the statement which itself contains several ambiguities and infirmities "the committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate the formulation with respect to physical characteristics (i.e bitter in taste and free from any dispersed solid particles) hence unanimously decided to turn down the retesting request of the firm"

A) It is pertinent to highlight that in our previous meetings of committee PQCB, when we requested to kindly evaluate our sample, committee members PQCB was of the opinion that product sample cannot be evaluated & tested in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIH Islamabad for conclusive report.. However, opinion of the committee PQCB regarding the same product has suddenly been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product, samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions.

B) Firm's representative never agreed with the findings of government analyst (bitter in taste and free from any dispersed solid particles) rather firm's representative always claimed that Parapol suspension ensure a palatable profile that supports patient compliance and also claimed presence of dispersed solid particles in Parapol suspension. However, firm's stance has been improperly and incompletely stated in the "impugned order"

C) Firm's claim regarding presence of dispersed particles and palatable taste profile can only be verified if samples will be sent to NIH, Islamabad for the conclusive and fair report. However, same has not been done and appeal for retesting has been turned down in slipshod manner without verifying firm's claim and arguments.

2. It is pertinent to highlight that since October 2023, our product "Parapol suspension" has been subjected to targeted

victimization, with test results from various DTLs influenced by external factors. This interference has led samples of Parapol suspension being improperly classified as substandard based on invalid, impermissible, and non-pharmacopeial grounds despite of the fact that there being no quality issue and product complied in all applicable USP tests. The targeted Victimization and unfair treatment by Punjab DTLS toward Parapol is further evidenced by an incident involving the Drug Testing Laboratory in Bahawalpur. On 09-03-2024, DTL Bahawalpur, initially declared Batch No. 178-24 and 179-24 of Parapol suspension as standard quality and uploaded the corresponding reports on their portal. However, these standard reports were subsequently removed due to external pressures, and substandard reports for the same batches were uploaded Several months later. This suspicious & doubtful act of DTL Bahawalpur emphasizes the need for an unbiased and fair analysis, which only NIH 1Slamabad, as an appellate laboratory, can provide for reassessment of the Samples. Furthermore, is also important to highlight that committee PQCB did not give satisfactory reasons and grounds on the basis of which honorable committee members of PQCB showed reliance and trust on the Sub-standard" reports by the government analyst while same batches were declared “standard" on 9-3- 2024 by DTL Bahawalpur.

3. The government analyst has stated that the samples of Parapol suspension are “bitter in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

4. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited "USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. Samples of Parapol suspension were declared substandard based solely on personal observation (bitter taste) without conducting chemical analysis for accurate and instrument based identification of sweetener in the composition.

5. It is very important to highlight and note that government analyst maliciously used reference of WHO working document (OAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely impermissible and hence makes report invalid. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining the concentration of propylene glycol.

6. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house / others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on ' In-house/other specifications' renders the report invalid and inaccurate

7. The government analyst has wrongfully claimed the products to be a "liquid" and free from any dispersed solid particles despite the same being a suspension. Government analyst has quoted reference of USP general chapters <l151> for showing non-compliance. However, it is important to highlight that USP general chapters <1151> on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to classify product as suspension, solution or syrup. Same has been confirmed in letters by NIH Islamabad dated 6-6-2024 and 29-8-2024 to POCB as below:

i) Letter dated 6" June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral Suspension have different tests including test from the general chapters ie performance test (uniformity of dosage units 905, deliverable? Volume - 698, impurities 4- Aminophenol in Acetaminophen containing Drug Products, 277). Specific test (p 791) etc. These different tests

from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the and The USP samples were declared substandard by DTLs Punjab General Chapter <I151> on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply". The foregoing infirmity makes the report invalid and baseless.

8. "It is pertinent to note that the esteemed Punjab Quality Control Board (PQCB) previously investigated the matter regarding the presence or absence of particles in Parapol suspension by constituting a special committee comprising five pharmaceutical experts, including two respected members from PQCB. The honorable members of this special committee conducted a thorough examination of the samples and reached conclusions in our favor, affirming our claim that Parapol qualifies as a 'suspension.' The committee's findings explicitly stated that Parapol is a 'biphasic liquid-like suspension' with a translucent appearance due to the presence of visible particles (a copy of the expert committee's findings is attached).

However, contrary to this initial finding, the same committee members, who were previously convinced of the presence of solid particles in Parapol suspension, subsequently disregarded these findings. They participated in the disputed decision "impugned order" that denied our request for retesting and upheld the remarks of the government analyst, who asserted that Parapol suspension is free from dispersed particles and does not comply with USP <1151>.
9. Government analyst has mentioned in form 7 «S.No# 6 that “USP 2024 / In-House / Others" has been applied. However, it is pertinent to highlight that neither USP 2024 nor method of analysis (In-House) of Parapol suspension provided by the firm gives any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension / solution / syrup. Therefore, Product Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

10. Since Parapol suspension was being declared of standard quality by DTL Bahawalpur till 10-10-2023 this proves that till this date, as per analysts of DTL Bahawalpur, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Bahawalpur must have received a revised and new method of analysis from the firm after 10-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 10-10-2023 which proves malice intention and act of victimization by government analyst.

Additionally, we would like to highlight grounds comprehensively which have already been discussed in difference committee meeting that further supports our stance in said case:

1. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:
"It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 {Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976}"

In this regard, committee POCB was duty bound to consider the foregoing c Wst 2allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

2. The malafide intentions of the Government Analysts and Director DTL Bahawalpur are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 76 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

3. Since, product “"Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe /instruct to conduct test

for determination of the taste of the products or test to classify product as syrup solution or suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopeial testing.

4. It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc.) of the "finished form" of the drug. In this context, the Products, like all other drugs, underwent a comprehensive manufacturing process wherein in addition to the active pharmaceutical ingredient; several other excipients were also added. Additionally, tests are prescribed in the specifications to ascertain the quality of a "finished form of drug". Thus, only tests that could have been performed by the government analyst were those prescribed in the USP and any additional information sought in relation to the excipients and or other ingredients or any testing carried out on the basis of the same is illegal and unlawful.

5. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the Samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the Substandard drugs". However, in our case, government analyst has shown her malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

6. Section 3(z) of the Drugs Act, 1976 defines the term specifications as.

(i) such specifications as may be prescribed;

(ii) or when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:-

(1) the Pakistan Pharmacopoeia;

(2) the International Pharmacopoeia;

(3) the European Pharmacopoeia;

(4) the United States Pharmacopoeia;

(5) the British Pharmacopoeia;

(6) the British Pharmaceutical Codex;

(7) the United States National Formulary; and

(8) Such other publication as may be prescribed:

In terms of the legislative scheme envisioned under the Drugs Act, 1976, more particularly, Section 3(zz) a drug shall only be deemed as substandard if it does not comply with the applicable specifications. Essentially, such determination can only be made if the drug fails to comply with the tests "prescribed" under the applicable specifications. The monograph of a drug provided under the applicable specifications lists down the requisite tests that need to be conducted in order to determine whether the drug is of standard quality. It is a matter of fact that the Drugs Act does not permit analysts to carry out inapplicable tests or tests, which have not been listed down in the applicable specifications. However, in context of the present case, the Government Analysts have malafidely declared the batches of the Product as substandard on the basis of their bitter taste & absence of solid particles without there being any criteria or test to determine the same. The foregoing action clearly constitutes a violation of the Drugs Act, 1976 as well as Rule 16 of The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal

Government Analysts) Rule 1976.

In the light of above highlighted facts and infirmities, it can be concluded that committee PQCB has failed to scrutinize the

case properly as it has overlooked above evidences and factual findings. The illegalities floating on the record of the case and as mentioned in above grounds have been completely overlooked and no heed has been paid to the wrongdoings of the government analyst who has declared the Products to be of substandard quality on a completely wrongful premise. t was mandatory upon this committee PQCB to properly scrutinize the subject especially in this case when samples comply with the stated specification chemically and physically and adjudicate upon the same. However, no such exercise has been carried out in the present case. Furthermore, it is to be noted that our firm petitioner Company" and its officials have not contravened the provisions of the Drug Laws and the rules made thereunder rather they are committed to ensure compliance thereof. PQCB passed an impugned order (turning down request for retesting) which completely disregard not just of the principles of fair trial and due process envisioned under Article 10-A and Article 4 of the Constitution but also disregard of the scheme of law envisioned under the Drugs Act, 1976 as-well as the fundamental rights of the Petitioner Company enshrined under the Constitution of Islamic Republic of Pakistan, 1973.

On the premise of foregoing submission and grounds highlighted above, it is mandatory and essential for the learned Board to review its decision. We reserves the right to agitate additional grounds at the time of arguments if needed. We as “Petitioners" are seeking the setting aside of the Impugned Decision in terms of clause 2 of Part VIII of the PQCB Regulations and pray as below:

PRAYER

In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:

i. Set aside the Impugned Order in which committee PQCB turned down appeal for re-testing and directed Provincial Inspector of and Drugs, CEO DHA BAHAWALPUR, to expedite investigation submission of final report.

ii. Pass an order for the samples of Suspension Parapol Batch No. 184- 24, 185-24 and Batch No. 186-24 to be sent to the National Institute of Health, Islamabad and allow retesting of samples for the conclusive report.

iii. Direct the government analyst of the Drug Testing Laboratory, Bahawalpur to bring the method and protocols of the test employed to determine the taste of the Suspension and test to determine presence or absence of particles in suspension.

iv. Permanently restrain the Provincial Inspector of Drugs, CEO DHA BAHAWALPUR from taking any adverse and/or coercive action against our firm “Petitioner Company" and against our officials based on the Impugned order / decision.

We hope that learned board will allow us to avail right of fair trial and accept above mentioned prayer.

5. Show cause/ Personal Hearing notice(s) issued to accused person(s) dated 01-01-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, vice-chairperson PQCB. Ms. Taiba Aslam Secretary DQCB Bahawalnagar attended the meeting online via zoom link and Mr. Muhammad Yahya Provincial Inspector of drugs Tehsil & District Bahawalnagar was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeial test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary

individual to individual basis and there will be no toxicity or adverse effects due to bitter taste

ii. We are confident that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension”.

iii. As far as declaring our samples substandard declaring them to be “free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.

iv. He further added that although the DTL has quantified Propylene Glycol in the test report but failed to mention the limit and to specify whether it complies or not with any official monograph.

v. He further reiterated firm’s request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting.

7. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 184-24, 185-24 & 186-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Bahawalpur on the basis of physical description as “Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles**” further reporting that “As per USP <1151> Pharmaceutical Dosage Forms; “*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*” while in actual the sample is clear viscous solution”. Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 14-06-2024 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was turn down in 283rd Special meeting of the Board held on 20-08-2024. Regarding firm’s review petition against retesting orders and the plea to send their subject batches to NIH for retesting, the Board observed that in 279th meeting held on 24-04-2024, the Board sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976. Hence, the re-submitted retesting request by the firm in its review petition received on 06-11-2024 cannot be accepted and hence, is **turned down** and previous decision taken in 283rd Special meeting of the Board held on 20-08-2024 is **upheld**.

8. Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

9. While perusing the case record, the Board remarked that the samples in question were declared substandard on the basis of physical description as per General Chapter <1151> of the USP and bitter taste of suspension by the Government Analyst DTL Bahawalpur. The firm claims the product as “Suspension” on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Bahawalpur. Furthermore, regarding bitter taste of the suspension, the Board was of the view that the product has been developed for pediatrics use and bitter taste of suspension as reported by the DTL in the subject reports, will result in non-compliance and reluctance to take medication by children.

10. The Board further observed that the DTL also determined the percentage of Propylene Glycol as 10.815% w/v

& 9.33% w/v in the batches under consideration by applying WHO Working Document QAS/23.922/rev3 Dated 31 October 2023.

Acceptable Dietary Intake of Propylene Glycol				
EMA		**50mg/kg/day**		
WHO		**25mg/kg/day**		
Batch No.	**PG Determined (as per DTL Report)**	**PG Content mg/kg/day (Calculated as per EMA Guidelines, keeping in view firm's own label recommended dose for a child weighing 10kg, 15kg & 18kg respectively)**		
		PG (mg/kg/day) (30mL Dose)	**PG (mg/kg/day) (60mL Dose)**	**PG (mg/kg/day) (120mL Dose)**
184-24	11.20%	348.10	464.13	773.55
185-24	11.54%	358.66	478.22	797.03
186-24	11.33%	352.14	469.52	782.53

The Board further observed that as per guidelines of European Medicine Agency published vide No. EMA/CHMP/704195/2013 dated 09.10.2017, propylene glycol is estimated to be one-third as intoxicating as ethanol, with administration of large volumes being associated with adverse effects most commonly on the central nervous system, especially in neonates and children. Other adverse reactions reported through generally isolated, include: ototoxicity, cardiovascular effects; seizures; and hyperosmolarity and lactic acidosis, both of which occur most frequently in patients with renal impairment. Adverse effects are more likely to occur following consumption of large quantities of propylene glycol or on administration to neonates, children under 4 years of age, pregnant women, and patients with hepatic or renal failure. Adverse events may also occur in patients treated with disulfiram or metronidazole. Keeping in view all aspects of case, the Board after due deliberation and detailed discussion, unanimously decided to **pend the case**.

11. Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025.

Summary of the case:

- **Mfg. date: 11-2023**
- **Exp. Date: 11-2025**
- **Sampling date (Form 4): 24-04-2024**
- **Sent to DTL (Form 6): 24-04-2024**
- **Date of receipt in DTL: 25-04-2024**
- **DTL Report Date (Form 7): 14-06-2024**
- **DI 1st intimation to firm: 15-06-2024**
- **Retesting request if any: 21-06-2024**

- **Fate of Retesting: Turned down in 283rd special meeting dated 20-08-2024**
- **Investigation report Dated: 12-08-2024**
- **Permission of SCN: 287-M dated 08-01-2025 (Post-Facto)**
- **SCN Issued: 01-01-2025**
- **Reply of the firm: NA**
- **History (2021 onwards): Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 3

PQCB/MSS-197408/ 2024

CEO DHA Bahawalpur

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Managing Director, Muzammil Nazar 2. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, o/o CEO DHA Bahawalpur, reported that: -

i. She, on 24-04-2024, inspected the premises of Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, took 03 different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 197408 dated 24-04-2024,
ii. Following drug sample, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Bahawalpur**, as detailed below:

Name of Drug	Batch no.	Manufacturer	TRA No. & Date
Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. date: 11-2023** **Exp. date: 11-2025** **Reg.No. 002772**	185-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	TRA 01-10097008320 /DTL 14-06-2024

Specs Applied: USP 2024/Others/In house

COMPOSITION: Each 5ml contains: **Paracetamol USP…. 120mg**

PHYSICAL CHARACTERISTICS:

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles,** filled in an amber plastic

bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms ***"A suspension is a biphasic***

preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9 Determined: 5.5 at 24.5ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml **Determined** 124.06 mg/5ml (103.38%) **Limit** 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Limit: NMT 0.1%	Limit: NMT 0.1%
Determined: Not Detected	Determined: Not Detected
Propylene Glycol	
Determined: 11.54%	

RESULT:The Sample is declared as **"SUB-STANDARD"** on basis of Physical Characteristics.

iii. Store Keeper, Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, provided invoice/ warranty No. 000776 dated 27-03-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi., as a proof of its purchase

iv. Warrantor portion of drug sample was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. Copy of test/analysis reports was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug samples from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its **283rd Special meeting** held on **20-08-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request for retesting.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/ Sale of Substandard Drug**
b. **Issuance of false warranty**

3. Show cause/Personal hearing Notice notice(s) issued to the accused persons(s) dated 01-01-2025.
4. The firm submitted review petition against the orders of 283rd special meeting dated 20-08-2024 vide letter no. Nil dated Nil (Received on 06-11-2024).

GROUNDS OF REVIEW PETITION:

5. Same as case MSS-197407/2024.
6. Show cause/ Personal Hearing notice(s) issued to accused person(s) dated 01-01-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

7. Same as case MSS-197407/2024.

8. Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 11-2023**
- **Exp. Date: 11-2025**
- **Sampling date (Form 4): 24-04-2024**
- **Sent to DTL (Form 6): 24-04-2024**
- **Date of receipt in DTL: 25-04-2024**
- **DTL Report Date (Form 7): 14-06-2024**
- **DI 1st intimation to firm: 15-06-2024**
- **Retesting request if any: 21-06-2024**
- **Fate of Retesting: Turned down in 283rd special meeting dated 20-08-2024**
- **Investigation report Dated: 12-08-2024**
- **Permission of SCN: 287-M dated 08-01-2025 (Post-Facto)**
- **SCN Issued: 01-01-2025**
- **Reply of the firm: NA**
- **History (2021 onwards): Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 4

PQCB/MSS-197409/2024

CEO DHA Bahawalpur

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Managing Director, Muzammil Nazar 2. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, o/o CEO DHA Bahawalpur, reported that: -

i. She, on 24-04-2024, inspected the premises of Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, took 03 different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 197409 dated 24-04-2024,
ii. Following drug sample, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Manufacturer	TRA No. & Date
Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. date: 11-2023** **Exp. date: 11-2025** **Reg.No. 002772**	186-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	TRA 01-10097008321/DTL 14-06-2024
Specs Applied: USP 2024/Others/In house **COMPOSITION:** Each 5ml contains: **Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated:** Pinkish red sweet suspension.			

Determined: Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles,** filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms ***"A suspension is a biphasic***

preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9 Determined: 5.4 at 24.5ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml **Determined** 125.08 mg/5ml (104.23%) **Limit** 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Limit: NMT 0.1%	Limit: NMT 0.1%
Determined: Not Detected	Determined: Not Detected
Propylene Glycol	
Determined: 11.33%	

RESULT:The Sample is declared as **"SUB-STANDARD"** on basis of Physical Characteristics.

iii. Store Keeper, Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, provided invoice/ warranty No. 000776 dated 27-03-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi., as a proof of its purchase

iv. Warrantor portion of drug sample were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. Copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug samples from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its **283rd Special meeting** held on **20-08-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request

for retesting.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/ Sale of Substandard Drug**
b. **Issuance of false warranty**

3. Show cause/Personal hearing Notice notice(s) issued to the accused persons(s) dated 01-01-2025.
4. The firm submitted review petition against the orders of 283rd special meeting dated 20-08-2024 vide letter no. Nil dated Nil (Received on 06-11-2024).

GROUNDS OF REVIEW PETITION:

5. Same as case MSS-197407/2024.

6. Show cause/ Personal Hearing notice(s) issued to accused person(s) dated 01-01-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

7. Same as case MSS-197407/2024.

8. Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 11-2023**
- **Exp. Date: 11-2025**
- **Sampling date (Form 4): 24-04-2024**
- **Sent to DTL (Form 6): 24-04-2024**
- **Date of receipt in DTL: 25-04-2024**
- **DTL Report Date (Form 7): 14-06-2024**
- **DI 1st intimation to firm: 15-06-2024**
- **Retesting request if any: 21-06-2024**
- **Fate of Retesting: Turned down in 283rd special meeting dated 20-08-2024**
- **Investigation report Dated: 12-08-2024**
- **Permission of SCN: 287-M dated 08-01-2025 (Post-Facto)**
- **SCN Issued: 01-01-2025**
- **Reply of the firm: NA**
- **History (2021 onwards): Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Managing Director, Muzammil Nazar 2. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, o/o CEO DHA Bahawalpur, reported that: -

i. She, on 24-04-2024, inspected the premises of Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, took 03 different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 197409 dated 24-04-2024,
ii. Following drug sample, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Manufacturer	TRA No. & Date
Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. date: 11-2023** **Exp. date: 11-2025** **Reg.No. 002772**	186-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	TRA 01-10097008321/DTL 14-06-2024

Specs Applied: USP 2024/Others/In house

COMPOSITION: Each 5ml contains: **Paracetamol USP…. 120mg**

PHYSICAL CHARACTERISTICS:

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles,** filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms ***"A suspension is a biphasic***

preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9 Determined: 5.4 at 24.5ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml **Determined** 125.08 mg/5ml (104.23%) **Limit** 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Limit: NMT 0.1%	Limit: NMT 0.1%
Determined: Not Detected	Determined: Not Detected
Propylene Glycol	
Determined: 11.33%	

RESULT:The Sample is declared as **"SUB-STANDARD"** on basis of Physical Characteristics.

iii. Store Keeper, Medicine Store, o/o Chief Executive Officer (DHA), Bahawalpur, provided invoice/ warranty No. 000776 dated 27-03-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi., as a proof of its purchase

iv. Warrantor portion of drug sample were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. Copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug samples from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its **283rd Special meeting** held on **20-08-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request for retesting.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/ Sale of Substandard Drug**

b. **Issuance of false warranty**

3. Show cause/Personal hearing Notice notice(s) issued to the accused persons(s) dated 01-01-2025.
4. The firm submitted review petition against the orders of 283rd special meeting dated 20-08-2024 vide letter no. Nil dated Nil (Received on 06-11-2024).

GROUNDS OF REVIEW PETITION:

5. Same as case MSS-197407/2024.

6. Show cause/ Personal Hearing notice(s) issued to accused person(s) dated 01-01-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

7. Same as case MSS-197407/2024.

8. Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 11-2023**
- **Exp. Date: 11-2025**
- **Sampling date (Form 4): 24-04-2024**
- **Sent to DTL (Form 6): 24-04-2024**
- **Date of receipt in DTL: 25-04-2024**
- **DTL Report Date (Form 7): 14-06-2024**
- **DI 1st intimation to firm: 15-06-2024**
- **Retesting request if any: 21-06-2024**
- **Fate of Retesting: Turned down in 283rd special meeting dated 20-08-2024**
- **Investigation report Dated: 12-08-2024**
- **Permission of SCN: 287-M dated 08-01-2025 (Post-Facto)**
- **SCN Issued: 01-01-2025**
- **Reply of the firm: NA**
- **History (2021 onwards): Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 5

PQCB/MSS-194360, 194359/2024

Tehsil and District Layyah

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Director, M. Muzammil Nazar 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Incharge 4. Naima Khanam Quality Control Manager/Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil and District Layyah, reported that: -

i. The then Drug Inspector, on 09-03-2024, inspected the premises of Main Medicine Store, O/o Chief Executive Officer (DHA), Layyah and took 09 different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.
ii. The subject drug samples, sent vide memo no. 194360 and 194359, dated: 09-03-2024, after test/analysis were declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Multan**, as detailed below:

Sr #	Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date
1	Parapol Paediatric Suspension **Mfg. date: 11-2023** **Exp. Date: 11-2025** **Reg. # 002772**	183-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-105005913/DTL Dated: 07.06.2024
	Specifications applied for test/analysis: USP 2024/Others/In house **PHYSICAL DESCRIPTION:** **Stated:** Pinkish red **sweet** suspension. **Determined:** Parapol is a pinkish red, viscous liquid having **bitter** taste, **free from any dispersed solid particles** in a labeled amber			

colored plastic bottle sealed with white screw cap packed in a labeled outer hard carton.

As per USP <1151> Pharmaceutical Dosage Forms; ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."*** **(Does not Comply)**

IDENTIFICATION Paracetamol is Identified.

ASSAY by HPLC:

Paracetamol Stated: 120 mg /5mL

Determined: 128.89 mg /5mL

Percentage: 107.41 %

Limit: 90 - 110% **(Complies)**

pH Range: 4.0-6.9

Determined: 5.31 at 24.5^{0}C **(Complies)**

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Stated: NMT 0.1%	Stated: NMT 0.1%
Determined: Not Detected	Determined: Not Detected
(Complies)	**(Complies)**
Propylene Glycol	
Determined: 10.42%w/v	

"Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-38/2024,

Dated 21-05-2024".

Result: The above-mentioned sample is declared **Sub-Standard** on the basis of Physical Characteristics.

2	**Parapol Paediatric Suspension** **Mfg. date: 11-2023**	180-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-105005912/DTL Dated: 07.06.2024

Exp. Date: 11-2025 **Reg # 002772**			

Specifications applied for test/analysis: USP 2024/Others/In house

PHYSICAL DESCRIPTION:

Stated: Pinkish red **sweet** suspension.

Determined: Parapol is a pinkish red, viscous liquid having **bitter** taste, **free from any dispersed solid particles** in a labeled amber colored plastic bottle sealed with white screw cap packed in a labeled outer hard carton.

As per USP <1151> Pharmaceutical Dosage Forms; ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."*** **(Does not Comply)**

IDENTIFICATION Paracetamol is Identified.

ASSAY by HPLC:

Paracetamol Stated: 120 mg /5mL

Determined: 112.28 mg /5mL

Percentage: 93.57 %

Limit: 90 - 110% **(Complies)**

pH Range: 4.0-6.9

Determined: 5.37 at 24.7^{0}C **(Complies)**

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol: Stated: NMT 0.1% Determined: Not Detected **(Complies)**	**Diethylene Glycol:** Stated: NMT 0.1% Determined: Not Detected **(Complies)**

Propylene Glycol

Determined: 9.14%w/v

"Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-38/2024,

Dated 21-05-2024".

Result: The above-mentioned sample is declared **Sub-Standard** on the basis of Physical Characteristics.

iii. Store Keeper, Main Medicine Store, O/o Chief Executive Officer (DHA), Layyah, provided invoice/ warranty No. 000692 dated 23-02-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi., as a proof of its purchase

iv. Warrantor portions of drug samples were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. A copy of test/analysis reports was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its **42nd Committee meeting** held on **30-07-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request for retesting..

2. The Drug Inspector requested for grant of permission for prosecution against the accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976(as amended)/DRAP Act 2012 and Rules framed there under by the way of:

   a. **Manufacture for Sale /stocking/selling of Substandard Drug**
   b. **Issuance of false warranty**

3. Show-cause/ Personal Hearing notice(s) issued to accused person(s) vide 01-01-2025.
4. The firm submitted review petition against the orders of **42nd Committee meeting** held on **30-07-2024** vide letter no. Nil dated Nil (Received on 06-11-2024).

GROUNDS OF REVIEW PETITION:

SUBJECT: REVIEW PETITION UNDER CLAUSE VIII O THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We M/S Lisko Pakistan (Pvt) Ltd **Petitioner Company"** would like to submit instant review petition A the learned Provincial Quality Control Board. Puniab against the order of committee PQCB dated 16-09-2024 (the **"impugned Decision"**) in which request of re-testing from NIH, Islamabad has been turned down orders attached) for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspector of Drugs, Layyah (the "Respondent Drug Inspector") has been directed to expedite Investigation so that permission for prosecution can be granted. Details of batches are as below:

Batch #	TRA #	DTL	Reason for Sub standard	Committee meeting in which impugned decision was taken	Meeting for show cause and personal hearing before permission for prosecution
183-24	01-105005913	Multan	Physical Characteristics (Bitter taste and absence of solid particles as per USP<1151>)	42nd meeting of committee PQCB dated 30-07-2024 (Order dated 20-09-2024)	Pending
180-24	01-105005912	Multan			

There are several grave infirmities and ambiguities in DTL reports **"Impugned reports"** issued by government analyst of DTL Multan and also in decision **"Impugned Order** by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, It is pertinent to **highlight the fresh grounds** that have arisen in the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. Committee PQCB has turned down request for retesting from NIH, Islamabad with the statement which itself contains several ambiguities and infirmities

> the committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate with the formulation with respect to bitter taste and propylene glycol concentration hence unanimously decided to turn down the retesting request of the firm"

However, government analyst has not declared samples substandard on the basis of concentration of propylene glycol rather it has been declared substandard on the basis of physical characteristics (Bitter taste and absence of solid particles as per USP <1151>). Once appeal for retesting has been submitted against impugned reports and errors are being highlighted by the firm, committee PQCB can only scrutinize grounds on the basis of which samples have been declared substandard but cannot introduce new grounds or raise additional issues in DTL report by their own if they were not shown as noncompliant by the government analyst in the initial report. Drug act 1976 and other existing laws have clearly defined duties and limitations of both government analyst and PQCB. Members of committee PQCB initiated discussion i.e toxicity due to propylene glycol, role of propylene glycol to solubilizing Paracetamol without having conclusive evidences and turned down appeal for retesting by relying on this premise. Therefore, all discussion in impugned order related to propylene glycol is unlawful and illegal and cannot be relied as ground on the basis of which appeal has been turned down.

2. It is very important to highlight and note that government analyst maliciously used reference of WHO working document (QAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely impermissible and unlawful. This act of analyst also raises serious concerns regarding the credibility cred and accuracy of the test protocol employed for determining the concentration of propylene glycol.

3. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house / others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on 'In- house/other specifications' renders the report invalid and inaccurate.

4. The government analyst has wrongfully claimed the products to be a "liquid" and "free from any dispersed solid particles" despite the same being a suspension. Government analyst has quoted reference of USP general chapters <1151> for showing non- compliance. However, it is important to highlight that USP general chapters <1151> on the basis of which samples were declared ubstandard has only the definition of suspension but no specific method or procedure to classify product as suspension,. solution or syrup. Same has been confirmed in letters by NIH, Islamabad dated 6-6-2024 and 29-8-2024 to PQCB as below:

i. Letter dated 6th June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any such test on the basis of which the samples are declared sub-standard by DTLs of Punjab
ii. Letter dated 29th August 2024 **"It is once again informed that USP monograph for Acetaminophen oral suspension have different tests including test from the general chapters Le performance test (uniformity of dosage units 905, deliverable volume 698, impurities (4-Aminophenol in Acetaminophen containing Drug Products-277), specific test (pH 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the samples were declared substandard by DTLs Punjab and "The USP General Chapter <1151> on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply"**

The foregoing infirmity makes the report invalid and baseless.

5. It is important to highlight that learned Board (PQCB) has already investigated matter of presence / absence of particles in "Parapol susp" by constituting a **special committee of 5 pharmaceutical experts among which 2 honorable members were from PQCB**. Honorable members of special committee comprehensively scrutinized samples and concluded their findings in our favor which supports our claim of being "suspension". It is categorically mentioned in findings that **Parapol is a "Biphasic liquid like suspension" having translucent appearance due to of presence of particles** (copy of findings of expert committee attached). However, in contrary, same members who were convinced enough that particles are present, later on starte ignored this finding and became part of that impugned decision in which request for retesting has been turned down. This act of contradiction cast a doubt on principle of "fair trail and due process".

6. It is pertinent to highlight **act of victimization and unfair attitude of DTLs of Punjab towards product "Parapol" which necessitate and make premise for re-testing from NIH, Islamabad for fair analysis and reassessment of samples**. Drug testing laboratory in Bahawalpur (DTL Bahawalpur) initially declared two batches of Parapol suspension (Batch No. 178-24 and 179-24) as standard quality on 09-03-2024 and uploaded the corresponding reports on their portal. However, these standard reports were later removed, and sub-standard reports for the same batches were uploaded instead. Such illegal act clear cast a doubt on credibility of process and protocols applied for testing and hence there is strong need for the conclusive report from the appellate lab through fair and unbiased analysis.

ILTO chi

7. Government analyst has mentioned in form 7 "S.No# 6" that **"USP 2024 / In-House / Others" has been applied**. However, it is pertinent to highlight that neither **USP 2024 nor method of analysis (In-House) of Parapol suspension (if) provided by the firm gives any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension/solution/syrup**. Therefore, Product "Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

8. The government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

9. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited 'USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. Samples of Parapol suspension were declared substandard based solely on personal observation (bitter taste) without conducting chemical analysis for accurate and instrument based identification of sweetener in the composition.

10. It is pertinent to inform that in our previous meetings of committee PQCB, when we requested to kindly evaluate our sample, cor nittee members PQCB was of the opinion that product sample cannot be evaluated & tested in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIH Islamabad for conclusive report. Similarly, taste profile (Sweetness / bitterness) and presence of particles as per USP <1151> can be tested and evaluated only in appellate lab if firm had already highlighted numerous errors in testing and findings of government analyst. However, opinion of the committee PQCB regarding the same product has suddenly been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product**, samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions.**

11. Since Parapol suspension was being declared of standard quality by DTL Multan till 30- 09-2023 this proves that till this date, as per analysts of DTL Multan, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Multan must have received a revised and new method of analysis from the firm after 30-9-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 30-09-2023 which proves malice intention and act of victimization by government analyst.

12. Here, we would like to highlight following numerous flaws and inaccuracies in the impugned order made by the committee PQCB in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. Representative of the firm never agreed with the findings of government analyst "bitter taste" rather strongly contested in all meetings that sweetener "neotame" is present in the formulation which has been added to mask bitter taste and firm has always claim in all meetings that Parapol suspension ensure a palatable profile that supports patient compliance. That is why, no any single complain has been reported due to bitter taste in any forum or by the procuring agency since its registration.

b. Firm's claim & appeal regarding presence of sweetener and sweetness of suspension could only be verified if the samples will be sent to NIH, Islamabad for the conclusive report however same has not been done as per the impugned order deprived us from right of justice.

c. Firm's claim & appeal regarding presence of small solid particles and product as suspension as per USP <1151> could only be verified if the samples will be sent to NIH, Islamabad for re-testing. However, same has not been done by the committee PQCB. It is also to be noted that PQCB has already sent 42 cases of Parapol suspension to NIH, Islamabad for the conclusive result in past and now for these disputed batches, appeal for retesting has been turned down.

d. It is to be noted that discussion and statements regarding toxicity and side effects of higher concentrations of propylene glycol makes no sense when government analyst admitted that method applied to determine exact concentration of propylene glycol is not as per WHO reference document rather it has been derived from it which cast clear doubt on credibility of method and its accuracy. Firm's claim of addition of less than 1% propylene glycol has been completely overlooked in the impugned order and no scrutiny was carried out by the committee PQCB to verify firm's claim. Firm stated in every committee meeting before honorable board that we are supplying same product with the same formulation across Pakistan for decades and millions of children have safely consumed this product to alleviate pain and fever without any reported clinical toxicity. Despite this, the PQCB committee exhibited an unfair approach by relying on the impugned results of the government analyst, who determined the concentration of propylene glycol using a non-reliable and non-pharmacopeial method.

e. On what basis and in what capacity did Mr. Ijaz Alvi, Director of DTL Rawalpindi, present his views regar og the toxicity of propylene glycol before the committee, given that the impugned reports pertain exclusively to DTL Multan? It is to be noted that Mr. Ijaz Alvi is not part of committee PQCB and firm has no faith on him as he is part of malicious campaign against our product. This raises concerns about the impartiality of the process and suggests a coordinated effort by all DTLs of Punjab to unfairly target the product 'Parapol' without relying on legal facts and objective findings.

f. How and on what grounds committee members got convinced by views of Mr. Ijaz Alvi (Director, DTL Rawalpindi), Director DTL Multan and Mr. Sohail Tofail (Government analyst, DTL Multan) in which they were trying to establish a view that firm has solubilized paracetamol in propylene glycol without counter verifying it with firm's claim?. Firm has already provided list of excipients with quantities before the committee PQCB in which it was mention that firm added propylene glycol less than 1% in the formulation of Parapol suspension only with the purpose as stabilizer and as preservative. Firm's representative comprehensively explained that it is practically impossible to solubilize paracetamol in an amount of propylene glycol and water that has been used in the formulation of Parapol suspension. Nevertheless, the PQCB committee chose to accept the unverified personal opinions of the individuals mentioned and issued a biased decision without validating the firm's assertions.

g. Question ie testing of propylene glycol in finished product duly raised by the committee members is inaccurate as firm is not bound to test excipients in finished form neither does tested by any DTL of Pakistan. Firm is always well aware of the fact that how much amount of any excipient is being added in formulation and as per GMP guidelines, all excipients are being consumed once passed initially from quality control department. Moreover, Specs claimed for Parapol suspension is USP and firm carries out all applicable test as per USP which specifically provide testing of API in a finished product only. Despite of the fact, committee PQCB turned down our appeal for retesting to prevent us from the right of justice.

h. The quality of propylene glycol as a raw material, along with its associated standards, cannot be questioned or used as grounds for denying the request for re- testing. The impugned DTL reports themselves acknowledge compliance with the WHO reference document and confirm the absence of impurities such as EG and DEG, which demonstrates that the quality of the propylene glycol used was fully compliant and without any issues. Furthermore, under the latest DRAP guidelines, propylene glycol cannot be released for use unless tested by federal laboratories. The firm has consistently stated in all meetings that the propylene glycol used in the batches of Parapol suspension was tested and approved by the Central Drug Laboratory (CDL) in Karachi prior to its consumption.

i. As per remarks mentioned in the impugned order "there is need to reevaluate with the formulation", it is to be noted that only the appellate lab (NIH) is the forum which can give conclusive report after reevaluation & reassessment of the samples in question and that is why we appealed for retesting from NIH, Islamabad. Board members of PQCB have stated several times that board / committee cannot examine and retest samples by their own against the grounds on the basis of which samples have been declared substandard hence it becomes necessary to get conclusive report from the appellate lab.

Additionally, we would like to highlight grounds comprehensively which have already been discussed im difference committee meeting that further supports our stance in said case:

1. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:

"It is also to inform you that the Federal Drag Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 (Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976)"

In this regard, committee PQCB was duty bound to consider the foregoing fact whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

2. The malafide intentions of the Government Analysts and Director DTL Multan are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Multan has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Multan contributing 80 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

3. Since, product "Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe/ instruct to conduct test for determination of the taste of the products, test to check whether product is syrup, solution or suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopieal testing.

4. It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc) of the "finished form" of the drug. In this context, the Products, like all other drugs, underwent a comprehensive manufacturing process wherein in addition to the active pharmaceutical ingredient, several other excipients were also added. Additionally, tests are prescribed in the specifications to ascertain the quality of a "finished form of drug". Thus, only tests that could have been performed

by the government analyst were those prescribed in the USP and any additional information sought in relation to the excipients and or other ingredients or any testing carried out on the basis of the same is illegal and unlawful.

5. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the substandard drugs". However, in our case, government analyst has shown her/his malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

6. Section 3(z) of the Drugs Act, 1976 defines the term specifications as.

(i) such specifications as may be prescribed;

(ii) or when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:-

(1) the Pakistan Pharmacopoeia;

(2) the International Pharmacopoeia;

(3) the European Pharmacopoeia;

(4) the United States Pharmacopoeia;

(5) the British Pharmacopoeia;

(6) the British Pharmaceutical Codex;

(7) the United States National Formulary; and

(8) Such other publication as may be prescribed:

In terms of the legislative scheme envisioned under the Drugs Act, 1976, more particularly, Section 3(zz) a drug shall only be deemed as substandard if it does not comply with the applicable specifications. Essentially, such determination can only be made if the drug fails to comply with the tests "prescribed" under the applicable specifications. The monograph of a drug provided under the applicable specifications lists down the requisite tests that need to be conducted in order to determine whether the drug is of standard quality. It is a matter of fact that the Drugs Act does not permit analysts to carry out inapplicable tests or tests, which have not been listed down in the applicable specifications. However, in context of the present case, **the Government Analysts have malafidely declared the batches of the Product as substandard on the basis of their bitter taste & absence of solid particles without there being any criteria or test to determine the same. The foregoing action clearly constitutes a violation of the Drugs Act, 1976 as well as Rule 16 of The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rule 1976.**

In the light of above highlighted facts and infirmities, it can be concluded that committee PQCB has failed to scrutinize the case properly as it has overlooked above evidences and factual findings. **The illegalities floating on the record of the case and as mentioned in above grounds have been completely overlooked and no heed has been paid to the wrongdoings of the government analyst who has declared the Products to be of substandard quality on a completely wrongful premise. It was mandatory upon this committee PQCB to properly scrutinize the subject especially in this case when samples comply with the stated specification chemically and physically and adjudicate upon the same.** However, no such exercise has been carried out in the present case.

Furthermore, it is to be noted that our firm petitioner Company" and its officials have not contravened the provisions of the Drug Laws and the rules made thereunder rather they are committed to ensure compliance thereof. **PQCB passed an impugned order (turning down request for retesting) which completely disregard not just of the principles of fair trial and due process envisioned under Article 10-A and Article 4 of the Constitution but also disregard of the scheme of law envisioned under the Drugs Act, 1976 as-well as the fundamental rights of the Petitioner Company enshrined under the Constitution of Islamic Republic of Pakistan, 1973**.

On the premise of foregoing submission and grounds highlighted above, it is mandatory and essential for the learned Board to review its decision. We reserves the right to agitate additional grounds at the time of arguments if needed. We as “Petitioners" are seeking the setting aside of the Impugned Decision in terms

of clause 2 of Part VIII of the PQCB Regulations and pray as below:

PRAYER

In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:

i. **Set aside the Impugned Order in which committee PQCB turned down appeal for re-testing and directed Provincial Inspector of and Drugs, Layyah, to expedite investigation submission of final report.**

ii. Pass an order for the samples of Suspension Parapol Batch No. 183- 24 and Batch No. 181-24 to be sent to the National Institute of Health, Islamabad and allow retesting of samples.

iii. Direct the government analyst of the Drug Testing Laboratory, Multan to bring the method and protocols of the test employed to determine the taste of the Suspension and test to determine presence or absence of particles in suspension.

v. Permanently restrain the Provincial Inspector of Drugs, Layyah from taking any adverse and/or coercive action against our firm "Petitioner Company" and against our officials based on the Impugned order / decision.

We hope that learned board will allow us to avail right of fair trial and accept above.

Previous Proceedings & Decision by the Board:

287th meeting held on 08-01-2025

5. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, vice-chairperson PQCB. Mr. Amir Shakeel, Secretary DQCB Layyah attended the meeting online via zoom link along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeil test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary individual to individual basis and there will be no toxicity or adverse effects due to bitter taste
ii. We are confident that our product is suspension and complies all applicable test of USP monograph "acetaminophen oral suspension".
iii. As far as declaring our samples substandard declaring them to be "free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iv. He further added that although the DTL has quantified Propylene Glycol in the test report but failed to mention the limit and to specify whether it complies or not with any official monograph.
v. He further reiterated firm's request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting.

7. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 183-24 & 180-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], ,

have been declared substandard by the Drugs Testing Laboratory, Multan on the basis of physical description as "Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles**" further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 14-06-2024 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was turn down in 42nd Committee meeting of the Board held on 30-07-2024. Regarding firm's review petition against retesting orders and the plea to send their subject batches to NIH for retesting, the Board observed that in 279th meeting held on 24-04-2024, the Board sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976. Hence, the re-submitted retesting request by the firm in its review petition received on 04-11-2024 cannot be accepted and hence, is **turned down** and **previous decision taken in 42nd Committee meeting dated 30-07-2024 is upheld**.

8. Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

9. While perusing the case record, the Board remarked that the samples in question were declared substandard on the basis of physical description as per General Chapter <1151> of the USP, bitter taste of suspension and quantification of polyethylene glycol by the Government Analyst DTL Multan. The firm claims the product as "Suspension" on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Multan. Furthermore, regarding bitter taste of the suspension, the Board was of the view that the product has been developed for pediatrics use and bitter taste of suspension as reported by the DTL in the subject reports, will result in non-compliance and reluctance to take medication by children.

10. The Board further observed that the DTL also determined the percentage of Propylene Glycol as 10.42% w/v & 9.14% w/v in the batches under consideration by applying WHO Working Document QAS/23.922/rev3 Dated 31 October 2023.

Acceptable Dietary Intake of Propylene Glycol				
EMA		**50mg/kg/day**		
WHO		**25mg/kg/day**		
Batch No.	**PG Determined (as per DTL Report)**	**PG Content mg/kg/day (Calculated as per EMA Guidelines, keeping in view firm's own label recommended dose for a child weighing 10kg, 15kg & 18kg respectively)**		
		PG (mg/kg/day)	**PG (mg/kg/day)**	**PG (mg/kg/day) (120mL Dose)**

		(30mL Dose)	(60mL Dose)	
183-24	9.14%	284.07	378.76	631.27
180-24	10.42%	323.85	431.80	719.67

The Board further observed that as per guidelines of European Medicine Agency published vide No. EMA/CHMP/704195/2013 dated 09.10.2017, propylene glycol is estimated to be one-third as intoxicating as ethanol, with administration of large volumes being associated with adverse effects most commonly on the central nervous system, especially in neonates and children. Other adverse reactions reported through generally isolated, include: ototoxicity, cardiovascular effects; seizures; and hyperosmolarity and lactic acidosis, both of which occur most frequently in patients with renal impairment. Adverse effects are more likely to occur following consumption of large quantities of propylene glycol or on administration to neonates, children under 4 years of age, pregnant women, and patients with hepatic or renal failure. Adverse events may also occur in patients treated with disulfiram or metronidazole. Keeping in view all aspects of case, the Board after due deliberation and detailed discussion, unanimously decided to **pend the case.**

5. Personal Hearing notice(s) issued to accused person(s) vide 01-01-2025
6. Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 11-2023**
- **Exp. Date: 11-2025**
- **Sampling date (Form 4): 09-03-2024**
- **Sent to DTL (Form 6): 09-03-2024**
- **Date of receipt in DTL: 13-03-2024**
- **DTL Report Date (Form 7): 07-06-2024**
- **DI 1st intimation to firm: 13-06-2024**
- **Retesting request if any: 14-06-2024**
- **Fate of Retesting: Turned down in 42nd Committee meeting dated 30-07-2024**
- **Investigation report Dated: 28-10-2024**
- **Permission of SCN: 287-M dated 08-01-2025 (Post-Facto)**
- **SCN Issued: 01-01-2025**
- **Reply of the firm: NA**
- **Retest Review Status:** Upheld in 287-M (08-01-2025)
- **History: Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-194360, 194359/2024

Tehsil and District Layyah

ATTENDANCE

Secretary DQCB **Drug Inspector**	**<u>Accused Persons involved in subject case</u>** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Director, M. Muzammil Nazar 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Incharge 4. Naima Khanam Quality Control Manager/Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.**

<u>BRIEF FACTS OF THE CASE:</u>

Provincial Inspector of Drugs, Tehsil and District Layyah, reported that: -

i. The then Drug Inspector, on 09-03-2024, inspected the premises of Main Medicine Store, O/o Chief Executive Officer (DHA), Layyah and took 09 different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.
ii. The subject drug samples, sent vide memo no. 194360 and 194359, dated: 09-03-2024, after test/analysis were declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Multan**, as detailed below:

Sr #	Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date
1	Parapol Paediatric Suspension **Mfg. date: 11-2023** **Exp. Date: 11-2025** **Reg. # 002772**	183-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-105005913/DTL Dated: 07.06.2024

<u>Specifications applied for test/analysis:</u> USP 2024/Others/In house

<u>PHYSICAL DESCRIPTION</u>:

Stated: Pinkish red **<u>sweet</u>** suspension.

Determined: Parapol is a pinkish red, viscous liquid having **<u>bitter</u>** taste, **<u>free from any dispersed solid particles</u>** in a labeled amber colored plastic bottle sealed with white screw cap packed in a labeled outer hard carton.

As per USP <1151> Pharmaceutical Dosage Forms; ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."*** **(Does not Comply)**

<u>IDENTIFICATION</u> Paracetamol is Identified.

<u>ASSAY by HPLC:</u>

Paracetamol Stated: 120 mg /5mL

Determined: 128.89 mg /5mL

Percentage: 107.41 %

Limit: 90 - 110% **(Complies)**

pH Range: 4.0-6.9

Determined: 5.31 at 24.5^{0}C **(Complies)**

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Stated: NMT 0.1%	Stated: NMT 0.1%
Determined: Not Detected	Determined: Not Detected
(Complies)	**(Complies)**

Propylene Glycol

Determined: 10.42%w/v

"Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-38/2024,

Dated 21-05-2024".

Result: The above-mentioned sample is declared **Sub-Standard** on the basis of Physical Characteristics.

2	**Parapol Paediatric Suspension** **Mfg. date: 11-2023** **Exp. Date: 11-2025** **Reg # 002772**	180-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-105005912/DTL Dated: 07.06.2024

Specifications applied for test/analysis: USP 2024/Others/In house

PHYSICAL DESCRIPTION:

Stated: Pinkish red **sweet** suspension.

Determined: Parapol is a pinkish red, viscous liquid having **bitter** taste, **free from any dispersed solid particles** in a labeled amber colored plastic bottle sealed with white screw cap packed in a labeled outer hard carton.

As per USP <1151> Pharmaceutical Dosage Forms; ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."*** **(Does not Comply)**

IDENTIFICATION Paracetamol is Identified.

ASSAY by HPLC:

Paracetamol	Stated:	120 mg /5mL	
	Determined:	112.28 mg /5mL	
	Percentage:	93.57 %	
	Limit:	90 - 110%	**(Complies)**
pH	Range:	4.0-6.9	
	Determined:	5.37 at 24.7^{0}C	**(Complies)**

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Stated: NMT 0.1%	Stated: NMT 0.1%
Determined: Not Detected	Determined: Not Detected
(Complies)	**(Complies)**

Propylene Glycol

Determined: 9.14%w/v

"Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-38/2024,

Dated 21-05-2024".

Result: The above-mentioned sample is declared **Sub-Standard** on the basis of Physical Characteristics.

iii. Store Keeper, Main Medicine Store, O/o Chief Executive Officer (DHA), Layyah, provided invoice/ warranty No. 000692 dated 23-02-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B.

Industrial Area, Karachi., as a proof of its purchase

iv. Warrantor portions of drug samples were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. A copy of test/analysis reports was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its **42nd Committee meeting** held on **30-07-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request for retesting..

2. The Drug Inspector requested for grant of permission for prosecution against the accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976(as amended)/DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for Sale /stocking/selling of Substandard Drug**
b. **Issuance of false warranty**

3. Show-cause/ Personal Hearing notice(s) issued to accused person(s) vide 01-01-2025.

4. The firm submitted review petition against the orders of **42nd Committee meeting** held on **30-07-2024** vide letter no. Nil dated Nil (Received on 06-11-2024).

GROUNDS OF REVIEW PETITION:

SUBJECT: REVIEW PETITION UNDER CLAUSE VIII O THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We M/S Lisko Pakistan (Pvt) Ltd **Petitioner Company"** would like to submit instant review petition A the learned Provincial Quality Control Board. Puniab against the order of committee PQCB dated 16-09-2024 (the **"impugned Decision"**) in which request of re-testing from NIH, Islamabad has been turned down orders attached) for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspector of Drugs, Layyah (the "Respondent Drug Inspector") has been directed to expedite Investigation so that permission for prosecution can be granted. Details of batches are as below:

Batch #	**TRA #**	**DTL**	**Reason for Sub standard**	**Committee meeting in which impugned decision was taken**	**Meeting for show cause and personal hearing before permission for prosecution**
183-24	01-105005913	Multan	Physical Characteristics (Bitter taste and absence of solid particles as per USP<1151>)	42nd meeting of committee PQCB dated 30-07-2024 (Order dated 20-09-2024)	Pending
180-24	01-105005912	Multan			

There are several grave infirmities and ambiguities in DTL reports **"Impugned reports"** issued by government analyst of DTL Multan and also in decision **"Impugned Order** by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, It is pertinent to **highlight the fresh grounds** that have arisen in the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. Committee PQCB has turned down request for retesting from NIH, Islamabad with the statement which itself contains several ambiguities and infirmities

the committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate with the formulation with respect to bitter taste and propylene glycol concentration hence unanimously decided to turn down the

retesting request of the firm"

However, government analyst has not declared samples substandard on the basis of concentration of propylene glycol rather it has been declared substandard on the basis of physical characteristics (Bitter taste and absence of solid particles as per USP <1151>). Once appeal for retesting has been submitted against impugned reports and errors are being highlighted by the firm, committee PQCB can only scrutinize grounds on the basis of which samples have been declared substandard but cannot introduce new grounds or raise additional issues in DTL report by their own if they were not shown as noncompliant by the government analyst in the initial report. Drug act 1976 and other existing laws have clearly defined duties and limitations of both government analyst and PQCB. Members of committee PQCB initiated discussion i.e toxicity due to propylene glycol, role of propylene glycol to solubilizing Paracetamol without having conclusive evidences and turned down appeal for retesting by relying on this premise. Therefore, all discussion in impugned order related to propylene glycol is unlawful and illegal and cannot be relied as ground on the basis of which appeal has been turned down.

2. It is very important to highlight and note that government analyst maliciously used reference of WHO working document (QAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely impermissible and unlawful. This act of analyst also raises serious concerns regarding the credibility cred and accuracy of the test protocol employed for determining the concentration of propylene glycol.

3. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house / others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on 'In- house/other specifications' renders the report invalid and inaccurate.

4. The government analyst has wrongfully claimed the products to be a "liquid" and "free from any dispersed solid particles" despite the same being a suspension. Government analyst has quoted reference of USP general chapters <1151> for showing non- compliance. However, it is important to highlight that USP general chapters <1151> on the basis of which samples were declared ubstandard has only the definition of suspension but no specific method or procedure to classify product as suspension,. solution or syrup. Same has been confirmed in letters by NIH, Islamabad dated 6-6-2024 and 29-8-2024 to PQCB as below:

i. Letter dated 6th June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any such test on the basis of which the samples are declared sub-standard by DTLs of Punjab
ii. Letter dated 29th August 2024 **"It is once again informed that USP monograph for Acetaminophen oral suspension have different tests including test from the general chapters Le performance test (uniformity of dosage units 905, deliverable volume 698, impurities (4-Aminophenol in Acetaminophen containing Drug Products-277), specific test (pH 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the samples were declared substandard by DTLs Punjab and "The USP General Chapter <1151> on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply"**

The foregoing infirmity makes the report invalid and baseless.

5. It is important to highlight that learned Board (PQCB) has already investigated matter of presence / absence of particles in "Parapol susp" by constituting a **special committee of 5 pharmaceutical experts among which 2 honorable members were from PQCB**. Honorable members of special committee comprehensively scrutinized samples and concluded their findings in our favor which supports our claim of being "suspension". It is categorically mentioned in findings that **Parapol is a "Biphasic liquid like suspension" having translucent appearance due to of presence of particles** (copy of findings of expert committee attached). However, in contrary, same members who were convinced enough that particles are present, later on starte ignored this finding and became part of that impugned decision in which request for retesting has been turned down. This act of contradiction cast a doubt on principle of "fair trail and due process".

6. It is pertinent to highlight **act of victimization and unfair attitude of DTLs of Punjab towards product "Parapol" which necessitate and make premise for re-testing from NIH, Islamabad for fair analysis and reassessment of samples**. Drug testing laboratory in Bahawalpur (DTL Bahawalpur) initially declared two batches of Parapol suspension (Batch No. 178-24 and 179-24) as standard quality on 09-03-2024 and uploaded the corresponding reports on their portal. However, these standard reports were later removed, and sub-standard reports for the same batches were uploaded instead. Such illegal act clear cast a doubt on credibility of process and protocols applied for testing and hence there is strong need for the conclusive report from the appellate lab through fair and unbiased analysis.

ILTO chi

7. Government analyst has mentioned in form 7 "S.No# 6" that **"USP 2024 / In-House / Others" has been applied**. However, it is pertinent to highlight that neither **USP 2024 nor method of analysis (In-House) of Parapol suspension (if) provided by the firm gives any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension/solution/syrup**. Therefore, Product "Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

8. The government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

9. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited 'USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. Samples of Parapol suspension were declared substandard based solely on personal observation (bitter taste) without conducting chemical analysis for accurate and instrument based identification of sweetener in the composition.

10. It is pertinent to inform that in our previous meetings of committee PQCB, when we requested to kindly evaluate our sample, cor nittee members PQCB was of the opinion that product sample cannot be evaluated & tested in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIH Islamabad for conclusive report. Similarly, taste profile (Sweetness / bitterness) and presence of particles as per USP <1151> can be tested and evaluated only in appellate lab if firm had already highlighted numerous errors in testing and findings of government analyst. However, opinion of the committee PQCB regarding the same product has suddenly been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product**, samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions.**

11. Since Parapol suspension was being declared of standard quality by DTL Multan till 30- 09-2023 this proves that till this date, as per analysts of DTL Multan, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Multan must have received a revised and new method of analysis from the firm after 30-9-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 30-09-2023 which proves malice intention and act of victimization by government analyst.

12. Here, we would like to highlight following numerous flaws and inaccuracies in the impugned order made by the committee PQCB in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. Representative of the firm never agreed with the findings of government analyst "bitter taste" rather strongly contested in all meetings that sweetener "neotame" is present in the formulation which has been added to mask bitter taste and firm has always claim in all meetings that Parapol suspension ensure a palatable profile that supports patient compliance. That is why, no any single complain has been reported due to bitter taste in any forum or by the procuring agency since its registration.

b. Firm's claim & appeal regarding presence of sweetener and sweetness of suspension could only be verified if the samples will be sent to NIH, Islamabad for the conclusive report however same has not been done as per the impugned order deprived us from right of justice.

c. Firm's claim & appeal regarding presence of small solid particles and product as suspension as per USP <1151> could only be verified if the samples will be sent to NIH, Islamabad for re-testing. However, same has not been done by the committee PQCB. It is also to be noted that PQCB has already sent 42 cases of Parapol suspension to NIH, Islamabad for the conclusive result in past and now for these disputed batches, appeal for retesting has been turned down.

d. It is to be noted that discussion and statements regarding toxicity and side effects of higher concentrations of propylene glycol makes no sense when government analyst admitted that method applied to determine exact concentration of propylene glycol is not as per WHO reference document rather it has been derived from it which cast clear doubt on credibility of method and its accuracy. Firm's claim of addition of less than 1% propylene glycol has been completely overlooked in the impugned order and no scrutiny was carried out by the committee PQCB to verify firm's claim. Firm stated in every committee meeting before honorable board that we are supplying same product with the same formulation across Pakistan for decades and millions of children have safely consumed this product to alleviate pain and fever without any reported clinical toxicity. Despite this, the PQCB committee exhibited an unfair approach by relying on the impugned results of the government analyst, who determined the concentration of propylene glycol using a non-reliable and non-pharmacopeial method.

e. On what basis and in what capacity did Mr. Ijaz Alvi, Director of DTL Rawalpindi, present his views regar og the toxicity of propylene glycol before the committee, given that the impugned reports pertain exclusively to DTL Multan? It is to be noted that Mr. Ijaz Alvi is not part of committee PQCB and firm has no faith on him as he is part of malicious campaign against our product. This raises concerns about the impartiality of the process and suggests a coordinated effort by all DTLs of Punjab to unfairly target the product 'Parapol' without relying on legal facts and objective findings.

f. How and on what grounds committee members got convinced by views of Mr. Ijaz Alvi (Director, DTL Rawalpindi), Director DTL Multan and Mr. Sohail Tofail (Government analyst, DTL Multan) in which they were trying to establish a view that firm has solubilized paracetamol in propylene glycol without counter verifying it with firm's claim?. Firm has already provided list of excipients with quantities before the committee PQCB in which it was mention that firm added propylene glycol less than 1% in the formulation of Parapol suspension only with the purpose as stabilizer and as preservative. Firm's representative comprehensively explained that it is practically impossible to solubilize paracetamol in an amount of propylene glycol and water that has been used in the formulation of Parapol suspension. Nevertheless, the PQCB committee chose to accept the unverified personal opinions of the individuals mentioned and issued a biased decision without validating the firm's assertions.

g. Question ie testing of propylene glycol in finished product duly raised by the committee members is inaccurate as firm is not bound to test excipients in finished form neither does tested by any DTL of Pakistan. Firm is always well aware of the fact that how much amount of any excipient is being added in formulation and as per GMP guidelines, all excipients are being consumed once passed initially from quality control department. Moreover, Specs claimed for Parapol suspension is USP and firm carries out all applicable test as per USP which specifically provide testing of API in a finished product only. Despite of the fact, committee PQCB turned down our appeal for retesting to prevent us from the right of justice.

h. The quality of propylene glycol as a raw material, along with its associated standards, cannot be questioned or used as grounds for denying the request for re- testing. The impugned DTL reports themselves acknowledge compliance with the WHO reference document and confirm the absence of impurities such as EG and DEG, which demonstrates that the quality of the propylene glycol used was fully compliant and without any issues. Furthermore, under the latest DRAP guidelines, propylene glycol cannot be released for use unless tested by federal laboratories. The firm has consistently stated in all meetings that the propylene glycol used in the batches of Parapol suspension was tested and approved by the Central Drug Laboratory (CDL) in Karachi prior to its consumption.

i. As per remarks mentioned in the impugned order "there is need to reevaluate with the formulation", it is to be noted that only the appellate lab (NIH) is the forum which can give conclusive report after reevaluation & reassessment of the samples in question and that is why we appealed for retesting from NIH, Islamabad. Board members of PQCB have stated several times that board / committee cannot examine and retest samples by

their own against the grounds on the basis of which samples have been declared substandard hence it becomes necessary to get conclusive report from the appellate lab.

Additionally, we would like to highlight grounds comprehensively which have already been discussed im difference committee meeting that further supports our stance in said case:

1. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:

"It is also to inform you that the Federal Drag Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 (Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976)"

In this regard, committee PQCB was duty bound to consider the foregoing fact whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

2. The malafide intentions of the Government Analysts and Director DTL Multan are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Multan has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Multan contributing 80 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

3. Since, product "Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe/ instruct to conduct test for determination of the taste of the products, test to check whether product is syrup, solution or suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopieal testing.

4. It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc) of the "finished form" of the drug. In this context, the Products, like all other drugs, underwent a comprehensive manufacturing process wherein in addition to the active pharmaceutical ingredient, several other excipients were also added. Additionally, tests are prescribed in the specifications to ascertain the quality of a "finished form of drug". Thus, only tests that could have been performed by the government analyst were those prescribed in the USP and any additional information sought in relation to the excipients and or other ingredients or any testing carried out on the basis of the same is illegal and unlawful.

5. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the substandard drugs". However, in our case, government analyst has shown her/his malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

6. Section 3(z) of the Drugs Act, 1976 defines the term specifications as.

(i) such specifications as may be prescribed;

(ii) or when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:-

(1) the Pakistan Pharmacopoeia;

(2) the International Pharmacopoeia;

(3) the European Pharmacopoeia;

(4) the United States Pharmacopoeia;

(5) the British Pharmacopoeia;

(6) the British Pharmaceutical Codex;

(7) the United States National Formulary; and

(8) Such other publication as may be prescribed:

In terms of the legislative scheme envisioned under the Drugs Act, 1976, more particularly, Section 3(zz) a drug shall only be deemed as substandard if it does not comply with the applicable specifications. Essentially, such determination can only be made if the drug fails to comply with the tests "prescribed" under the applicable specifications. The monograph of a drug provided under the applicable specifications lists down the requisite tests that need to be conducted in order to determine whether the drug is of standard quality. It is a matter of fact that the Drugs Act does not permit analysts to carry out inapplicable tests or tests, which have not been listed down in the applicable specifications. However, in context of the present case, **the Government Analysts have malafidely declared the batches of the Product as substandard on the basis of their bitter taste & absence of solid particles without there being any criteria or test to determine the same. The foregoing action clearly constitutes a violation of the Drugs Act, 1976 as well as Rule 16 of The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rule 1976.**

In the light of above highlighted facts and infirmities, it can be concluded that committee PQCB has failed to scrutinize the case properly as it has overlooked above evidences and factual findings. **The illegalities floating on the record of the case and as mentioned in above grounds have been completely overlooked and no heed has been paid to the wrongdoings of the government analyst who has declared the Products to be of substandard quality on a completely wrongful premise. It was mandatory upon this committee PQCB to properly scrutinize the subject especially in this case when samples comply with the stated specification chemically and physically and adjudicate upon the same.** However, no such exercise has been carried out in the present case.

Furthermore, it is to be noted that our firm petitioner Company" and its officials have not contravened the provisions of the Drug Laws and the rules made thereunder rather they are committed to ensure compliance thereof. **PQCB passed an impugned order (turning down request for retesting) which completely disregard not just of the principles of fair trial and due process envisioned under Article 10-A and Article 4 of the Constitution but also disregard of the scheme of law envisioned under the Drugs Act, 1976 as-well as the fundamental rights of the Petitioner Company enshrined under the Constitution of Islamic Republic of Pakistan, 1973**.

On the premise of foregoing submission and grounds highlighted above, it is mandatory and essential for the learned Board to review its decision. We reserves the right to agitate additional grounds at the time of arguments if needed. We as “Petitioners" are seeking the setting aside of the Impugned Decision in terms of clause 2 of Part VIII of the PQCB Regulations and pray as below:

PRAYER

In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:

i. **Set aside the Impugned Order in which committee PQCB turned down appeal for re-testing and directed Provincial Inspector of and Drugs, Layyah, to expedite investigation submission of final report.**

ii. Pass an order for the samples of Suspension Parapol Batch No. 183- 24 and Batch No. 181-24 to be sent to the National Institute of Health, Islamabad and allow retesting of samples.

iii. Direct the government analyst of the Drug Testing Laboratory, Multan to bring the method and protocols of the test employed to determine the taste of the Suspension and test to determine presence or absence of particles in suspension.

v. Permanently restrain the Provincial Inspector of Drugs, Layyah from taking any adverse and/or coercive action against our firm "Petitioner Company" and against our officials based on the Impugned order / decision.

We hope that learned board will allow us to avail right of fair trial and accept above.

Previous Proceedings & Decision by the Board:

287th meeting held on 08-01-2025

5. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, vice-chairperson PQCB. Mr. Amir Shakeel, Secretary DQCB Layyah attended the meeting online via zoom link along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeil test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary individual to individual basis and there will be no toxicity or adverse effects due to bitter taste
ii. We are confident that our product is suspension and complies all applicable test of USP monograph "acetaminophen oral suspension".
iii. As far as declaring our samples substandard declaring them to be "free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iv. He further added that although the DTL has quantified Propylene Glycol in the test report but failed to mention the limit and to specify whether it complies or not with any official monograph.
v. He further reiterated firm's request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting.

7. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 183-24 & 180-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Multan on the basis of physical description as "Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles**" further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 14-06-2024 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was turn down in 42nd Committee meeting of the Board held on 30-07-2024. Regarding firm's review petition against retesting orders and the plea to send their subject batches to NIH for retesting, the Board observed that in 279th meeting held on 24-04-2024, the Board sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976. Hence, the re-submitted retesting request by the

firm in its review petition received on 04-11-2024 cannot be accepted and hence, is **turned down** and **previous decision taken in 42nd Committee meeting dated 30-07-2024 is upheld**.

8. Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

9. While perusing the case record, the Board remarked that the samples in question were declared substandard on the basis of physical description as per General Chapter <1151> of the USP, bitter taste of suspension and quantification of polyethylene glycol by the Government Analyst DTL Multan. The firm claims the product as "Suspension" on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Multan. Furthermore, regarding bitter taste of the suspension, the Board was of the view that the product has been developed for pediatrics use and bitter taste of suspension as reported by the DTL in the subject reports, will result in non-compliance and reluctance to take medication by children.

10. The Board further observed that the DTL also determined the percentage of Propylene Glycol as 10.42% w/v & 9.14% w/v in the batches under consideration by applying WHO Working Document QAS/23.922/rev3 Dated 31 October 2023.

Acceptable Dietary Intake of Propylene Glycol				
EMA		**50mg/kg/day**		
WHO		**25mg/kg/day**		
Batch No.	**PG Determined (as per DTL Report)**	**PG Content mg/kg/day (Calculated as per EMA Guidelines, keeping in view firm's own label recommended dose for a child weighing 10kg, 15kg & 18kg respectively)**		
		PG (mg/kg/day) (30mL Dose)	**PG (mg/kg/day) (60mL Dose)**	**PG (mg/kg/day) (120mL Dose)**
183-24	9.14%	284.07	378.76	631.27
180-24	10.42%	323.85	431.80	719.67

The Board further observed that as per guidelines of European Medicine Agency published vide No. EMA/CHMP/704195/2013 dated 09.10.2017, propylene glycol is estimated to be one-third as intoxicating as ethanol, with administration of large volumes being associated with adverse effects most commonly on the central nervous

system, especially in neonates and children. Other adverse reactions reported through generally isolated, include: ototoxicity, cardiovascular effects; seizures; and hyperosmolarity and lactic acidosis, both of which occur most frequently in patients with renal impairment. Adverse effects are more likely to occur following consumption of large quantities of propylene glycol or on administration to neonates, children under 4 years of age, pregnant women, and patients with hepatic or renal failure. Adverse events may also occur in patients treated with disulfiram or metronidazole. Keeping in view all aspects of case, the Board after due deliberation and detailed discussion, unanimously decided to **pend the case.**

5. Personal Hearing notice(s) issued to accused person(s) vide 01-01-2025
6. Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 11-2023**
- **Exp. Date: 11-2025**
- **Sampling date (Form 4): 09-03-2024**
- **Sent to DTL (Form 6): 09-03-2024**
- **Date of receipt in DTL: 13-03-2024**
- **DTL Report Date (Form 7): 07-06-2024**
- **DI 1st intimation to firm: 13-06-2024**
- **Retesting request if any: 14-06-2024**
- **Fate of Retesting: Turned down in 42nd Committee meeting dated 30-07-2024**
- **Investigation report Dated: 28-10-2024**
- **Permission of SCN: 287-M dated 08-01-2025 (Post-Facto)**
- **SCN Issued: 01-01-2025**
- **Reply of the firm: NA**
- **Retest Review Status:** Upheld in 287-M (08-01-2025)
- **History: Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 6

PQCB/MSS-199514, 199517, 199520, 199523, 199516, 199515,199519,199518, 199510, 199511, 199522,199512, 199509, 199521, 199524, 199513/ 2024

Government Medical Store Depot, Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Lisko Pakistan Pvt. Ltd. L-10D Block-21, F.B. Industrial Area, Karachi** through its Managing Director Muzamil Nazar 2. Muzamil Nazar — Managing Director 3. Ghulam Nabi Khoso — Production In-charge 4. Naima Khanam — Quality Control In-charge/ Warrantor Of **M/s Lisko Pakistan Pvt. Ltd. L-10D Block-21, F.B. Industrial Area, Karachi.**

BREIF FACTS OF THE CASE

Provincial Inspector of Drugs, Government Medical Store Depot, Lahore reported that:

i. He, on 25-05-2024, inspected the premises of Govt. Sub-Medical Store Depot, Maraka, Multan Road, Lahore and took drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 199514, 199517, 199520, 199523, 199516, 199515,199519, 199518, 199510, 199511, 199522,199512, 199509, 199521, 199524, 199513 dated 25-05-2024.
ii. Following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

Sr. No.	Name of drug	Batch no.	Name of manufacturer	DTL Report No. & Date	DTL Test Report Results
1.	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date:** Aug-2023 **Exp. Date** : Aug-2025	080-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	01-10097008756/ DTL 15-07-2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is***

<table>
<tr>
<td></td>
<td>Reg. No. 002772</td>
<td></td>
<td></td>
<td></td>
<td>a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.” (DOES NOT COMPLY)

<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 23.8ºC

<u>IDENTIFICATION:</u> Paracetamol is identified.

<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml, Determined: 121.58 mg/5ml (101.32 %), Limit: 90.0-110.0%

<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY:</u> Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene
Glycol.
WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

<table>
<tr><td><u>Ethylene Glycol:</u>

Limit: NMT 0.1%
Determined: Not Detected</td><td><u>Diethylene Glycol:</u>

Limit: NMT 0.1%

Determined: Not Detected</td></tr>
<tr><td colspan="2"><u>Propylene Glycol</u>

Determined: 10.77%</td></tr>
</table>
<u>RESULT</u>: The Sample is declared as “SUB-STANDARD” on basis of Physical Characteristics.</td>
</tr>
<tr>
<td>2</td>
<td>Suspension Parapol Paediatric Suspension 120ml

(Paracetamol USP 120mg/5ml, 120ml)

Mfg. Date : Aug-2023

Exp. Date : Aug-2025

Reg. No. 002772</td>
<td>083-24</td>
<td>M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi</td>
<td>10097008759/DTL dated 15.07.2024</td>
<td><u>Specs Applied: USP 2024/Others/In house</u>

<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg

<u>PHYSICAL CHARACTERISTICS:</u>

Stated: Pinkish red sweet homogenous suspension.

Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.” (DOES NOT COMPLY)

<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 23.7ºC

<u>IDENTIFICATION:</u> Paracetamol is identified.</td>
</tr>
</table>

					ASSAY OF PARACETAMOL: Stated: 120 mg/5ml **Determined: 123.26 mg/5ml (102.72%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY:** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol: Limit: NMT 0.1% Determined: Not Detected** **Diethylene Glycol: Limit: NMT 0.1%, Determined: Not Detected** **Propylene Glycol: Determined: 10.197%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
3	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	086-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008762/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.9°C** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 124.27 mg/5ml (103.56%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document**

					QAS/23.922/rev3 Dated 31 October 2023 **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 11.40%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
4	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	089-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008765/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9,Determined: 5.5 at 25.0ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml, Determined: 127.34 mg/5ml (106.12%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%**

					<table><tr><td></td><td>**Determined: Not Detected**</td></tr><tr><td colspan="2">**Propylene Glycol** **Determined: 11.21%**</td></tr></table> **<u>RESULT:</u> The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
5	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	082-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008758/DTL dated 15.07.2024	**<u>Specs Applied: USP 2024/Others/In house</u>** **<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg** **<u>PHYSICAL CHARACTERISTICS:</u>** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* (DOES NOT COMPLY)** **<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 23.9ºC** **<u>IDENTIFICATION:</u> Paracetamol is identified.** **<u>ASSAY OF PARACETAMOL</u>: Stated: 120 mg/5ml, Determined: 122.83 mg/5ml (102.36%), Limit: 90.0-110.0%** **<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** <table><tr><td>**Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected**</td><td>**Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected**</td></tr><tr><td colspan="2">**Propylene Glycol**</td></tr></table>

					Determined: 11.06% **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
6	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	081-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008757/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 24.1º** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 122.68 mg/5ml (102.23%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.89%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis**

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td>of Physical Characteristics.</td></tr>
<tr><td>7</td><td>Suspension Parapol Paediatric Suspension 120ml

(Paracetamol USP 120mg/5ml, 120ml)

Mfg. Date : Aug-2023

Exp. Date : Aug-2025

Reg. No. 002772</td><td>085-24</td><td>M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi</td><td>1009700876/DTL dated 15.07.2024</td><td><u>Specs Applied: USP 2024/Others/In house</u>

<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg

<u>PHYSICAL CHARACTERISTICS:</u>

Stated: Pinkish red sweet homogenous suspension.

Determined: Parapol is a pinkish red<u>, bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase. (DOES NOT COMPLY)

<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 23.4ºC

<u>IDENTIFICATION:</u> Paracetamol is identified.

<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml

Determined: 127.03 mg/5ml (105.86%), Limit 90.0-110.0%

<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

<table><tr><td>Ethylene Glycol:

Limit: NMT 0.1%
Determined: Not Detected</td><td>Diethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected</td></tr><tr><td colspan="2">Propylene Glycol

Determined: 11.80%</td></tr></table>
<u>RESULT:</u> The Sample is declared as “SUB-STANDARD” on basis of Physical Characteristics.</td></tr>
<tr><td>8</td><td>Suspension Parapol</td><td>084-</td><td>M/S Lisko</td><td>10097008760/DTL</td><td><u>Specs Applied: USP 2024/Others/In house</u></td></tr>
</table>

<table>
<tr>
<td></td>
<td>Paediatric Suspension 120ml

(Paracetamol USP 120mg/5ml, 120ml)

Mfg. Date : Aug-2023

Exp. Date : Aug-2025

Reg. No. 002772</td>
<td>24</td>
<td>Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi</td>
<td>dated 15.07.2024</td>
<td><u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg

<u>PHYSICAL CHARACTERISTICS:</u>

Stated: Pinkish red sweet homogenous suspension.

Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.” (DOES NOT COMPLY)

<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 23.5ºC

<u>IDENTIFICATION:</u> Paracetamol is identified.

<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml

Determined: 127.29 mg/5ml (106.08%), Limit: 90.0-110.0%

<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

<table><tr><td>Ethylene Glycol:

Limit: NMT 0.1%
Determined: Not Detected</td><td>Diethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected</td></tr><tr><td colspan="2">Propylene Glycol

Determined: 10.65%</td></tr></table>
<u>RESULT:</u> The Sample is declared as “SUB-STANDARD” on basis of Physical Characteristics.</td>
</tr>
<tr>
<td>9</td>
<td>Suspension Parapol Paediatric Suspension 120ml

(Paracetamol USP 120mg/5ml, 120ml)</td>
<td>072-24</td>
<td>M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial</td>
<td>10097008752/DTL dated 15.07.2024</td>
<td><u>Specs Applied: USP 2024/Others/In house</u>

<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg

<u>PHYSICAL CHARACTERISTICS:</u></td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>Mfg. Date : Aug-2023

Exp. Date : Aug-2025

Reg. No. 002772</td>
<td></td>
<td>Area, Karachi</td>
<td></td>
<td>Stated: Pinkish red sweet homogenous suspension.

Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.” (DOES NOT COMPLY)

<u>pH:</u> Limit: 4.0-6.9, Determined: 5.6 at 24.4ºC

<u>IDENTIFICATION</u>: Paracetamol is identified.

<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml

Determined: 121.58 mg/5ml (101.32 %), Limit: 90.0-110.0%

<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

<table><tr><td>Ethylene Glycol:

Limit: NMT 0.1%
Determined: Not Detected</td><td>Diethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected</td></tr><tr><td colspan="2">Propylene Glycol

Determined: 11.93%</td></tr></table>
<u>RESULT:</u> The Sample is declared as “SUB-STANDARD” on basis of Physical Characteristics.</td>
</tr>
<tr>
<td>10</td>
<td>Suspension Parapol Paediatric Suspension 120ml

(Paracetamol USP 120mg/5ml, 120ml)

Mfg. Date : Aug-2023</td>
<td>077-24</td>
<td>M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi</td>
<td>10097008753/DTL dated 15.07.2024</td>
<td><u>Specs Applied: USP 2024/Others/In house</u>

<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg

<u>PHYSICAL CHARACTERISTICS:</u>

Stated: Pinkish red sweet homogenous suspension.

Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle,</td>
</tr>
</table>

	Exp. Date : Aug-2025 **Reg. No**. 002772				**sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 24.0ºC** **<u>IDENTIFICATION:</u> Paracetamol is identified.** **<u>ASSAY OF PARACETAMOL</u>: Stated: 120 mg/5ml** **Determined: 125.11 mg/5ml (104.26%), Limit: 90.0-110.0%** **<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.35%** **<u>RESULT:</u> The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
11	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	088-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008764/DTL dated 15.07.2024	**<u>Specs Applied: USP 2024/Others/In house</u>** **<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg** **<u>PHYSICAL CHARACTERISTICS:</u>** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is***

					a biphasic preparation consisting of solid particles dispersed throughout a liquid phase." **(DOES NOT COMPLY)** **<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 24.4ºC** **<u>IDENTIFICATION:</u> Paracetamol is identified.** **<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml** **Determined: 126.53 mg/5ml (105.44%), Limit 90.0-110.0%** **<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 11.93%** **<u>RESULT:</u> The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
12	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	078-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008754/DTL dated 15.07.2024	**<u>Specs Applied: USP 2024/Others/In house</u>** **<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg** **<u>PHYSICAL CHARACTERISTICS:</u>** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 23.0ºC**

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>
<u>IDENTIFICATION:</u> Paracetamol is identified.

<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml

Determined: 122.20 mg/5ml (101.83%), Limit: 90.0-110.0%

<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023
<table>
<tr><td>Ethylene Glycol:

Limit: NMT 0.1%
Determined: Not Detected</td><td>Diethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected</td></tr>
<tr><td colspan="2">Propylene Glycol

Determined: 10.37%</td></tr>
</table>
<u>RESULT:</u> The Sample is declared as “SUB-STANDARD” on basis of Physical Characteristics.
</td>
</tr>
<tr>
<td>13</td>
<td>Suspension Parapol Paediatric Suspension 120ml

(Paracetamol USP 120mg/5ml, 120ml)

Mfg. Date : Aug-2023

Exp. Date : Aug-2025

Reg. No. 002772</td>
<td>066-24</td>
<td>M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi</td>
<td>10097008751/DTL dated 15.07.2024</td>
<td>
<u>Specs Applied: USP 2024/Others/In house</u>

<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg

<u>PHYSICAL CHARACTERISTICS:</u>

Stated: Pinkish red sweet homogenous suspension.

Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase. (DOES NOT COMPLY)

<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 23.1°C

<u>IDENTIFICATION:</u> Paracetamol is identified.

<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml, Determined: 124.46 mg/5ml (103.72 %), Limit: 90.0-110.0%
</td>
</tr>
</table>

					TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.75%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
14	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	087-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008763/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.8ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 124.45 mg/5ml (103.71%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol,**

					Diethylene Glycol & Propylene Glycol. **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.40%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
15	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	090-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008766/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 24.5ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 128.39 mg/5ml (106.99%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document**

					QAS/23.922/rev3 Dated 31 October 2023 **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 11.24%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
16	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	079-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008755/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.4ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 124.64 mg/5ml (103.87%), Limit 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Diethylene Glycol:**

					Limit: NMT 0.1% **Determined: Not Detected**	**Limit: NMT 0.1%** **Determined: Not Detected**
					Propylene Glycol **Determined: 10.64%**	
					RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.	

iii. General Manager, Government Medical Store Depot, Gulberg-III, Lahore provided invoice/ warranty No. nil, dated: 09-10-2023, 11-10-2023, 13-10-2023, 14-10-2023 & 16-10-2023 issued by M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi, as a proof of purchase.

iv. Warrantor Portion of subject drug sample was sent to M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi.

v. Copies of Test/ Analysis reports were sent to M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi and they were directed to explain their position and provide the requisite information in this regard. In response, the firm requested for re-test/ analysis of the drug sample.

Pervious Proceedings & Decision by the Committee:

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **43rd meeting** held on **29.08.2024** under the Convenorship of Director General of Drug Control. Dr Sarfaraz Manager M/S Lisko Pakistan (Pvt) Ltd appeared before the Committee to plead the case. The committee observed that the above-mentioned batches were declared substandard by DTL Bahawalpur on the basis of physical description that is bitter in taste and free from any dispersed solid particles. The committee further observed that the DTL also determined the percentage of Propylene Glycol as 10.77%, 10.197%, 11.40%, 11.21%, 11.06%, 10.89%, 11.80%, 10.65%, 11.93%, 10.35%, 11.93%, 10.37%, 10.75%, 10.40%, 11.24% and 10.64% in the batches under consideration.

3. The committee observed that the maximum permissible daily intake of propylene glycol as a food additive by WHO is 25/mg/kg. The committee further observed that as per guidelines of EUROPEAN MEDICINE AGENCY published vide No. EMA/CHMP/704195/2013 dated 09.10.2017 the proposed dose limit of Propylene Glycol in children below 5 years down to 1 month of age is 50mg/kg. Mr Ijaz Alvi Director DTL Rawalpindi apprised the committee that the percentage of Propylene Glycol is critical when it is to be added in oral formulations for pediatrics, as it is associated with CNS Depression, renal and liver dysfunction and cardiotoxicity. He further stated that the solubility of Paracetamol is maximum in propylene glycol that is 1:9 parts.

4. The Government analyst DTL Bahawalpur (attended online) apprised the committee that the method for calculating the percentage of propylene glycol is derived from WHO Working document QAS/23.922/rev3 Dated 31 October 2023. They further stated that the use of propylene glycol solubilizes the paracetamol hence the firm cannot claim their product as a Suspension. The percentage of propylene glycol determined in Parapol Suspension by DTL Bahawalpur is higher than the permissible safe limits in children under 5years of age as per EMA guidelines.

The committee inquired from the firm representative about his stance on following points:

i. Bitter taste of suspension.

ii. Percentage of Propylene glycol in formulation and its use.

iii. Does the firm test percentage of Propylene glycol in finished product. ?

iv. Does the firm test propylene glycol as a raw material?

v. Does the firm have standard for propylene glycol testing?

vi. Does the firm is using the same formulation since its registration or it is modified after that, if modified it is communicated to Registration Board or not?

5. The firm representative Mr. Sarfaraz (BUH) given his stance on above mentioned points as follows:

i. The firm is using artificial sweetener Neotame (0.52kg) in batch of 4600 liter to mask the bitter taste of suspension, there is need of improvement in the taste of suspension and the firm is considering this point already.

ii. The firm representative provided the formulation of Parapol Suspension before the committee and stated that the percentage of propylene glycol is less than 1% in the formulation. He further stated that they are not using propylene glycol as a Co-solvent instead using it as a preservative/ stabilizer along with other preservatives like methyl paraben and propyl paraben.

iii. The firm is not testing the percentage of propylene glycol in the finished product.

iv. The firm representative was unaware that they are testing the propylene glycol as a raw material or not.

v. The firm representative stated that he is not sure about the testing and standard of propylene glycol.

vi. The firm representative was unaware of changes made in the formulation and its intimation to DRAP.

6. The committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate the formulation with respect to bitter taste and Propylene glycol concentration hence unanimously decided to **Turn Down** the retesting request of the firm. The Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

7. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacturing for sale/ Sale of Substandard drug**

b. **Issuance of false warranty**

8. Show-cause/ personal hearing notice issued to accused person(s).

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi submitted written reply in response to show-cause/ personal hearing notice vide letter dated 30-10-2024 as mentioned below:

We would like to submit our reply against show cause/personal hearing notice dated 22-10-2024 in which we have been asked to appear before honorable PQCB on 30-10-2024 for below mentioned cases against which ou firm submitted appeal for re-testing from NIH, Islamabad. Subsequently, committee PQCB meeting was held on dated 29-8-2024 in which we presented our stance comprehensively and highlighted several grave infirmities an ambiguity in DTL. reports Despite this, we have been informed that our appeal for retesting has been turn down. Details of the batches are as below:

B.no	DTL report	DTL report Date
066-24	01-10097008751	15/07/2024
072-24	01-10097008752	15/07/2024
077-24	01-10097008753	15/07/2024
078-24	01-10097008754	15/07/2024
079-24	01-10097008755	15/07/2024
080-24	01-10097008756	15/07/2024
081-24	01-10097008757	15/07/2024
082-24	01-10097008758	15/07/2024
083-24	01-10097008759	15/07/2024
084-24	01-10097008760	15/07/2024
085-24	01-10097008761	15/07/2024
086-24	01-10097008762	15/07/2024
087-24	01-10097008763	15/07/2024
088-24	01-10097008764	15/07/2024
089-24	01-10097008765	15/07/2024
090-24	01-10097008766	15/07/2024

We again like to highlight below mentioned facts and ambiguities through our reply of show cause/ person hearing notice and request honorable PQCB to review decision of committee PQCB and send samples above batches of Parapol suspension to NIIH, Islamabad (Appellate lab) for the conclusive report

A POINTS OF DEFENSE & CONTRAVENTION IN CONCENTRATION OF "PROPYLENE

GLYCOL" DETERMINDED BY GOVERNMENT ANLAYST

A1 Committee PQCB failed to provide fair trail and due process in subject case as most of the discussion during committee meeting was linked to concentration of propylene glycol instead of discussions on contravention & scrutiny on the grounds on the basis of which samples has been declared substandard by the government analyst. Committee PQCB cannot introduce new grounds or raise additional issues in DTL report by their own if they were not shown as noncompliant by the government analyst in the initial report. None of the sample have been declared substandard on the basis of concentration of propylene glycol and therefore reliance on any such discussion will sabotage principle of fair trail and due process.

A2 It is very important to highlight and note that government analyst maliciously used reference of WHO working document (QAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely illegal and unlawful. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining the concentration of propylene glycol.

A3 It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc) of the "finished form" of the drug. In contrary, government analyst tested and qualified excipient "Propylene glycol" in a finished product using non-reliable method which is illegal and unlawful.

A4. The victimization of the firm and product "Parapol" is further evinced by the fact that the drug testing laboratory in Bahawalpur (DTL Bahawalpur) initially declared two batches of Parapol suspension (Batch No. 178-24 and 179-24) as standard quality on 09-03-2024 and uploaded the corresponding reports on their portal. However, these standard reports were later removed, and substandard reports for the same batches were uploaded instead. We duly highlighted this discriminatory behavior multiple times in different PQCB meeting, however no action was taken against the government analyst at DTL Bahawalpur. Instead, same government analyst who did such act of victimization for batch no# 178-24 and 179-24 declared further samples of Parapol suspension substandard on illegal and unlawful grounds.

B POINTS OF DEFENSE & CONTRAVENTION AGAINST REMARKS "BITTER TASTE" BY GOVERNMENT ANALYST

BI. The government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless

B2. Government analyst has mentioned in form 7 "S.Nof# 6" that he/she has applied spees ie USP 2024/In-House/Others. However, it is pertinent to highlight that neither USP 2024 nor method of analysis (In-

House) of Parapol suspension (if) provided by the firm gives any test to determine sweetness/bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension/solution/ syrup. Therefore, Product "Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst

B3. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:

"It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 (Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976)"

In this regard, committee PQCB was duty bound to consider the foregoing fact whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

B4.The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house/others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on "In-house/other specifications' renders the report invalid and inaccurate.

B5. Since Parapol suspension was being declared of standard quality by DTL Bahawalpur till 10- 10-2023 this proves that till this date, as per analysts of DTL Bahawalpur, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Bahawalpur must have received a revised and new method of analysis from the firm after 30-9-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 10-10-2023 which proves malice intention and act of victimization by government analyst.

B6. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited 'USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard & testing method for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. No such request or chemical analysis was made, and the product was instead declared substandard based solely on personal observation (bitter taste) without conducting or verifying any formal test.

B7. The malafide intentions of the Government Analysts and Director DTL Bahawalpur are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 76 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

B8. Since, product "Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe/ instruct to conduct test for determination of the taste of the products, test to check dispersed particles in a

suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopical testing.

B9. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the substandard drugs". However, in our case, government analyst has shown her/his malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

C= POINTS OF DEFENSE AGAINST REMARKS OF GOVERNMENT ANALYST "SAMPLE IS FREE FROM ANY DISPERSED SOLID PARTICLES <USP 1151>"

The government analyst has wrongfully claimed the Products to be a "liquid" despite the same being a suspension. Government analyst also stated that "samples is free from any dispersed solid particles" and declared samples substandard using reference USP <1151> It is pertinent to highlight that PQCB has already investigated this case and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst holding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to of presence of particles (copy of findings of expert committee attached).

It is also important to highlight that USP general chapters <1151> on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to determine product is suspension, solution or syrup. Same has been confirmed in letters by NIH, Islamabad dated 6-6-2024 and 29-8-2024 as below:

i. *Letter dated 6th June 2024 "**It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any such test on the basis of which the samples are declared sub-standard by DTLs of Punjab".***
ii. *Letter dated 29 August 2024 "**It is once again informed that USP monograph for Acetaminophen oral suspension have different tests including test from the general chapters le performance test (uniformity of dosage units-905, deliverable volume - 698, impurities (4-Aminophenol in Acetaminophen containing Drug Products-277) specific test (pH 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the samples were declared substandard by DTLs Punjab" and "The USP General Chapter <1151> on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply"***

Furthermore, point no# B2, B3, B4, B5 B7, B8 and B9 also supports our stance and provides strong defense and contravention against conclusion of government analyst "absence of dispersed solid particles". The foregoing infirmity makes the report invalid and baseless.

POINTS OF DEFENSE & CONTRAVENTIONS IN DISCUSSIONS OF COMMITTEE POCB IN WHICH REQUEST FOR RETESTING HAS BEEN TURNED DOWN

We would like to highlight following numerous flaws and inaccuracies in the discussions during committee PQCB meeting and the grounds on the basis of which "impugned decision" made by the committee PQCB:

1. *During committee PQCB meeting, members introduced new grounds and raise additional issues by*

discussing matter of propylene glycol in DTL report by their own while they were not shown as noncompliant by the government analyst in the initial report. All such discussion related to propylene glycol is unlawful and illegal and cannot be relied as ground on the basis of which appeal has been turned down.

2. *It is pertinent to inform that in our previous meetings when we requested the board to kindly evaluate our sample board was of the opinion that product sample cannot be evaluated in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIII Islamabad for conclusive report. However, opinion regarding the same product has been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product, samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions. On the basis of numerous highlighted ambiguities in impugned reports, there is a need for conclusive reevaluation. Following are the scope of retesting for said cases:*

a. Presence or absence of sweetener (neotame) in the composition as claimed by our firm.

b. Presence of small solid particles and product as suspension as per USP <1151> as claimed by the firm.

3 We strongly contested in all meetings that sweetener is present in the formulation which has been added to mask bitter taste and firm has always claim in all meetings that Parapol suspension ensure a palatable profile that supports patient compliance. That is why, no any single complain has been reported due to bitter taste in any forum or by the procuring agency since its registration.

4. Our firm has been supplying the same product with the same formulation across Pakistan for decades, with millions of children having safely consumed the product to alleviate pain and fever without any reported clinical toxicity. The firm asserts that the addition of propylene glycol at less than 1% in the formulation is entirely safe for pediatric use and complies with the guidelines of the European Medicines Agency (EMA). There has not been a single reported case of clinical toxicity related to Parapol suspension in any province of Pakistan.

In the light of above highlighted infirmities and weakness in reports, we request honorable PQCB to send mentioned 16 samples of Parapol suspension to NIIH, Islamabad for the conclusive report and give us fair chance of re-evaluation from the appellate lab. We request honorable PQCB and concerned drug inspector to not initiate prosecution against us as we have not contravened provisions of Drug act 1976.

PREVIOUS PROCEEDINGS BY THE BOARD:

PQCB 286th Meeting dated 30-10-2024:

10. Case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **286th** meeting held on **30-10-2024** under the chairmanship of Special Secretary Primary & Secondary Healthcare Department, vice-chairperson PQCB. Mr Hassan Saeed Secretary DQCB District Lahore was present. No-one among nominated accused was present, however, Dr. Sarfraz (Manager) appeared before the Board on behalf of M/s Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi and retreated the points as mentioned above in reply to show-cause/ personal hearing notice and emphasized to send the sample to Appellate Laboratory for retest/ analysis. He pleaded his case on following grounds:

i. He submitted that government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs.
ii. Government analyst declared that "samples is free from any dispersed solid particles" and declared samples substandard using reference USP <1151>, whereas it is pertinent to highlight that PQCB has already investigated this case and constituted a committee of pharmaceutical experts which concluded its findings in our favour whilst holding that Parapol is a "Biphasic liquid like suspension" having translucent appearance

due to presence of particles.

iii. Government Analyst maliciously used reference of WHO working document (QAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely illegal and unlawful. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining the concentration of propylene glycol.

iv. He requested to send their sample for retest/ analysis.

11. The Board after careful perusal of the case record observed that subject drug samples has been declared substandard from Drug testing Laboratory, Bahawalpur on the basis that Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, whereas, the firm in its method of analysis claims that it is pinkish red sweet homogeneous suspension. Moreover, the Government analyst has determined the percentage of Propylene glycol, however, the samples were not declared substandard on the basis of concentration of propylene glycol. The Board was of the view that:

i. Propylene glycol is widely used as solvent, extractant and preservative in variety of pharmaceutical formulations. The permitted concentration of propylene glycol as solvent/ co-solvent in oral solutions is 10-25% as excipient in a variety of parenteral and non-parenteral pharmaceutical preparations as per EMA guidelines issued on 09 October 2017, EMA/CHMP/704195/2013 committee for human medicinal products. Moreover, the product is not declared substandard on the basis of concentration of propylene glycol by the Government Analyst. However, WHO has set a maximum permissible daily intake of Propylene Glycol as food additive at 25 mg/ kg.

ii. The Board showed serious apprehensions about the taste of subject product is intended for pediatric patients and the bitter taste of the suspension must be masked, and it must be palatable to ensure patient compliance. The Board was of the opinion that the firm must redesign its formulation to mask the bitter taste of suspension.

iii. The board considering the other analyzed parameters by the Government analyst that assay and pH of the formulation lies well within the prescribed limits.

12. Keeping in view the facts of the case, the Board after due deliberation and discussion decided to **pend** the case.

GROUNDS OF REVIEW PETITION (ON RETESTING ORDERS):

SUBJECT: REVIEW PETITION UNDER CLAUSE VIII O THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We, M/S Lisko Pakistan (Pvt) Ltd Petitioner Company" would like to submit instant review petition to the learned Provincial Quality Control Board Punjab against the order of committee PQCB dated 20-09-2024 (the "impugned Decision") in which request of re-testing from NIH, Islamabad has been turned down for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspectors of Drugs, (the "Respondent Drug Inspector") has been directed to expedite Investigation so that permission for prosecution can be granted.

There are several grave infirmities and ambiguities in TL reports "Impugned reports" issued by government analyst of DTL Bahawalpur and also in decision "Impugned Order by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, It 1s pertinent to highlight the fresh grounds that have arisen in the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. Committee PQCB has turned down request for retesting from NIH, Islamabad with the statement which itself contains several ambiguities and infirmities. “the committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate the formulation with respect to bitter in taste and propylene glycol concentration hence unanimously decided to

turn down the retesting request of the firm".

A) Government analyst has not declared samples substandard on the basis of concentration of propylene glycol rather it has been declared substandard on the basis of physical characteristics (Bitter taste and absence of solid particles as per USP <151>). Once appeal for retesting has been submitted against impugned Reports and errors are being highlighted by the firm, committee PQCB can only Scrutinize grounds on the basis of which samples have been declared substandard but cannot introduce new grounds or raise additional issues in DTL report by their own if they were not shown as noncompliant by the government analyst In the initial report. Drug act 1976 and other existing laws have clearly defined duties and limitations of both government analyst and PQCB. Members of committee PQCB initiated discussion i.e toxicity due to propylene glycol, role of propylene glycol to solubilizing Paracetamol without having conclusive evidences and turned down appeal for retesting by relying on this premise. Therefore, all discussion in impugned order related to propylene glycol is unlawful and illegal and cannot be relied as ground on the basis of which appeal has been turned down.

b. It is pertinent to highlight that in our previous meetings of committee PQCB, when we requested to kindly evaluate our sample, committee members PQCB was of the opinion that product sample cannot be evaluated & tested in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIH Islamabad for conclusive report.. However, opinion of the committee PQCB regarding the same product has suddenly been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product, samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions.

C. Firm's representative never agreed with the findings of government analyst (bitter in taste and free from any dispersed solid particles) rather firm's representative always claimed that Parapol suspension ensure a palatable profile that supports patient compliance and also claimed presence of dispersed solid particles in Parapol suspension. However, firm's stance has been improperly and incompletely stated in the "impugned order"

d. Firm's claim regarding presence of dispersed particles and palatable taste profile can only be verified if samples will be sent to NIH, Islamabad for the conclusive and fair report. However, same has not been done and appeal for retesting has been turned down in slipshod manner without verifying firm's claim and arguments.

2. It is pertinent to highlight that since October 2023, our product "Parapol suspension" has been subjected to targeted victimization, with test results from various DTLs influenced by external factors. This interference has led samples of Parapol suspension being improperly classified as substandard based on invalid, impermissible, and non-pharmacopeial grounds despite of the fact that there being no quality issue and product complied in all applicable USP tests. The targeted Victimization and unfair treatment by Punjab DTLS toward Parapol is further evidenced by an incident involving the Drug Testing Laboratory in Bahawalpur. On 09-03-2024, DTL Bahawalpur, initially declared Batch No. 178-24 and 179-24 of Parapol suspension as standard quality and uploaded the corresponding reports on their portal. However, these standard reports were subsequently removed due to external pressures, and substandard reports for the same batches were uploaded Several months later. This suspicious & doubtful act of DTL Bahawalpur emphasizes the need for an unbiased and fair analysis, which only NIH 1Slamabad, as an appellate laboratory, can provide for reassessment of the Samples. Furthermore, is also important to highlight that committee PQCB did not give satisfactory reasons and grounds on the basis of which honorable committee members of PQCB showed reliance and trust on the Sub-standard" reports by the government analyst while same batches were declared "standard" on 9-3- 2024 by DTL Bahawalpur.

3. It is very important to highlight and note that government analyst maliciously used reference of WHO working document (OAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely impermissible and hence makes report invalid. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining the concentration of propylene glycol.

4. The government analyst has stated that the samples of Parapol suspension are "bitter in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

5. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited "USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. Samples of Parapol suspension were declared substandard based solely on personal observation (bitter taste) without conducting chemical analysis for accurate and instrument based identification of sweetener in the composition

6. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house / others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on ' In- house/other specifications' renders the report invalid and inaccurate

7. The government analyst has wrongfully claimed the products to be a "liquid" and free from any dispersed solid particles despite the same being a suspension. Government analyst has quoted reference of USP general chapters <l15|> for showing non-compliance. However, it is important to highlight that USP general chapters <1151> on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to classify product as suspension, solution or syrup. Same has been confirmed in letters by NIH Islamabad dated 6-6-2024 and 29-8-2024 to POCB as below:

i) Letter dated 6" June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any Such test on the basis of which the samples are declared sub-standard by DTLs of Punjab"

ii) Letter dated 29" August 2024 "It is once again informed that USP monograph for Acetaminophen oral Suspension have different tests including test from the general chapters i.e. performance test (uniformity 905, deliverable? volume - 698, impurities 4- of dosage units 277). Aminophenol in Acetaminophen containing Drug Products Specific test (p 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the and The USP samples were declared substandard by DTLs Punjab General Chapter <I151> on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply".The foregoing infirmity makes the report invalid and baseless.

8. "It is pertinent to note that the esteemed Punjab Quality Control Board (PQCB) previously investigated the matter regarding the presence or absence of particles in Parapol suspension by constituting a special committee comprising five pharmaceutical experts, including two respected members from PQCB. The honorable members of this special committee conducted a thorough examination of the samples and reached conclusions in our favor, affirming our claim that Parapol qualifies as a 'suspension.' The committee's findings explicitly stated that Parapol is a 'biphasic liquid-like suspension' with a translucent appearance due to the presence of visible particles (a copy of the expert committee's findings is attached).

However, contrary to this initial finding, the same committee members, who were previously convinced of the presence of solid particles in Parapol suspension, subsequently disregarded these findings. They participated in the disputed decision "impugned order" that denied our request for retesting and upheld the remarks of the government analyst, who asserted that Parapol suspension is free from dispersed particles and does not comply with USP <1151>.

9. Government analyst has mentioned in form 7 S.No# 6 that "USP 2024 / In-House / Others" has been applied. However, it is pertinent to highlight that neither USP 2024 nor method of analysis (In-House) of Parapol suspension provided by the firm gives any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension / solution / syrup. Therefore, Product Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

10. Since Parapol suspension was being declared of standard quality by DTL Bahawalpur till 10-10-2023 this proves that till this date, as per analysts of DTL Bahawalpur, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Bahawalpur must have received a revised and new method of analysis from the firm after 10-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 10-10-2023 which proves malice intention and act of victimization by government analyst.

11. In continuation of Point no# 1, in which few flaws and inaccuracies in the impugned order made by the committee PQCB were highlighted, we would further like to add more infirmities in the order in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. It is to be noted that point of discussion regarding toxicity and side effects of higher concentrations of propylene glycol is inapplicable and inappropriate when government analyst categorically admitted in committee meetings that method applied to determine exact concentration of propylene glycol is not as per WHO reference document rather it has been derived from it. Firm's claim of addition of less than 1% propylene glycol has been completely overlooked in the impugned order and no scrutiny was carried out by the committee PQCB to verify firm's claim. Firm stated in every committee meeting before honorable board that ye are supplying same product with the same formulation across Pakistan for decades and millions of children have safely consumed this product to alleviate pain and fever without any reported clinical toxicity. Despite this, the PQCB committee exhibited an unfair approach by relying on the impugned results of the government analyst, who determined the concentration of propylene glycol using a non-reliable and non-pharmacopeial method.
b. On what basis and in what capacity did Mr. Ijaz Alvi, Director of DTL Rawalpindi, present his views regarding the toxicity of propylene glycol before the committee, given that the impugned reports pertain exclusively to DTL Multan? It is to be noted that Mr liaz Alvi is not part of committee PQCB and firm has no faith on him as he is part of malicious campaign against our product. This raises concerns about the impartiality of the Process and suggests a coordinated effort by all DTLS of Punjab to unfairly target the product 'Parapol' without relying on legal facts and objective findings.

c. How and on what grounds committee members got convinced by views of Director, DTL Rawalpindi and Government Analyst, DTL Bahawalpur in which they were trying to establish a view that firm has solubilized paracetamol in propylene glycol without counter verifying it with firm's claim?. Firm has already provided list of excipients with quantities before the committee POCB in which it was mention that firm added propylene glycol less than 1% in the formulation of Parapol Suspension only with the purpose as stabilizer and as preservative. Firm's representative comprehensively explained that it is practically impossible to solubilize paracetamol in an amount of propylene glycol and water that has been used in the formulation of Parapol suspension. Nevertheless, the PQCB Committee chose to accept the unverified personal opinions of the individuals mentioned and issued a biased decision without validating the firm's assertions.

d. Question i.e testing of propylene glycol in finished product duly raised by the committee members is inaccurate, as firm is not bound to test excipients in finished form neither does tested by any DTL of Pakistan. Firm is always well aware of the fact that how much amount of any excipient is being added in formulation and as per GMP guidelines, all excipients are being consumed once passed initially from quality control department. Moreover, Specs claimed for Parapol suspension is USP and firm carries out all applicable test as per USP which specifically provide testing of API in a finished product only. Despite of the fact, committee POCB turned down our appeal for retesting to prevent us from the right of justice.

e. The quality of propylene glycol as a raw material, along with its associated standards, cannot be questioned or used as grounds for denying the request for re-testing. The impugned DTL reports themselves acknowledge compliance with the WHO reference document and confirm the absence of impurities such as EG and DEG, which demonstrates that the quality of the propylene glycol used was fully compliant and without any issues. Furthermore, under the latest DRAP guidelines, propylene glycol cannot be released for use unless tested by federal laboratories. The firm has consistently stated in all meetings that the propylene glycol used in the batches of Parapol suspension was tested and approved by the Central Drug Laboratory (CDL) in Karachi prior to its consumption. Additionally, we would like to highlight grounds comprehensively which have already been discussed in difference committee meeting that further supports our stance in said case:
1. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024: "It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 {Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976}" In this regard, committee POCB was duty bound to consider the foregoing while scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

2. The malafide intentions of the Government Analysts and Director DTL Bahawalpur are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 76 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of

comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

3. Since, product “"Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe /instruct to conduct test for determination of the taste of the products or test to classify product as syrup solution or suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopeial testing.

4. It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc.) of the "finished form" of the drug. In this context, the Products, like all other drugs, underwent a comprehensive manufacturing process wherein in addition to the active pharmaceutical ingredient; several other excipients were also added. Additionally, tests are prescribed in the specifications to ascertain the quality of a "finished form of drug". Thus, only tests that could have been performed by the government analyst were those prescribed in the USP and any additional information sought in relation to the excipients and or other ingredients or any testing carried out on the basis of the same is illegal and unlawful.

5. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the Samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the Substandard drugs". However, in our case, government analyst has shown her malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

6. Section 3(z) of the the Drugs Act, 1976 defines the term specifications as.

(i) such specifications as may be prescribed;
(ii) or when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:-
(1) the Pakistan Pharmacopoeia;
(2) the International Pharmacopoeia;
(3) the European Pharmacopoeia;
(4) the United States Pharmacopoeia;
(5) the British Pharmacopoeia;
(6) the British Pharmaceutical Codex;
(7) the United States National Formulary; and

(8) such other publication as may be prescribed:

In terms of the legislative scheme envisioned under the Drugs Act, 1976, more particularly, Section 3(zz) a drug shall only be deemed as substandard if it does not comply with the applicable specifications. Essentially, such determination can only be made if the drug fails to comply with the tests "prescribed" under the applicable specifications. The monograph of a drug provided under the applicable specifications lists down the requisite tests that need to be conducted in order to determine whether the drug is of standard quality. It is a matter of fact that the Drugs Act does not permit analysts to carry out inapplicable tests or tests, which have not been listed down in the applicable specifications. However, in context of the present case, the Government Analysts have malafidely declared the batches of the Product as substandard on the basis of their bitter taste & absence of solid particles without there being any criteria or test to determine the same. The foregoing action clearly constitutes a violation of the Drugs Act, 1976 as well as Rule 16 of The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rule 1976.

In the light of above highlighted facts and infirmities, it can be concluded that committee PQCB has failed to scrutinize the case properly as it has overlooked above evidences and factual findings. The illegalities floating on the record of the case and as mentioned in above grounds have been completely overlooked and no heed has been paid to the wrongdoings of the government analyst who has declared the Products to be of substandard quality on a completely wrongful premise. t was mandatory upon this committee PQCB to properly scrutinize the subject especially in this case when samples comply with the stated specification chemically and physically and adjudicate upon the same. However, no such exercise has been carried out in the present case. Furthermore, it is to be noted that our firm petitioner Company" and its officials have not contravened the provisions of the Drug Laws and the rules made thereunder rather they are committed to ensure compliance thereof. PQCB passed an impugned order (turning down request for retesting) which completely disregard not just of the principles of fair trial and due process envisioned under Article 10-A and Article 4 of the Constitution but also disregard of the scheme of law envisioned under he Drugs Act, 1976 as-well as the fundamental rights of the Petitioner Company enshrined under the Constitution of Islamic Republic

of Pakistan, 1973.

On the premise of foregoing submission and grounds highlighted above, it is mandatory and essential for the learned Board to review its decision. We reserves the right to agitate additional grounds at the time of arguments if needed. We as "Petitioners" are seeking the setting aside of the Impugned Decision in terms of clause 2 of Part VIII of the PQCB Regulations and pray as below:

PRAYER

In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:

i. Set aside the Impugned Order in which committee PQCB turned down appeal for re-testing and directed Provincial Inspectors of Drugs, to expedite investigation submission of final report.

ii. Pass an order for the samples of above mentioned Suspension Parapol Batches to be sent to the National Institute of Health, Islamabad and allow retesting of samples for the conclusive report.

iii. Direct the government analyst of the Drug Testing Laboratory, Bahawalpur and Multan to bring the method and protocols of the test employed to determine the taste of the Suspension and test to determine presence or absence of particles in suspension.

iv. Share transparent findings, causes and measures against the incident in which DTL Bahawalpur issued standard report for Batch No. 178-24 and Batch No. 179-24 and reports were removed later on and sub-standard reports were issued for same batches.

v. Permanently restrain the Provincial Inspectors of Drugs from taking any adverse and/or coercive action against our firm "Petitioner Company" and against our officials based on the Impugned order / decision.

We hope that learned board will allow us to avail right of fair trial and accept above.

14. `Personal hearing notice issued to accused person(s)

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

15. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **287th Meeting held on 08.01.2025** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Chairperson PQCB). Mr. Hassan Saeed, Secretary DQCB, Lahore and Mr. Ubaid Ullah Anwar, Drug Inspector, Government Medical Store Deport, Lahore attended the meeting along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeil test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary individual to individual basis and there will be no toxicity or adverse effects due to bitter taste
ii. We are confident that our product is suspension and complies all applicable test of USP monograph "acetaminophen oral suspension".
iii. As far as declaring our samples substandard declaring them to be "free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iv. He further added that although the DTL has quantified Propylene Glycol in the test report but failed to mention the limit and to specify whether it complies or not with any official monograph.
v. He further reiterated firm's request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting.

16. The Board after careful perusal of the case record and scrutiny of DTL report observed that various batches of the subject drug sample of **Parapol Suspension (Each 5ml contains: Paracetamol USP…120mg)**, have been declared substandard by the Drugs Testing Laboratory, Bahawalpur on the basis of physical description as "Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles**" further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 14-06-2024 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was turn down in 43rd Committee meeting of the Board held on 29-08-2024. Regarding firm's review petition against retesting orders and the plea to send their subject batches to NIH for retesting, the Board observed that in 279th meeting held on 24-04-2024, the Board sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976. Hence, the Board unanimously decided to **Turn Down** the subject review petition and **upheld the previous decision** as taken in its **43rd Committee meeting** held on **29-08-2024** as the firm did not provide any satisfactory argument in their review petition to the question regarding the physical characteristics, bitter taste and quantification of polyethylene glycol of the subject samples.

17. Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

18. While perusing the case record, the Board remarked that the samples in question were declared substandard on the basis of physical description as per General Chapter <1151> of the USP and bitter taste of suspension by the Government Analyst DTL Bahawalpur. The firm claims the product as "Suspension" on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Bahawalpur. Furthermore, regarding bitter taste of the suspension, the Board was of the view that the product has been developed for pediatrics use and bitter taste of suspension as reported by the DTL in the subject reports, will result in non-compliance and reluctance to take medication by children.

19. The Board further observed that the DTL also determined the variable percentage of Propylene Glycol in the batches under consideration by applying WHO Working Document QAS/23.922/rev3 Dated 31 October 2023.

Acceptable Dietary Intake of Propylene Glycol				
EMA		**50mg/kg/day**		
WHO		**25mg/kg/day**		
Batch No.	**PG Determined (as per DTL Report)**	**PG Content mg/kg/day (Calculated as per EMA Guidelines, keeping in view firm's own label recommended dose for a child weighing 10kg, 15kg & 18kg respectively)**		
		PG (mg/kg/day) (30mL Dose)	**PG (mg/kg/day) (60mL Dose)**	**PG (mg/kg/day) (120mL Dose)**

080-24	10.77%	334.73	446.31	743.85
083-24	10.20%	317.02	422.69	704.48
086-24	11.40%	354.31	472.42	787.36
089-24	11.21%	348.41	464.54	774.24
082-24	11.06%	343.74	458.33	763.88
081-24	10.89%	338.46	451.28	752.14
085-24	11.80%	366.74	488.99	814.99
084-24	10.65%	331.00	441.34	735.56
072-24	11.93%	370.78	494.38	823.97
077-24	10.35%	321.68	428.90	714.84
088-24	11.93%	370.78	494.38	823.97
078-24	10.37%	322.30	429.73	716.22
066-24	10.75%	334.11	445.48	742.47
087-24	10.40%	323.23	430.98	718.29
090-24	11.24%	349.34	465.79	776.31
079-24	10.64%	330.69	440.92	734.87

20. The Board further observed that as per guidelines of European Medicine Agency published vide No. EMA/CHMP/704195/2013 dated 09.10.2017, propylene glycol is estimated to be one-third as intoxicating as ethanol, with administration of large volumes being associated with adverse effects most commonly on the central nervous system, especially in neonates and children. Other adverse reactions reported through generally isolated, include: ototoxicity, cardiovascular effects; seizures; and hyperosmolarity and lactic acidosis, both of which occur most frequently in patients with renal impairment. Adverse effects are more likely to occur following consumption of large quantities of propylene glycol or on administration to neonates, children under 4 years of age, pregnant women, and patients with hepatic or renal failure. Adverse events may also occur in patients treated with disulfiram or metronidazole. Keeping in view all aspects of case, the Board after due deliberation and detailed discussion, unanimously decided to **pend the case**.

Personal hearing notice issued to accused person(s)

Sr.	Summary of the case	
1.	**Date of sampling**	25-05-2024
2.	**Sent to DTL**	25-05-2024
3.	**Date of receipt in DTL**	27-05-2024
4.	**Issuance of DTL Report**	15-07-2024
5.	**Time Extension**	N/A
6.	**1st DI Communication with firm**	**03-08-2024**
7.	**Retesting Request**	Yes.
8.	**Fate of retesting request**	Turn-Down 43rd Committee meeting dated 29-08-2024
9.	**Investigation Report of DI**	06-08-2024
10.	**Permission of SCN**	285th meeting dated 26-09-2024
11.	**SC/ PH Notice Issued**	22-10-2024
12.	**Reply of the firm**	No
13	**History (3 years)**	111 cases of the firm 87 cases of the product

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-199514, 199517, 199520, 199523, 199516, 199515,199519,199518, 199510, 199511, 199522,199512, 199509, 199521, 199524, 199513/ 2024

Government Medical Store Depot, Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Lisko Pakistan Pvt. Ltd. L-10D Block-21, F.B. Industrial Area, Karachi** through its Managing Director Muzamil Nazar 2. Muzamil Nazar — Managing Director 3. Ghulam Nabi Khoso — Production In-charge 4. Naima Khanam — Quality Control In-charge/ Warrantor Of **M/s Lisko Pakistan Pvt. Ltd. L-10D Block-21, F.B. Industrial Area, Karachi.**

BREIF FACTS OF THE CASE

Provincial Inspector of Drugs, Government Medical Store Depot, Lahore reported that:

i. He, on 25-05-2024, inspected the premises of Govt. Sub-Medical Store Depot, Maraka, Multan Road, Lahore and took drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 199514, 199517, 199520, 199523, 199516, 199515,199519, 199518, 199510, 199511, 199522,199512, 199509, 199521, 199524, 199513 dated 25-05-2024.
ii. Following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

Sr. No.	Name of drug	Batch no.	Name of manufacturer	DTL Report No. & Date	DTL Test Report Results
1.	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date:** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	080-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	01-10097008756/ DTL 15-07-2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.8ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml, Determined: 121.58 mg/5ml (101.32 %), Limit: 90.0-110.0%**

					TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY: **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.77%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
2	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	083-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008759/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms "A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase." (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.7ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 123.26 mg/5ml (102.72%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY:** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.**

					WHO Working Document **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol: Limit: NMT 0.1% Determined: Not Detected** **Diethylene Glycol: Limit: NMT 0.1%, Determined: Not Detected** **Propylene Glycol: Determined: 10.197%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
3	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	086-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008762/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.9°C** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 124.27 mg/5ml (103.56%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected**

					Propylene Glycol **Determined: 11.40%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
4	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	089-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008765/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.*" (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9,Determined: 5.5 at 25.0ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml, Determined: 127.34 mg/5ml (106.12%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 11.21%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**

<table>
<tr>
<td>5</td>
<td>Suspension Parapol Paediatric Suspension 120ml

(Paracetamol USP 120mg/5ml, 120ml)

Mfg. Date : Aug-2023

Exp. Date : Aug-2025

Reg. No. 002772</td>
<td>082-24</td>
<td>M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi</td>
<td>10097008758/DTL dated 15.07.2024</td>
<td><u>Specs Applied: USP 2024/Others/In house</u>

<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg

<u>PHYSICAL CHARACTERISTICS:</u>

Stated: Pinkish red sweet homogenous suspension.

Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase. (DOES NOT COMPLY)

<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 23.9ºC

<u>IDENTIFICATION:</u> Paracetamol is identified.

<u>ASSAY OF PARACETAMOL</u>: Stated: 120 mg/5ml, Determined: 122.83 mg/5ml (102.36%), Limit: 90.0-110.0%

<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

<table><tr><td>Ethylene Glycol:

Limit: NMT 0.1%
Determined: Not Detected</td><td>Diethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected</td></tr><tr><td colspan="2">Propylene Glycol

Determined: 11.06%</td></tr></table>
<u>RESULT:</u> The Sample is declared as “SUB-STANDARD” on basis of Physical Characteristics.</td>
</tr>
<tr>
<td>6</td>
<td>Suspension Parapol Paediatric Suspension 120ml

(Paracetamol USP</td>
<td>081-24</td>
<td>M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B</td>
<td>10097008757/DTL dated 15.07.2024</td>
<td><u>Specs Applied: USP 2024/Others/In house</u>

<u>COMPOSITION</u>: Each 5ml contains: Paracetamol USP…. 120mg</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>120mg/5ml, 120ml)

Mfg. Date : Aug-2023

Exp. Date : Aug-2025

Reg. No. 002772</td>
<td></td>
<td>Industrial Area, Karachi</td>
<td></td>
<td><u>PHYSICAL CHARACTERISTICS:</u>

Stated: Pinkish red sweet homogenous suspension.

Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.” (DOES NOT COMPLY)

<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 24.1º

<u>IDENTIFICATION:</u> Paracetamol is identified.

<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml

Determined: 122.68 mg/5ml (102.23%), Limit: 90.0-110.0%

<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

<table><tr><td>Ethylene Glycol:

Limit: NMT 0.1%
Determined: Not Detected</td><td>Diethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected</td></tr><tr><td colspan="2">Propylene Glycol

Determined: 10.89%</td></tr></table>
<u>RESULT:</u> The Sample is declared as “SUB-STANDARD” on basis of Physical Characteristics.</td>
</tr>
<tr>
<td>7</td>
<td>Suspension Parapol Paediatric Suspension 120ml

(Paracetamol USP 120mg/5ml, 120ml)</td>
<td>085-24</td>
<td>M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi</td>
<td>1009700876/DTL dated 15.07.2024</td>
<td><u>Specs Applied: USP 2024/Others/In house</u>

<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg

<u>PHYSICAL CHARACTERISTICS:</u>

Stated: Pinkish red sweet homogenous suspension.</td>
</tr>
</table>

	Mfg. Date : Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772				**Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.4ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 127.03 mg/5ml (105.86%), Limit 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 11.80%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
8	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	084-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008760/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.**

					As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY) **<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 23.5ºC** **<u>IDENTIFICATION:</u> Paracetamol is identified.** **<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml** **Determined: 127.29 mg/5ml (106.08%), Limit: 90.0-110.0%** **<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.65%** **<u>RESULT:</u> The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
9	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	072-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008752/DTL dated 15.07.2024	**<u>Specs Applied: USP 2024/Others/In house</u>** **<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg** **<u>PHYSICAL CHARACTERISTICS:</u>** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)**

					pH: Limit: 4.0-6.9, Determined: 5.6 at 24.4ºC **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 121.58 mg/5ml (101.32 %), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 11.93%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
10	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	077-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008753/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 24.0ºC** **IDENTIFICATION: Paracetamol is identified.**

					ASSAY OF PARACETAMOL: Stated: 120 mg/5ml **Determined: 125.11 mg/5ml (104.26%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.35%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
11	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	088-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008764/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 24.4ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 126.53 mg/5ml (105.44%), Limit 90.0-110.0%**

					TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** / **Diethylene Glycol:** **Limit: NMT 0.1%** / **Limit: NMT 0.1%** **Determined: Not Detected** / **Determined: Not Detected** **Propylene Glycol** **Determined: 11.93%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
12	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	078-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008754/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.0ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 122.20 mg/5ml (101.83%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol,**

					Diethylene Glycol & Propylene Glycol. **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.37%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
13	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	066-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008751/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.1ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml, Determined: 124.46 mg/5ml (103.72 %), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023**

					Ethylene Glycol: **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.75%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
14	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	087-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008763/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.8ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 124.45 mg/5ml (103.71%), Limit: 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%**

					<table><tr><td></td><td>**Determined: Not Detected**</td></tr><tr><td colspan="2">**Propylene Glycol** **Determined: 10.40%**</td></tr></table> **<u>RESULT:</u> The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
15	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	090-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008766/DTL dated 15.07.2024	**<u>Specs Applied: USP 2024/Others/In house</u>** **<u>COMPOSITION:</u> Each 5ml contains: Paracetamol USP…. 120mg** **<u>PHYSICAL CHARACTERISTICS:</u>** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, <u>bitter</u> viscous liquid and <u>free from any dispersed solid particles</u>, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* (DOES NOT COMPLY)** **<u>pH:</u> Limit: 4.0-6.9, Determined: 5.5 at 24.5ºC** **<u>IDENTIFICATION:</u> Paracetamol is identified.** **<u>ASSAY OF PARACETAMOL:</u> Stated: 120 mg/5ml** **Determined: 128.39 mg/5ml (106.99%), Limit: 90.0-110.0%** **<u>TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY</u>** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** <table><tr><td>**Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected**</td><td>**Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected**</td></tr><tr><td colspan="2">**Propylene Glycol**</td></tr></table>

					Determined: 11.24% **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Characteristics.**
16	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	079-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	10097008755/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg** **PHYSICAL CHARACTERISTICS:** **Stated: Pinkish red sweet homogenous suspension.** **Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.** **As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."* (DOES NOT COMPLY)** **pH: Limit: 4.0-6.9, Determined: 5.5 at 23.4ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL: Stated: 120 mg/5ml** **Determined: 124.64 mg/5ml (103.87%), Limit 90.0-110.0%** **TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY** **Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 October 2023** **Ethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Diethylene Glycol:** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 10.64%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis**

					of Physical Characteristics.

iii. General Manager, Government Medical Store Depot, Gulberg-III, Lahore provided invoice/ warranty No. nil, dated: 09-10-2023, 11-10-2023, 13-10-2023, 14-10-2023 & 16-10-2023 issued by M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi, as a proof of purchase.
iv. Warrantor Portion of subject drug sample was sent to M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi.
v. Copies of Test/ Analysis reports were sent to M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi and they were directed to explain their position and provide the requisite information in this regard. In response, the firm requested for re-test/ analysis of the drug sample.

Pervious Proceedings & Decision by the Committee:

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **43rd meeting** held on **29.08.2024** under the Convenorship of Director General of Drug Control. Dr Sarfaraz Manager M/S Lisko Pakistan (Pvt) Ltd appeared before the Committee to plead the case. The committee observed that the above-mentioned batches were declared substandard by DTL Bahawalpur on the basis of physical description that is bitter in taste and free from any dispersed solid particles. The committee further observed that the DTL also determined the percentage of Propylene Glycol as 10.77%, 10.197%, 11.40%, 11.21%, 11.06%, 10.89%, 11.80%, 10.65%, 11.93%, 10.35%, 11.93%, 10.37%, 10.75%, 10.40%, 11.24% and 10.64% in the batches under consideration.

3. The committee observed that the maximum permissible daily intake of propylene glycol as a food additive by WHO is 25/mg/kg. The committee further observed that as per guidelines of EUROPEAN MEDICINE AGENCY published vide No. EMA/CHMP/704195/2013 dated 09.10.2017 the proposed dose limit of Propylene Glycol in children below 5 years down to 1 month of age is 50mg/kg. Mr Ijaz Alvi Director DTL Rawalpindi apprised the committee that the percentage of Propylene Glycol is critical when it is to be added in oral formulations for pediatrics, as it is associated with CNS Depression, renal and liver dysfunction and cardiotoxicity. He further stated that the solubility of Paracetamol is maximum in propylene glycol that is 1:9 parts.

4. The Government analyst DTL Bahawalpur (attended online) apprised the committee that the method for calculating the percentage of propylene glycol is derived from WHO Working document QAS/23.922/rev3 Dated 31 October 2023. They further stated that the use of propylene glycol solubilizes the paracetamol hence the firm cannot claim their product as a Suspension. The percentage of propylene glycol determined in Parapol Suspension by DTL Bahawalpur is higher than the permissible safe limits in children under 5years of age as per EMA guidelines.

The committee inquired from the firm representative about his stance on following points:

i. Bitter taste of suspension.
ii. Percentage of Propylene glycol in formulation and its use.
iii. Does the firm test percentage of Propylene glycol in finished product. ?
iv. Does the firm test propylene glycol as a raw material?
v. Does the firm have standard for propylene glycol testing?
vi. Does the firm is using the same formulation since its registration or it is modified after that, if modified it is communicated to Registration Board or not?

5. The firm representative Mr. Sarfaraz (BUH) given his stance on above mentioned points as follows:

i. The firm is using artificial sweetener Neotame (0.52kg) in batch of 4600 liter to mask the bitter taste of suspension, there is need of improvement in the taste of suspension and the firm is

considering this point already.

ii. The firm representative provided the formulation of Parapol Suspension before the committee and stated that the percentage of propylene glycol is less than 1% in the formulation. He further stated that they are not using propylene glycol as a Co-solvent instead using it as a preservative/ stabilizer along with other preservatives like methyl paraben and propyl paraben.

iii. The firm is not testing the percentage of propylene glycol in the finished product.

iv. The firm representative was unaware that they are testing the propylene glycol as a raw material or not.

v. The firm representative stated that he is not sure about the testing and standard of propylene glycol.

vi. The firm representative was unaware of changes made in the formulation and its intimation to DRAP.

6. The committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate the formulation with respect to bitter taste and Propylene glycol concentration hence unanimously decided to **Turn Down** the retesting request of the firm. The Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

7. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacturing for sale/ Sale of Substandard drug**

b. **Issuance of false warranty**

8. Show-cause/ personal hearing notice issued to accused person(s).

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi submitted written reply in response to show-cause/ personal hearing notice vide letter dated 30-10-2024 as mentioned below:

We would like to submit our reply against show cause/personal hearing notice dated 22-10-2024 in which we have been asked to appear before honorable PQCB on 30-10-2024 for below mentioned cases against which ou firm submitted appeal for re-testing from NIH, Islamabad. Subsequently, committee PQCB meeting was held on dated 29-8-2024 in which we presented our stance comprehensively and highlighted several grave infirmities an ambiguity in DTL. reports Despite this, we have been informed that our appeal for retesting has been turn down. Details of the batches are as below:

B.no	DTL report	DTL report Date
066-24	01-10097008751	15/07/2024
072-24	01-10097008752	15/07/2024
077-24	01-10097008753	15/07/2024

078-24	01-10097008754	15/07/2024
079-24	01-10097008755	15/07/2024
080-24	01-10097008756	15/07/2024
081-24	01-10097008757	15/07/2024
082-24	01-10097008758	15/07/2024
083-24	01-10097008759	15/07/2024
084-24	01-10097008760	15/07/2024
085-24	01-10097008761	15/07/2024
086-24	01-10097008762	15/07/2024
087-24	01-10097008763	15/07/2024
088-24	01-10097008764	15/07/2024
089-24	01-10097008765	15/07/2024
090-24	01-10097008766	15/07/2024

We again like to highlight below mentioned facts and ambiguities through our reply of show cause/ person hearing notice and request honorable PQCB to review decision of committee PQCB and send samples above batches of Parapol suspension to NIIH, Islamabad (Appellate lab) for the conclusive report

A POINTS OF DEFENSE & CONTRAVENTION IN CONCENTRATION OF "PROPYLENE GLYCOL" DETERMINDED BY GOVERNMENT ANLAYST

A1 Committee PQCB failed to provide fair trail and due process in subject case as most of the discussion during committee meeting was linked to concentration of propylene glycol instead of discussions on contravention & scrutiny on the grounds on the basis of which samples has been declared substandard by the government analyst. Committee PQCB cannot introduce new grounds or raise additional issues in DTL report by their own if they were not shown as noncompliant by the government analyst in the initial report. None of the sample have been declared substandard on the basis of concentration of propylene glycol and therefore reliance on any such discussion will sabotage principle of fair trail and due process.

A2 It is very important to highlight and note that government analyst maliciously used reference of WHO

working document (QAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely illegal and unlawful. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining the concentration of propylene glycol.

A3 It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc) of the "finished form" of the drug. In contrary, government analyst tested and qualified excipient "Propylene glycol" in a finished product using non-reliable method which is illegal and unlawful.

A4. The victimization of the firm and product "Parapol" is further evinced by the fact that the drug testing laboratory in Bahawalpur (DTL Bahawalpur) initially declared two batches of Parapol suspension (Batch No. 178-24 and 179-24) as standard quality on 09-03-2024 and uploaded the corresponding reports on their portal. However, these standard reports were later removed, and substandard reports for the same batches were uploaded instead. We duly highlighted this discriminatory behavior multiple times in different PQCB meeting, however no action was taken against the government analyst at DTL Bahawalpur. Instead, same government analyst who did such act of victimization for batch no# 178-24 and 179-24 declared further samples of Parapol suspension substandard on illegal and unlawful grounds.

B POINTS OF DEFENSE & CONTRAVENTION AGAINST REMARKS "BITTER TASTE" BY GOVERNMENT ANALYST

BI. The government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless

B2. Government analyst has mentioned in form 7 "S.Nof# 6" that he/she has applied spees ie USP 2024/In-House/Others. However, it is pertinent to highlight that neither USP 2024 nor method of analysis (In-House) of Parapol suspension (if) provided by the firm gives any test to determine sweetness/bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension/solution/ syrup. Therefore, Product "Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst

B3. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:

"It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 (Rule 16 of Drugs (Federal Drug inspectors, Federal

Drug Laboratories, Federal Government analyst) Rules, 1976)"

In this regard, committee PQCB was duty bound to consider the foregoing fact whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

B4.The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house/others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on "In-house/other specifications' renders the report invalid and inaccurate.

B5. Since Parapol suspension was being declared of standard quality by DTL Bahawalpur till 10- 10-2023 this proves that till this date, as per analysts of DTL Bahawalpur, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Bahawalpur must have received a revised and new method of analysis from the firm after 30-9-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 10-10-2023 which proves malice intention and act of victimization by government analyst.

B6. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited 'USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard & testing method for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. No such request or chemical analysis was made, and the product was instead declared substandard based solely on personal observation (bitter taste) without conducting or verifying any formal test.

B7. The malafide intentions of the Government Analysts and Director DTL Bahawalpur are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 76 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

B8. Since, product "Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe/ instruct to conduct test for determination of the taste of the products, test to check dispersed particles in a suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopical testing.

B9. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the substandard drugs". However, in our case, government analyst has shown her/his malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

C= POINTS OF DEFENSE AGAINST REMARKS OF GOVERNMENT ANALYST "SAMPLE IS FREE FROM ANY DISPERSED SOLID PARTICLES <USP 1151>"

The government analyst has wrongfully claimed the Products to be a "liquid" despite the same being a suspension. Government analyst also stated that "samples is free from any dispersed solid particles" and declared samples substandard using reference USP <1151> It is pertinent to highlight that PQCB has already investigated this case and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst holding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to of presence of particles (copy of findings of expert committee attached).

It is also important to highlight that USP general chapters <1151> on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to determine product is suspension, solution or syrup. Same has been confirmed in letters by NIH, Islamabad dated 6-6-2024 and 29-8-2024 as below:

1. 1. *Letter dated 6th June 2024 "**It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any such test on the basis of which the samples are declared sub-standard by DTLs of Punjab".***
   2. *Letter dated 29 August 2024 "**It is once again informed that USP monograph for Acetaminophen oral suspension have different tests including test from the general chapters le performance test (uniformity of dosage units-905, deliverable volume - 698, impurities (4-Aminophenol in Acetaminophen containing Drug Products-277) specific test (pH 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the samples were declared substandard by DTLs Punjab" and "The USP General Chapter <1151> on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply"***

Furthermore, point no# B2, B3, B4, B5 B7, B8 and B9 also supports our stance and provides strong defense and contravention against conclusion of government analyst "absence of dispersed solid particles". The foregoing infirmity makes the report invalid and baseless.

POINTS OF DEFENSE & CONTRAVENTIONS IN DISCUSSIONS OF COMMITTEE POCB IN WHICH REQUEST FOR RETESTING HAS BEEN TURNED DOWN

We would like to highlight following numerous flaws and inaccuracies in the discussions during committee PQCB meeting and the grounds on the basis of which "impugned decision" made by the committee PQCB:

1. *During committee PQCB meeting, members introduced new grounds and raise additional issues by discussing matter of propylene glycol in DTL report by their own while they were not shown as noncompliant by the government analyst in the initial report. All such discussion related to propylene glycol is unlawful and illegal and cannot be relied as ground on the basis of which appeal has been turned down.*
2. *It is pertinent to inform that in our previous meetings when we requested the board to kindly evaluate our sample board was of the opinion that product sample cannot be evaluated in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIII Islamabad for conclusive report. However, opinion regarding the same product has been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product, samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions. On the basis of numerous highlighted ambiguities in impugned reports, there is a need for conclusive reevaluation. Following are the scope of retesting for said cases:*

a. Presence or absence of sweetener (neotame) in the composition as claimed by our firm.

b. Presence of small solid particles and product as suspension as per USP <1151> as claimed by the firm.

3 We strongly contested in all meetings that sweetener is present in the formulation which has been added to mask bitter taste and firm has always claim in all meetings that Parapol suspension ensure a palatable profile that supports patient compliance. That is why, no any single complain has been reported due to bitter taste in any forum or by the procuring agency since its registration.

4. Our firm has been supplying the same product with the same formulation across Pakistan for decades, with millions of children having safely consumed the product to alleviate pain and fever without any reported clinical toxicity. The firm asserts that the addition of propylene glycol at less than 1% in the formulation is entirely safe for pediatric use and complies with the guidelines of the European Medicines Agency (EMA). There has not been a single reported case of clinical toxicity related to Parapol suspension in any province of Pakistan.

In the light of above highlighted infirmities and weakness in reports, we request honorable PQCB to send mentioned 16 samples of Parapol suspension to NIIH, Islamabad for the conclusive report and give us fair chance of re-evaluation from the appellate lab. We request honorable PQCB and concerned drug inspector to not initiate prosecution against us as we have not contravened provisions of Drug act 1976.

PREVIOUS PROCEEDINGS BY THE BOARD:

PQCB 286th Meeting dated 30-10-2024:

10. Case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **286th** meeting held on **30-10-2024** under the chairmanship of Special Secretary Primary & Secondary Healthcare Department, vice-chairperson PQCB. Mr Hassan Saeed Secretary DQCB District Lahore was present. No-one among nominated accused was present, however, Dr. Sarfraz (Manager) appeared before the Board on behalf of M/s Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi and retreated the points as mentioned above in reply to show-cause/ personal hearing notice and emphasized to send the sample to Appellate Laboratory for retest/ analysis. He pleaded his case on following grounds:

i. He submitted that government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs.
ii. Government analyst declared that "samples is free from any dispersed solid particles" and declared samples substandard using reference USP <1151>, whereas it is pertinent to highlight that PQCB has already investigated this case and constituted a committee of pharmaceutical experts which concluded its findings in our favour whilst holding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iii. Government Analyst maliciously used reference of WHO working document (QAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely illegal and unlawful. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining the concentration of propylene glycol.
iv. He requested to send their sample for retest/ analysis.

11. The Board after careful perusal of the case record observed that subject drug samples has been declared substandard from Drug testing Laboratory, Bahawalpur on the basis that Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, whereas, the firm in its method of analysis claims that it is pinkish

red sweet homogeneous suspension. Moreover, the Government analyst has determined the percentage of Propylene glycol, however, the samples were not declared substandard on the basis of concentration of propylene glycol. The Board was of the view that:

i. Propylene glycol is widely used as solvent, extractant and preservative in variety of pharmaceutical formulations. The permitted concentration of propylene glycol as solvent/ co-solvent in oral solutions is 10-25% as excipient in a variety of parenteral and non-parenteral pharmaceutical preparations as per EMA guidelines issued on 09 October 2017, EMA/CHMP/704195/2013 committee for human medicinal products. Moreover, the product is not declared substandard on the basis of concentration of propylene glycol by the Government Analyst. However, WHO has set a maximum permissible daily intake of Propylene Glycol as food additive at 25 mg/ kg.
ii. The Board showed serious apprehensions about the taste of subject product is intended for pediatric patients and the bitter taste of the suspension must be masked, and it must be palatable to ensure patient compliance. The Board was of the opinion that the firm must redesign its formulation to mask the bitter taste of suspension.
iii. The board considering the other analyzed parameters by the Government analyst that assay and pH of the formulation lies well within the prescribed limits.

12. Keeping in view the facts of the case, the Board after due deliberation and discussion decided to **pend** the case.

GROUNDS OF REVIEW PETITION (ON RETESTING ORDERS):

SUBJECT: REVIEW PETITION UNDER CLAUSE VIII O THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We, M/S Lisko Pakistan (Pvt) Ltd Petitioner Company" would like to submit instant review petition to the learned Provincial Quality Control Board Punjab against the order of committee PQCB dated 20-09-2024 (the "impugned Decision") in which request of re-testing from NIH, Islamabad has been turned down for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspectors of Drugs, (the "Respondent Drug Inspector") has been directed to expedite Investigation so that permission for prosecution can be granted.

There are several grave infirmities and ambiguities in TL reports "Impugned reports" issued by government analyst of DTL Bahawalpur and also in decision "Impugned Order by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, It 1s pertinent to highlight the fresh grounds that have arisen in the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. Committee PQCB has turned down request for retesting from NIH, Islamabad with the statement which itself contains several ambiguities and infirmities. “the committee after due deliberation and discussion concluded that the arguments given by the firm are unsatisfactory and there is need to reevaluate the formulation with respect to bitter in taste and propylene glycol concentration hence unanimously decided to turn down the retesting request of the firm".

A) Government analyst has not declared samples substandard on the basis of concentration of propylene glycol rather it has been declared substandard on the basis of physical characteristics (Bitter taste and absence of solid particles as per USP <151>). Once appeal for retesting has been submitted against impugned Reports and errors are being highlighted by the firm, committee PQCB can only Scrutinize grounds on the basis of which samples have been declared substandard but cannot introduce new grounds or raise additional issues in DTL report by their own if they were not shown as noncompliant by the government analyst In the initial report. Drug act 1976 and other existing laws have clearly defined duties and limitations of both government analyst and PQCB. Members of committee PQCB initiated discussion i.e toxicity due to propylene glycol, role of propylene glycol to solubilizing Paracetamol without having conclusive evidences and turned down appeal for retesting by relying on this premise. Therefore, all discussion in impugned order related to propylene glycol is unlawful and illegal and cannot be relied as ground on the basis of which appeal has been turned down.

b. It is pertinent to highlight that in our previous meetings of committee PQCB, when we requested to kindly evaluate our sample, committee members PQCB was of the opinion that product sample cannot be evaluated & tested in PQCB as it is not a forum for evaluation of samples and it is very important to send samples to NIH Islamabad for conclusive report.. However, opinion of the committee PQCB regarding the same product has suddenly been changed now and despite of endorsing fact by PQCB that there is need of reevaluation of the product,

samples of Parapol suspension are not sent to NIH that is a clear contradiction from its previous decisions.

C. Firm's representative never agreed with the findings of government analyst (bitter in taste and free from any dispersed solid particles) rather firm's representative always claimed that Parapol suspension ensure a palatable profile that supports patient compliance and also claimed presence of dispersed solid particles in Parapol suspension. However, firm's stance has been improperly and incompletely stated in the "impugned order"

d. Firm's claim regarding presence of dispersed particles and palatable taste profile can only be verified if samples will be sent to NIH, Islamabad for the conclusive and fair report. However, same has not been done and appeal for retesting has been turned down in slipshod manner without verifying firm's claim and arguments.

2. It is pertinent to highlight that since October 2023, our product "Parapol suspension" has been subjected to targeted victimization, with test results from various DTLs influenced by external factors. This interference has led samples of Parapol suspension being improperly classified as substandard based on invalid, impermissible, and non-pharmacopeial grounds despite of the fact that there being no quality issue and product complied in all applicable USP tests. The targeted Victimization and unfair treatment by Punjab DTLS toward Parapol is further evidenced by an incident involving the Drug Testing Laboratory in Bahawalpur. On 09-03-2024, DTL Bahawalpur, initially declared Batch No. 178-24 and 179-24 of Parapol suspension as standard quality and uploaded the corresponding reports on their portal. However, these standard reports were subsequently removed due to external pressures, and substandard reports for the same batches were uploaded Several months later. This suspicious & doubtful act of DTL Bahawalpur emphasizes the need for an unbiased and fair analysis, which only NIH 1Slamabad, as an appellate laboratory, can provide for reassessment of the Samples. Furthermore, is also important to highlight that committee PQCB did not give satisfactory reasons and grounds on the basis of which honorable committee members of PQCB showed reliance and trust on the Sub-standard" reports by the government analyst while same batches were declared "standard" on 9-3- 2024 by DTL Bahawalpur.

3. It is very important to highlight and note that government analyst maliciously used reference of WHO working document (OAS/23.922/rev3 dated 31-10-2023) and deliberately misquoted and mislead by using this reference in report while it is a matter of fact that WHO working document does not provide any test to determine concentration of propylene glycol in the finished pharmaceutical product. During committee meeting, we strongly challenged this point and in our presence government analyst also admitted before the committee members that the method for determination of concentration of propylene glycol is not mentioned in WHO reference document rather method has been derived from it. Performing test on altered and non-reliable method and quoting reference of WHO working document is completely impermissible and hence makes report invalid. This act of analyst also raises serious concerns regarding the credibility and accuracy of the test protocol employed for determining the concentration of propylene glycol.

4. The government analyst has stated that the samples of Parapol suspension are "bitter in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

5. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited "USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. Samples of Parapol suspension were declared substandard based solely on personal observation (bitter taste) without conducting chemical analysis for accurate and instrument based identification of sweetener in the composition

6. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house / others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on ' In- house/other specifications' renders the report invalid and inaccurate

7. The government analyst has wrongfully claimed the products to be a "liquid" and free from any dispersed solid particles despite the same being a suspension. Government analyst has quoted reference of USP general chapters <l15|> for showing non-compliance. However, it is

important to highlight that USP general chapters <1151> on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to classify product as suspension, solution or syrup. Same has been confirmed in letters by NIH Islamabad dated 6-6-2024 and 29-8-2024 to POCB as below:

i) Letter dated 6" June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any Such test on the basis of which the samples are declared sub-standard by DTLs of Punjab"

ii) Letter dated 29" August 2024 "It is once again informed that USP monograph for Acetaminophen oral Suspension have different tests including test from the general chapters i.e. performance test (uniformity 905, deliverable? volume - 698, impurities 4- of dosage units 277). Aminophenol in Acetaminophen containing Drug Products Specific test (p 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any test on the basis of which the and The USP samples were declared substandard by DTLs Punjab General Chapter <I151> on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply".The foregoing infirmity makes the report invalid and baseless.

8. "It is pertinent to note that the esteemed Punjab Quality Control Board (PQCB) previously investigated the matter regarding the presence or absence of particles in Parapol suspension by constituting a special committee comprising five pharmaceutical experts, including two respected members from PQCB. The honorable members of this special committee conducted a thorough examination of the samples and reached conclusions in our favor, affirming our claim that Parapol qualifies as a 'suspension.' The committee's findings explicitly stated that Parapol is a 'biphasic liquid-like suspension' with a translucent appearance due to the presence of visible particles (a copy of the expert committee's findings is attached).

However, contrary to this initial finding, the same committee members, who were previously convinced of the presence of solid particles in Parapol suspension, subsequently disregarded these findings. They participated in the disputed decision "impugned order" that denied our request for retesting and upheld the remarks of the government analyst, who asserted that Parapol suspension is free from dispersed particles and does not comply with USP <1151>.

9. Government analyst has mentioned in form 7 S.No# 6 that "USP 2024 / In-House / Others" has been applied. However, it is pertinent to highlight that neither USP 2024 nor method of analysis (In-House) of Parapol suspension provided by the firm gives any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension / solution / syrup. Therefore, Product Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

10. Since Parapol suspension was being declared of standard quality by DTL Bahawalpur till 10-10-2023 this proves that till this date, as per analysts of DTL Bahawalpur, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Bahawalpur must have received a revised and new method of analysis from the firm after 10-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 10-10-2023 which proves malice intention and act of victimization by government analyst.

11. In continuation of Point no# 1, in which few flaws and inaccuracies in the impugned order made by the committee PQCB were highlighted, we would further like to add more infirmities in the order in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. It is to be noted that point of discussion regarding toxicity and side effects of higher concentrations of propylene glycol is inapplicable and inappropriate when government analyst categorically admitted in committee meetings that method applied to determine exact concentration of propylene glycol is not as per WHO reference document rather it has been derived from it. Firm's claim of addition of less than 1% propylene glycol has been completely overlooked in the impugned order and no scrutiny was carried out by the committee PQCB to verify firm's claim. Firm stated in every committee meeting before honorable board that ye are supplying same product with the same formulation across Pakistan for decades and millions of children have safely consumed this product to alleviate pain and fever without any reported clinical toxicity. Despite this, the PQCB committee exhibited an unfair approach by relying on the impugned results of the government analyst, who determined the concentration of propylene glycol using a non-reliable and non-pharmacopeial method.
b. On what basis and in what capacity did Mr. Ijaz Alvi, Director of DTL Rawalpindi, present his views regarding the toxicity of propylene glycol before the committee, given that the impugned reports pertain exclusively to DTL Multan? It is to be noted that Mr liaz Alvi is not part of committee PQCB and firm has no faith on him as he is part of malicious campaign against our product. This raises concerns about the

impartiality of the Process and suggests a coordinated effort by all DTLS of Punjab to unfairly target the product 'Parapol' without relying on legal facts and objective findings.

c. How and on what grounds committee members got convinced by views of Director, DTL Rawalpindi and Government Analyst, DTL Bahawalpur in which they were trying to establish a view that firm has solubilized paracetamol in propylene glycol without counter verifying it with firm's claim?. Firm has already provided list of excipients with quantities before the committee POCB in which it was mention that firm added propylene glycol less than 1% in the formulation of Parapol Suspension only with the purpose as stabilizer and as preservative. Firm's representative comprehensively explained that it is practically impossible to solubilize paracetamol in an amount of propylene glycol and water that has been used in the formulation of Parapol suspension. Nevertheless, the PQCB Committee chose to accept the unverified personal opinions of the individuals mentioned and issued a biased decision without validating the firm's assertions.

d. Question i.e testing of propylene glycol in finished product duly raised by the committee members is inaccurate, as firm is not bound to test excipients in finished form neither does tested by any DTL of Pakistan. Firm is always well aware of the fact that how much amount of any excipient is being added in formulation and as per GMP guidelines, all excipients are being consumed once passed initially from quality control department. Moreover, Specs claimed for Parapol suspension is USP and firm carries out all applicable test as per USP which specifically provide testing of API in a finished product only. Despite of the fact, committee POCB turned down our appeal for retesting to prevent us from the right of justice.

e. The quality of propylene glycol as a raw material, along with its associated standards, cannot be questioned or used as grounds for denying the request for re-testing. The impugned DTL reports themselves acknowledge compliance with the WHO reference document and confirm the absence of impurities such as EG and DEG, which demonstrates that the quality of the propylene glycol used was fully compliant and without any issues. Furthermore, under the latest DRAP guidelines, propylene glycol cannot be released for use unless tested by federal laboratories. The firm has consistently stated in all meetings that the propylene glycol used in the batches of Parapol suspension was tested and approved by the Central Drug Laboratory (CDL) in Karachi prior to its consumption. Additionally, we would like to highlight grounds comprehensively which have already been discussed in difference committee meeting that further supports our stance in said case:
1. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024: "It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 {Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976}" In this regard, committee POCB was duty bound to consider the foregoing while scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

2. The malafide intentions of the Government Analysts and Director DTL Bahawalpur are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 76 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

3. Since, product "\"Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe /instruct to conduct test for determination of the taste of the products or test to classify product as syrup solution or suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopeial testing.
4. It may be noted that drugs are manufactured using various excipients and active ingredients. The drug undergoes several procedures and protocols before it is converted into its finished form. USP does not provide any testing of the excipients individually in finished product rather the same prescribe the tests to determine only the quality (Assay & identification of API, final pH, etc.) of the "finished form" of the drug. In this context, the Products, like all other drugs, underwent a comprehensive manufacturing process wherein in addition to the active pharmaceutical ingredient; several other excipients were also added. Additionally, tests are prescribed in the specifications to ascertain the quality of a "finished form of drug". Thus, only tests that could have been performed by the government analyst were those prescribed in the USP and any additional information sought in relation to the excipients and or other ingredients or any testing carried out on the basis of the same is illegal and unlawful.

5. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the Samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the Substandard drugs". However, in our case, government analyst has shown her malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.
6. Section 3(z) of the the Drugs Act, 1976 defines the term specifications as.

(i) such specifications as may be prescribed;
(ii) or when the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely:-
(1) the Pakistan Pharmacopoeia;
(2) the International Pharmacopoeia;
(3) the European Pharmacopoeia;
(4) the United States Pharmacopoeia;
(5) the British Pharmacopoeia;
(6) the British Pharmaceutical Codex;
(7) the United States National Formulary; and

(8) such other publication as may be prescribed:

In terms of the legislative scheme envisioned under the Drugs Act, 1976, more particularly, Section 3(zz) a drug shall only be deemed as substandard if it does not comply with the applicable specifications. Essentially, such determination can only be made if the drug fails to comply with the tests "prescribed" under the applicable specifications. The monograph of a drug provided under the applicable specifications lists down the requisite tests that need to be conducted in order to determine whether the drug is of standard quality. It is a matter of fact that the Drugs Act does not permit analysts to carry out inapplicable tests or tests, which have not been listed down in the applicable specifications. However, in context of the present case, the Government Analysts have malafidely declared the batches of the Product as substandard on the basis of their bitter taste & absence of solid particles without there being any criteria or test to determine the same. The foregoing action clearly constitutes a violation of the Drugs Act, 1976 as well as Rule 16 of The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rule 1976.

In the light of above highlighted facts and infirmities, it can be concluded that committee PQCB has failed to scrutinize the case properly as it has overlooked above evidences and factual findings. The illegalities floating on the record of the case and as mentioned in above grounds have been completely overlooked and no heed has been paid to the wrongdoings of the government analyst who has declared the Products to be of substandard quality on a completely wrongful premise. t was mandatory upon this committee PQCB to properly scrutinize the subject especially in this case when samples comply with the stated specification chemically and physically and adjudicate upon the same. However, no such exercise has been carried out in the present case. Furthermore, it is to be noted that our firm petitioner Company" and its officials have not contravened the provisions of the Drug Laws and the rules made thereunder rather they are committed to ensure compliance thereof. PQCB passed an impugned order (turning down request for retesting) which completely disregard not just of the principles of fair trial and due process envisioned under Article 10-A and Article 4 of the Constitution but also disregard of the scheme of law envisioned under he Drugs Act, 1976 as-well as the fundamental rights of the Petitioner Company enshrined under the Constitution of Islamic Republic of Pakistan, 1973.

On the premise of foregoing submission and grounds highlighted above, it is mandatory and essential for the learned Board to review its decision. We reserves the right to agitate additional grounds at the time of arguments if needed. We as "Petitioners" are seeking the setting aside of the Impugned Decision in terms of clause 2 of Part VIII of the PQCB Regulations and pray as below:

PRAYER
In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:
i. Set aside the Impugned Order in which committee PQCB turned down appeal for re-testing and directed Provincial Inspectors of Drugs, to expedite investigation submission of final report.

ii. Pass an order for the samples of above mentioned Suspension Parapol Batches to be sent to the National Institute of Health, Islamabad and allow retesting of samples for the conclusive report.

iii. Direct the government analyst of the Drug Testing Laboratory, Bahawalpur and Multan to bring the method and protocols of the test

employed to determine the taste of the Suspension and test to determine presence or absence of particles in suspension.
iv. Share transparent findings, causes and measures against the incident in which DTL Bahawalpur issued standard report for Batch No. 178-24 and Batch No. 179-24 and reports were removed later on and sub-standard reports were issued for same batches.
v. Permanently restrain the Provincial Inspectors of Drugs from taking any adverse and/or coercive action against our firm "Petitioner Company" and against our officials based on the Impugned order / decision.

We hope that learned board will allow us to avail right of fair trial and accept above.

14. `Personal hearing notice issued to accused person(s)

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

15. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **287th Meeting held on 08.01.2025** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Chairperson PQCB). Mr. Hassan Saeed, Secretary DQCB, Lahore and Mr. Ubaid Ullah Anwar, Drug Inspector, Government Medical Store Deport, Lahore attended the meeting along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeil test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary individual to individual basis and there will be no toxicity or adverse effects due to bitter taste
ii. We are confident that our product is suspension and complies all applicable test of USP monograph "acetaminophen oral suspension".
iii. As far as declaring our samples substandard declaring them to be "free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iv. He further added that although the DTL has quantified Propylene Glycol in the test report but failed to mention the limit and to specify whether it complies or not with any official monograph.
v. He further reiterated firm's request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting.

16. The Board after careful perusal of the case record and scrutiny of DTL report observed that various batches of the subject drug sample of **Parapol Suspension (Each 5ml contains: Paracetamol USP…120mg)**, have been declared substandard by the Drugs Testing Laboratory, Bahawalpur on the basis of physical description as "Parapol is a pinkish red, **bitter** viscous liquid and free from any **dispersed solid particles**" further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 14-06-2024 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was turn down in 43rd Committee meeting of the Board held on 29-08-2024. Regarding firm's review petition against retesting orders and the plea to send their subject batches to NIH for retesting, the Board observed that in 279th meeting held on 24-04-2024, the Board sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976. Hence, the Board unanimously decided to **Turn Down** the subject review petition and **upheld the previous decision** as taken in its **43rd Committee meeting** held on **29-08-2024** as the firm did not provide any satisfactory argument in their review petition to the question regarding the physical characteristics,

bitter taste and quantification of polyethylene glycol of the subject samples.

17. Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

18. While perusing the case record, the Board remarked that the samples in question were declared substandard on the basis of physical description as per General Chapter <1151> of the USP and bitter taste of suspension by the Government Analyst DTL Bahawalpur. The firm claims the product as “Suspension” on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Bahawalpur. Furthermore, regarding bitter taste of the suspension, the Board was of the view that the product has been developed for pediatrics use and bitter taste of suspension as reported by the DTL in the subject reports, will result in non-compliance and reluctance to take medication by children.

19. The Board further observed that the DTL also determined the variable percentage of Propylene Glycol in the batches under consideration by applying WHO Working Document QAS/23.922/rev3 Dated 31 October 2023.

Acceptable Dietary Intake of Propylene Glycol				
EMA		**50mg/kg/day**		
WHO		**25mg/kg/day**		
Batch No.	**PG Determined (as per DTL Report)**	**PG Content mg/kg/day (Calculated as per EMA Guidelines, keeping in view firm's own label recommended dose for a child weighing 10kg, 15kg & 18kg respectively)**		
		PG (mg/kg/day) (30mL Dose)	**PG (mg/kg/day) (60mL Dose)**	**PG (mg/kg/day) (120mL Dose)**
080-24	10.77%	334.73	446.31	743.85
083-24	10.20%	317.02	422.69	704.48
086-24	11.40%	354.31	472.42	787.36
089-24	11.21%	348.41	464.54	774.24
082-24	11.06%	343.74	458.33	763.88

081-24	10.89%	338.46	451.28	752.14
085-24	11.80%	366.74	488.99	814.99
084-24	10.65%	331.00	441.34	735.56
072-24	11.93%	370.78	494.38	823.97
077-24	10.35%	321.68	428.90	714.84
088-24	11.93%	370.78	494.38	823.97
078-24	10.37%	322.30	429.73	716.22
066-24	10.75%	334.11	445.48	742.47
087-24	10.40%	323.23	430.98	718.29
090-24	11.24%	349.34	465.79	776.31
079-24	10.64%	330.69	440.92	734.87

20. The Board further observed that as per guidelines of European Medicine Agency published vide No. EMA/CHMP/704195/2013 dated 09.10.2017, propylene glycol is estimated to be one-third as intoxicating as ethanol, with administration of large volumes being associated with adverse effects most commonly on the central nervous system, especially in neonates and children. Other adverse reactions reported through generally isolated, include: ototoxicity, cardiovascular effects; seizures; and hyperosmolarity and lactic acidosis, both of which occur most frequently in patients with renal impairment. Adverse effects are more likely to occur following consumption of large quantities of propylene glycol or on administration to neonates, children under 4 years of age, pregnant women, and patients with hepatic or renal failure. Adverse events may also occur in patients treated with disulfiram or metronidazole. Keeping in view all aspects of case, the Board after due deliberation and detailed discussion, unanimously decided to **pend the case**.

Personal hearing notice issued to accused person(s)

Sr.	**Summary of the case**	
1.	**Date of sampling**	25-05-2024
2.	**Sent to DTL**	25-05-2024
3.	**Date of receipt in DTL**	27-05-2024
4.	**Issuance of DTL Report**	15-07-2024

5.	**Time Extension**	N/A
6.	**1st DI Communication with firm**	**03-08-2024**
7.	**Retesting Request**	Yes.
8.	**Fate of retesting request**	Turn-Down 43rd Committee meeting dated 29-08-2024
9.	**Investigation Report of DI**	06-08-2024
10.	**Permission of SCN**	285th meeting dated 26-09-2024
11.	**SC/ PH Notice Issued**	22-10-2024
12.	**Reply of the firm**	No
13	**History (3 years)**	111 cases of the firm 87 cases of the product

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 7

PQCB/MSS-194251/2024

DHQ Hospital Mandi Bahauddin

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi** through its Managing Director/ Chief Executive Officer M. Muzammil Nazar 2. M. Muzammil Nazar — Managing Director/ Chief Executive Officer 3. Ghulam Nabi Khoso — Production Incharge 4. Naima Khanam — Quality Control Manager/ Warrantor Of **M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs, DHQ Hospital Mandi Bahauddin reported that: -

i. He, on 07-03-2024, inspected Main Medicine DHQ Hospital Mandi Bahauddin, took sample of six different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum No. 0000194251 dated 08-03-2024.

ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Suspension Parapol 120ml (Paracetamol 120 mg/5ml)	048-24	M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi	TRA 01-68029101/DTL dated 08-05-2024 by DTL-Faisalabad

Specification applied: USP 2024/Others/In-House

DESCRIPTION: Pinkish red viscous liquid having bitter taste, contained in amber colored plastic bottle with sealed plastic screw cap, packed in outer hard carton.
NOTE: Manufacturer specifies, "Pinkish Red Sweet Suspension" in its method of analysis but given sample is "Pinkish red bitter liquid" that does not comply the physical characteristics. (Does not Comply)

IDENTIFICATION Paracetamol is identified

ASSAY (By HPLC)

Stated: 120 mg / 5ml Determined: 125.8788 mg /5ml Percentage: 104.899 % (Complies) Limit: 90 - 110% of the labeled amount of acetaminophen.

pH: Stated: 4.0 - 6.9 Determined: 5.33 at 24.0 °C (Complies)

DELIVERABLE VOLUME

Stated: The average volume of liquid obtained from the 10 containers is NLT 100%, and the volume of no container is less than 95% of the volume declared in the labeling.

Determined: 123.6 ml (Average volume of 10 containers) (Complies)

TEST FOR DIETHYLENE GLYCOL AND ETHYLENE GLYCOL IN ORAL LIQUIDS

By Gas Chromatography:

Test	Acceptance criteria (m/m)	Result	Remarks	Reference
Ethylene Glycol	NMT 0.10 %	Not detected	Complies	WHO Working document QAS/23.922/rev3 31 October 2023
Diethylene Glycol	NMT 0.10 %	0.00019 %	Complies	WHO Working document QAS/23.922/rev3 31 October 2023

RESULT: **Given sample is Sub-Standard with regards to physical characteristics.**

iii. Store Keeper Main Medicine DHQ Hospital Mandi Bahauddin provided invoice/DC/warranty bearing No. 000152 dated 06-09-2023 issued by M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi as a proof of its purchase of the said drug.

iv. Warrantor Portion and a copy of test report of the drug sample was sent to M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi and they were asked to provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

Previous Proceedings & Descion by The Committee

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **41st meeting** held on **27-06-2024** under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, and Punjab. Mr. M. Akhtar Manager of M/S Lisko Pakistan (Pvt) Ltd., appeared before the Committee to plead the case. The Secretary PQCB apprised the committee that Manufacturer requested for retesting vide letter No. Nil dated 14-05-2024.

3. The office of the Provincial Quality Control Board asked to appear for personal hearing along with evidence in controversion of Govt. Analyst Test Report vide letter No PQCB-MSS-194251/24 dated 20-06-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard) but firm did not provide evidence.

4. The Committee observed that Firm has not submitted Evidence or any relevant data so, it is very difficult to establish the validity of the adopted testing methods / protocols. The Committee further observed that the subject drug sample was declared Sub-standard with regards to **physical characteristics.** Facts provided by the Government Analyst clearly indicate that the given sample is **"Pinkish red bitter liquid"** that does not comply the physical characteristics as Manufacturer specifies**, "Pinkish Red Sweet Suspension"** in its method of analysis given with DTL Faisalabad.

5. The Committee further scrutinized the all the relevant data submitted by the Government Analyst regarding the test /analysis and observed that Government Analyst has fulfilled all requirements of the test protocol as described in the USP. The test was performed using calibrated instruments. Moreover, after revamping the Drug Testing Laboratories of the Punjab are testing the drug samples according to the International Standard of the test / analysis and all these laboratories are ISO 17025:2017 Certified and WHO prequalified. Considering the above facts in view, the Committee after due deliberation unanimously decided to **Turn Down** the subject request for retesting of the sample as these is no ground for retesting of the subject sample. The Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

2. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976/ DRAP Act 2012 and Rules framed there under by the way of :-
    i. **Manufacture for sale/ Sale of Substandard drug**
    ii. **Issuance of false warranty**
3. Show cause notice(s) issued to accused person(s) on 27-09-2024.

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi submitted written reply in response to show-cause/ personal hearing notice vide letter dated 30-10-2024 as mentioned below:

We would like to submit our reply against show cause / personal hearing notice dated 22-10-2024 in which we have been asked to appear before honorable PQCB on 30-10-2024 for below mentioned cases against which our firm submitted appeal for re-testing from NIII, Islamabad. Subsequently, committee PQCB meeting was held on dated 27-6-2024 in which we presented our stance comprehensively and highlighted several grave infirmities and ambiguities in DTL reports. Despite this, impugned decision was taken in which committee PQCB turned down our appeal for retesting on inaccurate and invalid grounds and failed to conduct fair trail & scrutiny of records on merit. Details of the batches are as below:

B.no	DTL report	DTL report date
048-24	01-68029101	8-5-2024

We again like to highlight below mentioned facts and ambiguities through our reply of show cause / personal hearing notice and request honorable PQCB to review decision of committee PQCB and send samples of above batches of Parapol suspension to NIH, Islamabad (Appellate lab) for the conclusive report:

B= POINTS OF DEFENSE & CONTRAVENTION AGAINST REMARKS "BITTER TASTE" BY GOVERNMENT ANALYST

Al. The government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

A2. Government analyst has mentioned in form 7 "S.No# 6" that he/she has applied specs USP 2024. However, it is pertinent to highlight that USP 2024 does not provide any test to determine sweetness/bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension/solution/syrup. Therefore, Product "Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

A3. As per point no# 6 (Form 7) of all substandard reports by DTL Faisalabad, USP specs were applied for complete testing which is contrary to the statement of government analyst in which manufacturer's method of analysis was taken into consideration for conclusion of results.

A4. Government analyst has fraudulently declared samples substandard on the basis of physical characteristics using reference of In-House specs as our firm vide letter dated 03-11-2021 (copy attached) categorically informed in advance to the government analyst of DTL Faisalabad that the applicable specifications are USP and hence the only tests that could be performed on the Products were those prescribed in the applicable specifications. Therefore, the statement of the government analyst vis-a-vis the manufacturer claim of the Products being "sweet" is factually incorrect and the reliance, if any, placed on any previous in-house specs, is invalid and incorrect.

A5. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:

"It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 (Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976)"

In this regard, committee PQCB was duty bound to consider the foregoing fact whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

A6. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house/others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on 'In-house/other specifications' renders the report invalid and inaccurate.

A7. Since Parapol suspension was being declared of standard quality by DTL Faisalabad till 06- 10-2023 this proves that till this date, as per analysts of DTL Faisalabad, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Faisalabad must have received a revised and new method of analysis from the firm after 06-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 06-10-2023 which proves malice intention and act of victimization by government analyst.

A8. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited 'USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard & testing method for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. No such request or chemical analysis was made, and the product was instead declared substandard based solely on personal observation (bitter taste) without conducting or verifying any formal test.

A9. The malafide intentions of the Government Analysts and Director DTL. Faisalabad are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL. Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL. Bahawalpur contributing 62 of those reports. A comparison between the hatches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

A10. Since, product "Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe/ instruct to conduct test for determination of the taste of the products, test to check dispersed particles in a suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopeial testing.

A11. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the substandard drugs. However, in our case, government analyst has shown her/his malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

C= POINTS OF DEFENSE AGAINST REMARKS OF GOVERNMENT ANALYST "LIQUID" WHILE FIRM CLAIM IS "SUSPENSION"

The government analyst has wrongfully claimed the Products to be a "liquid" despite the same being a suspension. It is pertinent to highlight that PQCB has already investigated this case and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst holding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to of presence of particles (copy of findings of expert committee attached).

It is also important to highlight that USP on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to determine product is suspension, solution or syrup. Same has been confirmed in letters by NIH, Islamabad dated 6-6-2024 and 29-8-2024 as below:

i. *Letter dated 6 June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any such test on the basis of which the samples are declared sub-standard by DTLs of Punjab*
ii. *Letter dated 29 August 2024 "It is once again informed that USP monograph for Acetaminophen oral suspension have different tests including test from the general chapters Le performance text (uniformity of dosage units-905, deliverable volume- 698, impurities (4-Aminophenol in Acetaminophen containing Drug Products-277), specific text (pH 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any text on the basis of which the samples were declared substandard by DTLs Punjab and "The USP General Chapter <1151 on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply.*

Furthermore, point no# A2, A4, A5, A6, A7, A9, A10 and All also supports our stance and provides strong defense and contravention against conclusion of

government analyst "absence of dispersed solid particles". The foregoing infirmity makes the report invalid and baseless.

POINTS OF DEFENSE & CONTRAVENTIONS IN DISCUSSIONS OF COMMITTEE POCB IN WHICH REQUEST FOR RETESTING HAS BEEN TURNED DOWN

We would like to highlight following numerous flaws and inaccuracies in the impugned order made by the committee PQCB in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. The statement that the firm failed to submit evidence or relevant data is inaccurate. The firm has, in fact, provided evidence during multiple committees and PQCB meetings, confirming the addition of the sweetener 'Neotame' in the composition of Parapol suspension for taste masking purpose. Neotame, which is 7,000 το 13,000 times sweeter than sucrose with a similar taste profile is widely use sweetener in pharmaceutical and food products. The firm also presented import documentation for Neotame in different committee meeting. If required, the firm is ready to resubmit the import records and the composition of Parapol suspension. Despite this, the firm's stance and claim regarding the inclusion & presence of the sweetener has been disregarded by the committee members. This failure to consider firm's stance not only undermined our right to justice but also demonstrated violation of the principles of a "fair trial and due process'.

b. The statement made by the committee member, i.e, 'the test was performed using calibrated instruments,' is itself indicative of a bogus, fictitious, and fabricated activity. It is illogical to assert that the calibration of instruments could be validated when the sample in question is substandard on physical grounds which makes no relevance to the use of any instruments. This further demonstrates that no investigation into the firm's appeal was conducted in accordance with the principles of a fair trial and due process and that there was a failure to fulfill the duties as mandated by the Drug Act of 1976.

c. The conclusion drawn by the committee member, stating that 'the government analyst has fulfilled all test protocol requirements as outlined in the USP' and 'testing according to international standards' is indicative of a flawed, fictitious, and baseless investigation. The USP contains no protocol for determining the taste (sweetness/bitterness) of a product, nor does it provide a method for classifying a product as a suspension, liquid, solution, or syrup. This further underscores that the firm's appeal was not investigated in accordance with the principles of a 'fair trial and due process and that there was a failure to uphold the duties prescribed under the Drug Act of 1976.

d. Firm's claim & appeal regarding presence of sweetener or sweetness of suspension could only be verified if the samples will be sent to NIH, Islamabad for the conclusive report however same has not been done as per the impugned order by the committee PQCB.

e. Firm's claim & appeal regarding Parapol being "suspension" against government analyst claim "Liquid" could only be verified if the samples will be sent to NIH, Islamabad for re-testing so as to get conclusive report. PQCB has already sent 42 cases of Parapol suspension to NIH, Islamabad for the conclusive result while samples were initially declared substandard on similar grounds i.e. government analyst claimed that sample is not being suspension. However, in this case, committee PQCB turned down appeal for re-testing and issued contradictory decision "impugned order".

In the light of above highlighted infirmities and weakness, we request honorable PQCB to send mentioned batch of Parapol suspension to NIH, Islamabad for the conclusive report and give us fair chance of reevaluation from the appellate lab. We request honorable PQCB and concerned drug inspector to not initiate prosecution against us as we have not contravened provisions of Drug act 1976.

4. Personal hearing notice(s) issued to accused person(s) dated 22-10-2024.

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **286th meeting** held on **30-10-2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab /Vice-Chairperson PQCB. Ms. Uzma Mazhar Secretary DQCB Mandi Bahauddin attended the meeting online via zoom link. No one among the nominated accused persons of M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi was present. However, Dr. Sarfaraz (Manager) appeared before the Board on behalf of the firm and reiterated the arguments as mentioned above in reply to show-cause/ personal hearing notice and emphasized to send the sample to Appellate Laboratory for retest/ analysis. He pleaded his case on following grounds:

i. He submitted that government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs.
ii. Government analyst also stated that "samples is free from any dispersed solid particles" and declared samples substandard using

reference USP <1151> It is pertinent to highlight that PQCB has already investigated this case and constituted a special committee of pharmaceutical experts which concluded its findings in our favour whilst holding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.

iii. He requested to send their sample for retest/ analysis.

6. The Board after careful perusal of the case record observed that subject drug sample has been declared substandard from Drug Testing Laboratory, Faisalabad on the basis that Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, whereas, the firm in its method of analysis claims that it is pinkish red sweet homogeneous suspension. Keeping in view the facts of the case, the Board after due deliberation and discussion decided to issue **Pend the case.**

GROUNDS OF REVIEW PETITION

SUBJECT: REVIEW PETITION UNDER CLAUSE VIII O THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

The firm submitted review petition vide letter no. Nil Dated Nil Received in PQCB via diary no. 69866 dated 19-12-2024.

Grounds:

We. M/S Lisko Pakistan (Pvt) Ltd "Petitioner Company" would like to submit instant review petition before the learned Provincial Quality Control Board, Punjab against the order of committee PQCB dated 27-6-2024 (the "Impugned Decision") in which request of re-testing from NIH, Islamabad has been turned down (orders attached) for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspector of Drugs, District Mandi Bahauddin (the "Respondent Drug Inspector") has been directed to expedite investigation and submit final report before the learned board so that permission for prosecution can be granted.

There are several grave infirmities and ambiguities in DTL reports "Impugned reports" issued by government analyst of DTL Bahawalpur and also in decision "Impugned Order" by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, it is pertinent to highlight the fresh grounds that have arisen to the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. We would like to highlight following numerous flaws and inaccuracies in the impugned order made by the committee PQCB in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. The statement that the firm failed to submit evidence or relevant data is inaccurate The firm has, in fact, provided evidence during multiple committee and PQCB meetings, confirming the addition of the sweetener 'Neotane' in the composition of Parapol suspension for taste masking purpose. Neotane, which is 7000 to 13,000 times sweeter than sucrose with a similar taste profile is widely use sweetener in pharmaceutical and food products. The firm also presented import documentation for Neotane in different committee meeting. If required, the firm is reads to resubmit the import records and the composition of Parapol suspension Despite the firm's stance and claim regarding the inclusion & presence of the sweetener has been disregarded by the committee members. This failure to consider firm's stance not only undermined our right to justice but also demonstrated violation of the principles of a fair trial and due process.

b. The statement made by the committee member i.e the test was performed using calibrated instruments, is itself indicative of a bogus, fictitious, and fabricated activity. It is illogical to assert that the calibration of instruments could be validated when the sample in question is substandard on physical grounds which makes no relevance to the use of any instruments. This further demonstrates that no investigation into the firm's appeal was conducted in accordance with the principles of a fair trial and due process and that there was a failure to fulfill the duties as mandated by the Drug Act of 1976.

c. The conclusion drawn by the committee member, stating that 'the government analyst has fulfilled all test protocol requirements as outlined in the USP" and testing according to international standards' is indicative of a flawed, fictitious, and baseless investigation. The USP contains no protocol for determining the taste (sweetness/bitterness) of a product, nor does it provide a method for classifying a product as a suspension, liquid solution, or syrup. The further underscores that the firm's appeal was not investigated in accordance with the principles of a fair trial and due process and that there was a failure to uphold the duties prescribed under the Drug Act of 1976.

d. Firm's claim & appeal regarding presence of sweetener or sweetness of suspension could only be verified if the samples will be sent to NIII. Islamabad for the conclusive report however same has not been done as per the impugned order by the committee POCB.

e. Firm's claim & appeal regarding Parapol being "suspension" against government analyst claim "Liquid" could only be verified if the samples will be went to NIIL, Islamabad for re-testing so as to get conclusive report POD has already sent 42 cases of Parapol suspension to NIH Islamabad for the conclusive result while samples were initially declared substandard on similar rounds government analyst claimed that sample is not being suspension conclusive result while samples were initially declared substandard on similar grounds Le government analyst claimed that sample is not being suspension. However, in this case, committee PQCB turned down appeal for re-testing and issued contradictory decision "impugned order"

2. As per point no 6 (Form 7) of all substandard reports by DTL Faisalabad, USP specs were applied for complete testing which is contrary to the statement of government analyst in which manufacturer's method of analysis was taken into consideration for conclusion of results.

3. The government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitt bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committer PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly targets and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

4. The government analyst has wrongfully claimed the Products to be a "liquid" despite the same being a suspension. It is pertinent to highlight that PQCB already investigated this case and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst holding that Parapol is a "Biphasic liquid like suspension having translucent appearance due to of presence of particles (copy of findings of expert committer attached).

It is also important to highlight that USP on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to determine product is suspension, solution of syrup. Name has been confirmed in letters by Fill, Islamabad dated 6-6-2024 and 29-8-2024 as below.

Latter dated 6 June 2014 Its pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any such test on the basis of which the samples are declared Substandard by DILs et Punjab.

Latter dated 27 August 2024 It is once again informed that USP monograph for Acetaminophen oral suspension have different texts, including test from the general chapter is performance test conformity of dosage units 903, deliverable volume 698, impurities (4 Aminophenol in Acetaminophen containing Deng Products 2770 specific test tell (91) etc. These different tests from the General chapters.

5. Government analyst has mentioned in form 7 "S. No # 6" that he / she has applied Spec. USP 2024. However, it is pertinent to highlight that USP 2024 does not provide any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension / solution/ syrup. Therefore, Product "Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

6. Government analyst has fraudulently declared samples substandard on the basis of physical characteristics using reference of In-House specs as our firm vide letter dated 03-11-2023 (copy attached) categorically informed in advance to the government analyst of DTL Faisalabad that the applicable specifications are USP and hence the only tests that could be performed on the Products were those prescribed in the applicable specifications. Therefore, the statement of the government analyst vis-à-vis the manufacturer claim of the Products being "sweet" is factually incorrect and the reliance, if any placed on any previous in-house specs, is invalid and incorrect.

7. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:

"It is inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 (Rule 16 of Drugs (Faders! Drug inspectors, Federal Drug Laboratories. Federal Government analyst) Rules, 1976)"

In this regard, committee PQCB was duty bound to consider the foregoing fact whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

8. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house/others

specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on In house/other specifications' renders the report invalid and inaccurate.

9. Since Parapol suspension was being declared of standard quality by DTL Faisalabad till 06-10-2023 this proves that till this date, as per analysts of DTL Faisalabad, our product complied USP specs and last available In-House specs submitted by the firm. So, Definitely. DTL Faisalabad must have received a revised and new method of analysis from the firm after 06-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 06-10-2023 which proves malice intention and act of victimization by government analyst.

10. Although the firm has not made any claim regarding the term 'sweet on the packaging material of Parapol suspension and has only cited 'USP specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard & testing method for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for 1 awing conclusions. No such request or chemical analysis was made, and the product was instead declared substandard based solely on personal observation (bitter taste) without conducting or verifying any formal test.

Additionally, we would like to highlight grounds comprehensively which have already been discussed in difference committee meeting that further supports our stance in said case:

1. The malafide intentions of the Government Analysts and Director DTL Faisalabad are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 62 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

2. Since, product "Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe/ instruct to conduct test for determination of the taste of the products, test to check dispersed particles in a suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopical testing.

3. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the substandard drugs" However, in our case, government analyst has shown her/his malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

PRAYER:

In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:

i. Set aside the Impugned Decision (Dated 27-6-2024) in which request for re-testing has been turned down.

ii. Pass an order for the samples of suspension Parapol Batch No. 048-24 to be sent to the National Institute of Health, Islamabad for conclusive report on physical characteristic.

iii. Direct the government analyst of the Drug Testing Laboratory, Faisalabad to bring the method and protocols of the test employed to determine the taste along with the protocol to declare sample "Liquid" on record.

iv. Permanently restrain the Provincial Inspector of Drugs, District Mandi Bahauddin from taking any adverse and/or coercive action against our firm "Petitioner Company" and its officials along with final report based on the Impugned Decision. We hope that learned board will give us chance of fair trial and accept our review petition.

7. Personal hearing notice(s) issued to accused person(s) dated 02-01-2025.

PERVIOUS PROCEEDINGS & DECISION BY THE BOARD:

8. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, vice-chairperson PQCB. Ms. Uzma Mazhar Secretary DQCB Mandi Bahauddin attended the meeting online via zoom link. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeil test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary individual to individual basis and there will be no toxicity or adverse effects due to bitter taste
ii. We are confident that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension”.
iii. As far as declaring our samples substandard declaring them to be “free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iv. He further reiterated firm’s request to send the subject drug sample to Appellate Laboratory, National Institute of Health Islamabad for retesting.

9. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample of Parapol Suspension (Each 5ml contains: Paracetamol USP…120mg), Batch No. 048-24, has been declared substandard by the Drugs Testing Laboratory, Faisalabad on the basis of physical characeristics i.e., Pinkish red viscous liquid having bitter taste, whereas, manufacturer specifies, “Pinkish Red Sweet Suspension” in its method of analysis. The Board also observed that the firm’s retesting request was also turned down in 41st committee meeting dated 27-06-2024. This is also in context to mention that Board in its 279th meeting dated 24-04-2024 sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976. Hence, the Board unanimously decided to **Turn Down** the subject review petition regarding retesting request and **upheld the previous decision** as taken in its **41st Committee meeting** held on **27-06-2024** as the firm did not provide any satisfactory argument in their review petition to the question regarding the physical characteristics and bitter taste of the subject sample.

10. Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

11. Keeping in view the case record and correspondence between NIH & PQCB, the Board remarked that the sample in question was declared substandard by DTL Faisalabad on the basis of physical description of suspension as per General Chapter <1151> of the USP and upon bitter taste as well. The firm

claims the product as “Suspension” on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Faisalabad. The Board was certain/ convinced that it is the legal binding of the Appellate Laboratory to issue the test/ analysis reports as conclusive evidence in the light of clarification/ justification already submitted by the DRAP vide letter no. 13-22/2024-QC dated 15-11-2024, email by the USP and replies of PQCB dated 21-08-2024 & 20-09-2024.

12. The Board disagreed with the point of view of Chief, DC & TMD, NIH Islamabad as conveyed to PQCB vide letter no. F.No.1-20/17-Misc/2021-DC&TMD dated 04-12-2024 recommending the PQCB to *“consider withdrawing the retesting request for all samples based on physical description”* as there is no such provision in the prevailing Drugs Act and Rules which encourages withdrawal of samples/ retesting request sent to Appellate Laboratory. Hence, taking into account all aspects of the subject cases and arguments pleaded by the firm’s representatives, the Board was of the unanimous opinion that the Appellate Laboratory (NIH) should furnish the test report in the form of certificate of analysis on its prescribed Form-6 under sub-section (1) of Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976 as the Drugs Control & Traditional Medicines Division (DC&TMD), National Institute of Health (NIH) serves as a laboratory specified by the Federal Government vide notification No. F.2-12/76-QCA dated, the 10th September, 1976 & SRO No. 542 (1)/92 dated 19th May, 1992 for the purpose of sub-section (5) of section 22 of the Drugs Act, 1976. The Board after due deliberation and detailed discussion, unanimously decided to **pend the case.**

Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

Summary of the case:

- **Mfg. date: 07-2023**
- **Exp. Date: 07-2025**
- **Sampling date (Form 4): 07-03-2024**
- **Sent to DTL (Form 6): 08-03-2024**
- **Date of receipt in DTL: 11-03-2024**
- **DTL Report Date (Form 7): 08-05-2024**
- **DI 1st intimation to firm: 14-05-2024**
- **Retesting request if any: 14-05-2024**
- **Fate of Retesting: Turned Down in 41st Committee meeting dated 27-06-2024**
- **Investigation report Dated: 22-08-2024**
- **Permission of SCN: 285th meeting dated 26-09-2024**
- **SCN Issued: 27-09-2024**
- **Reply of the firm: Yes dated 30-10-2024**
- **History (2021 onwards): Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

DHQ Hospital Mandi Bahauddin

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi** through its Managing Director/ Chief Executive Officer M. Muzammil Nazar 2. M. Muzammil Nazar — Managing Director/ Chief Executive Officer 3. Ghulam Nabi Khoso — Production Incharge 4. Naima Khanam — Quality Control Manager/ Warrantor Of **M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs, DHQ Hospital Mandi Bahauddin reported that: -

i. He, on 07-03-2024, inspected Main Medicine DHQ Hospital Mandi Bahauddin, took sample of six different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum No. 0000194251 dated 08-03-2024.

ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Suspension Parapol 120ml (Paracetamol 120 mg/5ml)	048-24	M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi	TRA 01-68029101/DTL dated 08-05-2024 by DTL-Faisalabad

Specification applied: USP 2024/Others/In-House

DESCRIPTION: Pinkish red viscous liquid having bitter taste, contained in amber colored plastic bottle with sealed plastic screw cap, packed in outer hard carton.
NOTE: Manufacturer specifies, "Pinkish Red Sweet Suspension" in its method of analysis but given sample is "Pinkish red bitter liquid" that does not comply the physical characteristics. (Does not Comply)

IDENTIFICATION Paracetamol is identified

ASSAY (By HPLC)

Stated: 120 mg / 5ml Determined: 125.8788 mg /5ml Percentage: 104.899 % (Complies) Limit: 90 - 110% of the labeled amount of acetaminophen.

pH: Stated: 4.0 - 6.9 Determined: 5.33 at 24.0 °C (Complies)

DELIVERABLE VOLUME

Stated: The average volume of liquid obtained from the 10 containers is NLT 100%, and the volume of no container is less than 95% of the volume declared in the labeling.

Determined: 123.6 ml (Average volume of 10 containers) (Complies)

TEST FOR DIETHYLENE GLYCOL AND ETHYLENE GLYCOL IN ORAL LIQUIDS

By Gas Chromatography:

Test	Acceptance criteria (m/m)	Result	Remarks	Reference
Ethylene Glycol	NMT 0.10 %	Not detected	Complies	WHO Working document QAS/23.922/rev3 31 October 2023
Diethylene Glycol	NMT 0.10 %	0.00019 %	Complies	WHO Working document QAS/23.922/rev3 31 October 2023

RESULT: **Given sample is Sub-Standard with regards to physical characteristics.**

iii. Store Keeper Main Medicine DHQ Hospital Mandi Bahauddin provided invoice/DC/warranty bearing No. 000152 dated 06-09-2023 issued by M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi as a proof of its purchase of the said drug.

iv. Warrantor Portion and a copy of test report of the drug sample was sent to M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi and they were asked to provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

Previous Proceedings & Descion by The Committee

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **41st meeting** held on **27-06-2024** under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, and Punjab. Mr. M. Akhtar Manager of M/S Lisko Pakistan (Pvt) Ltd., appeared before the Committee to plead the case. The Secretary PQCB apprised the committee that Manufacturer requested for retesting vide letter No. Nil dated 14-05-2024.

3. The office of the Provincial Quality Control Board asked to appear for personal hearing along with evidence in controversion of Govt. Analyst Test Report vide letter No PQCB-MSS-194251/24 dated 20-06-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard) but firm did not provide evidence.

4. The Committee observed that Firm has not submitted Evidence or any relevant data so, it is very difficult to establish the validity of the adopted testing methods / protocols. The Committee further observed that the subject drug sample was declared Sub-standard with regards to **physical characteristics.** Facts provided by the Government Analyst clearly indicate that the given sample is **"Pinkish red bitter liquid"** that does not comply the physical characteristics as Manufacturer specifies**, "Pinkish Red Sweet Suspension"** in its method of analysis given with DTL Faisalabad.

5. The Committee further scrutinized the all the relevant data submitted by the Government Analyst regarding the test /analysis and observed that Government Analyst has fulfilled all requirements of the test protocol as described in the USP. The test was performed using calibrated instruments. Moreover, after revamping the Drug Testing Laboratories of the Punjab are testing the drug samples according to the International Standard of the test / analysis and all these laboratories are ISO 17025:2017 Certified and WHO prequalified. Considering the above facts in view, the Committee after due deliberation unanimously decided to **Turn Down** the subject request for retesting of the sample as these is no ground for retesting of the subject sample. The Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

2. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976/ DRAP Act 2012 and Rules framed there under by the way of :-

i. **Manufacture for sale/ Sale of Substandard drug**

ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) on 27-09-2024.

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi submitted written reply in response to show-cause/ personal hearing notice vide letter dated 30-10-2024 as mentioned below:

We would like to submit our reply against show cause / personal hearing notice dated 22-10-2024 in which we have been asked to appear before honorable PQCB on 30-10-2024 for below mentioned cases against which our firm submitted appeal for re-testing from NIII, Islamabad. Subsequently, committee PQCB meeting was held on dated 27-6-2024 in which we presented our stance comprehensively and highlighted several grave infirmities and ambiguities in DTL reports. Despite this, impugned decision was taken in which committee PQCB turned down our appeal for retesting on inaccurate and invalid grounds and failed to conduct fair trail & scrutiny of records on merit. Details of the batches are as below:

B.no	DTL report	DTL report date
048-24	01-68029101	8-5-2024

We again like to highlight below mentioned facts and ambiguities through our reply of show cause / personal hearing notice and request honorable PQCB to review decision of committee PQCB and send samples of above batches of Parapol suspension to NIH, Islamabad (Appellate lab) for the conclusive report:

B= POINTS OF DEFENSE & CONTRAVENTION AGAINST REMARKS "BITTER TASTE" BY GOVERNMENT ANALYST

Al. The government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committee PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly target and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

A2. Government analyst has mentioned in form 7 "S.No# 6" that he/she has applied specs USP 2024. However, it is pertinent to highlight that USP 2024 does not provide any test to determine sweetness/bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension/solution/syrup. Therefore, Product "Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

A3. As per point no# 6 (Form 7) of all substandard reports by DTL Faisalabad, USP specs were applied for complete testing which is contrary to the statement of government analyst in which manufacturer's method of analysis was taken into consideration for conclusion of results.

A4. Government analyst has fraudulently declared samples substandard on the basis of physical characteristics using reference of In-House specs as our firm vide letter dated 03-11-2021 (copy attached) categorically informed in advance to the government analyst of DTL Faisalabad that the applicable specifications are USP and hence the only tests that could be performed on the Products were those prescribed in the applicable specifications. Therefore, the statement of the government analyst vis-a-vis the manufacturer claim of the Products being "sweet" is factually incorrect and the reliance, if any, placed on any previous in-house specs, is invalid and incorrect.

A5. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:

"It is also to inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 (Rule 16 of Drugs (Federal Drug inspectors, Federal Drug Laboratories, Federal Government analyst) Rules, 1976)"

In this regard, committee PQCB was duty bound to consider the foregoing fact whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

A6. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house/others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on 'In-house/other specifications' renders the report invalid and inaccurate.

A7. Since Parapol suspension was being declared of standard quality by DTL Faisalabad till 06- 10-2023 this proves that till this date, as per analysts of DTL Faisalabad, our product complied USP specs and last available In-House specs submitted by the firm. So, definitely, DTL Faisalabad must have received a revised and new method of analysis from the firm after 06-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 06-10-2023 which proves malice intention and act of victimization by government analyst.

A8. Although the firm has not made any claim regarding the term 'sweet' on the packaging material of Parapol suspension and has only cited 'USP' specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard & testing method for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate, as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for drawing conclusions. No such request or chemical analysis was made, and the product was instead declared substandard based solely on personal observation (bitter taste) without conducting or verifying any formal test.

A9. The malafide intentions of the Government Analysts and Director DTL. Faisalabad are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL. Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL. Bahawalpur contributing 62 of those reports. A comparison between the hatches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description. Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

A10. Since, product "Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe/ instruct to conduct test for determination of the taste of the products, test to check dispersed particles in a suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopeial testing.

A11. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the substandard drugs. However, in our case, government analyst has shown her/his malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

C= POINTS OF DEFENSE AGAINST REMARKS OF GOVERNMENT ANALYST "LIQUID" WHILE FIRM CLAIM IS "SUSPENSION"

The government analyst has wrongfully claimed the Products to be a "liquid" despite the same being a suspension. It is pertinent to highlight that PQCB has already investigated this case and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst holding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to of presence of particles (copy of findings of expert committee attached).

It is also important to highlight that USP on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to determine product is suspension, solution or syrup. Same has been confirmed in letters by NIH, Islamabad dated 6-6-2024 and 29-8-2024 as below:

i. *Letter dated 6 June 2024 "It is pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any such test on the basis of which the samples are declared sub-standard by DTLs of Punjab*
ii. *Letter dated 29 August 2024 "It is once again informed that USP monograph for Acetaminophen oral suspension have different tests including test from the general chapters Le performance text (uniformity of dosage units-905, deliverable volume- 698, impurities (4-Aminophenol in Acetaminophen containing Drug Products-277), specific text (pH 791) etc. These different tests from the General chapters as referred by the USP monograph for acetaminophen oral suspension have definite test protocol on the basis of which the tests are performed but the said Monograph does not refer any text on the basis of which the samples were declared substandard by DTLs Punjab and "The USP General Chapter <1151 on the basis of which the samples were declared substandard has only the definition of the suspension but no specific method or procedure as mention in the USP representative reply.*

Furthermore, point no# A2, A4, A5, A6, A7, A9, A10 and All also supports our stance and provides strong defense and contravention against conclusion of government analyst "absence of dispersed solid particles". The foregoing infirmity makes the report invalid and baseless.

POINTS OF DEFENSE & CONTRAVENTIONS IN DISCUSSIONS OF COMMITTEE POCB IN WHICH REQUEST FOR RETESTING HAS BEEN

TURNED DOWN

We would like to highlight following numerous flaws and inaccuracies in the impugned order made by the committee PQCB in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. The statement that the firm failed to submit evidence or relevant data is inaccurate. The firm has, in fact, provided evidence during multiple committees and PQCB meetings, confirming the addition of the sweetener 'Neotame' in the composition of Parapol suspension for taste masking purpose. Neotame, which is 7,000 το 13,000 times sweeter than sucrose with a similar taste profile is widely use sweetener in pharmaceutical and food products. The firm also presented import documentation for Neotame in different committee meeting. If required, the firm is ready to resubmit the import records and the composition of Parapol suspension. Despite this, the firm's stance and claim regarding the inclusion & presence of the sweetener has been disregarded by the committee members. This failure to consider firm's stance not only undermined our right to justice but also demonstrated violation of the principles of a "fair trial and due process'.

b. The statement made by the committee member, i.e, 'the test was performed using calibrated instruments,' is itself indicative of a bogus, fictitious, and fabricated activity. It is illogical to assert that the calibration of instruments could be validated when the sample in question is substandard on physical grounds which makes no relevance to the use of any instruments. This further demonstrates that no investigation into the firm's appeal was conducted in accordance with the principles of a fair trial and due process and that there was a failure to fulfill the duties as mandated by the Drug Act of 1976.

c. The conclusion drawn by the committee member, stating that 'the government analyst has fulfilled all test protocol requirements as outlined in the USP' and 'testing according to international standards' is indicative of a flawed, fictitious, and baseless investigation. The USP contains no protocol for determining the taste (sweetness/bitterness) of a product, nor does it provide a method for classifying a product as a suspension, liquid, solution, or syrup. This further underscores that the firm's appeal was not investigated in accordance with the principles of a 'fair trial and due process and that there was a failure to uphold the duties prescribed under the Drug Act of 1976.

d. Firm's claim & appeal regarding presence of sweetener or sweetness of suspension could only be verified if the samples will be sent to NIH, Islamabad for the conclusive report however same has not been done as per the impugned order by the committee PQCB.

e. Firm's claim & appeal regarding Parapol being "suspension" against government analyst claim "Liquid" could only be verified if the samples will be sent to NIH, Islamabad for re-testing so as to get conclusive report. PQCB has already sent 42 cases of Parapol suspension to NIH, Islamabad for the conclusive result while samples were initially declared substandard on similar grounds i.e. government analyst claimed that sample is not being suspension. However, in this case, committee PQCB turned down appeal for re-testing and issued contradictory decision "impugned order".

In the light of above highlighted infirmities and weakness, we request honorable PQCB to send mentioned batch of Parapol suspension to NIH, Islamabad for the conclusive report and give us fair chance of reevaluation from the appellate lab. We request honorable PQCB and concerned drug inspector to not initiate prosecution against us as we have not contravened provisions of Drug act 1976.

4. Personal hearing notice(s) issued to accused person(s) dated 22-10-2024.

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **286th meeting** held on **30-10-2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab /Vice-Chairperson PQCB. Ms. Uzma Mazhar Secretary DQCB Mandi Bahauddin attended the meeting online via zoom link. No one among the nominated accused persons of M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block-21, F.B Industrial Area, Karachi was present. However, Dr. Sarfaraz (Manager) appeared before the Board on behalf of the firm and reiterated the arguments as mentioned above in reply to show-cause/ personal hearing notice and emphasized to send the sample to Appellate Laboratory for retest/ analysis. He pleaded his case on following grounds:

i. He submitted that government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs.
ii. Government analyst also stated that "samples is free from any dispersed solid particles" and declared samples substandard using reference USP <1151> It is pertinent to highlight that PQCB has already investigated this case and constituted a special committee of pharmaceutical experts which concluded its findings in our favour whilst holding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.

iii. He requested to send their sample for retest/ analysis.

6. The Board after careful perusal of the case record observed that subject drug sample has been declared substandard from Drug Testing Laboratory, Faisalabad on the basis that Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, whereas, the firm in its method of analysis claims that it is pinkish red sweet homogeneous suspension. Keeping in view the facts of the case, the Board after due deliberation and discussion decided to issue **Pend the case.**

GROUNDS OF REVIEW PETITION

SUBJECT: REVIEW PETITION UNDER CLAUSE VIII O THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

The firm submitted review petition vide letter no. Nil Dated Nil Received in PQCB via diary no. 69866 dated 19-12-2024.

Grounds:

We. M/S Lisko Pakistan (Pvt) Ltd "Petitioner Company" would like to submit instant review petition before the learned Provincial Quality Control Board, Punjab against the order of committee PQCB dated 27-6-2024 (the "Impugned Decision") in which request of re-testing from NIH, Islamabad has been turned down (orders attached) for the below mentioned batches of Parapol suspension 120mg/5ml whereby Provincial Inspector of Drugs, District Mandi Bahauddin (the "Respondent Drug Inspector") has been directed to expedite investigation and submit final report before the learned board so that permission for prosecution can be granted.

There are several grave infirmities and ambiguities in DTL reports "Impugned reports" issued by government analyst of DTL Bahawalpur and also in decision "Impugned Order" by the committee PQCB in which request for retesting has been turned down. Prior to delving into the facts of the case, it is pertinent to highlight the fresh grounds that have arisen to the case necessitating the review of the Impugned Decision in terms of Clause 2 of Part VIII of the PQCB Regulations:

1. We would like to highlight following numerous flaws and inaccuracies in the impugned order made by the committee PQCB in which request for retesting has been turned down on the basis of invalid and inaccurate grounds:

a. The statement that the firm failed to submit evidence or relevant data is inaccurate The firm has, in fact, provided evidence during multiple committee and PQCB meetings, confirming the addition of the sweetener 'Neotane' in the composition of Parapol suspension for taste masking purpose. Neotane, which is 7000 to 13,000 times sweeter than sucrose with a similar taste profile is widely use sweetener in pharmaceutical and food products. The firm also presented import documentation for Neotane in different committee meeting. If required, the firm is reads to resubmit the import records and the composition of Parapol suspension Despite the firm's stance and claim regarding the inclusion & presence of the sweetener has been disregarded by the committee members. This failure to consider firm's stance not only undermined our right to justice but also demonstrated violation of the principles of a fair trial and due process.

b. The statement made by the committee member i.e the test was performed using calibrated instruments, is itself indicative of a bogus, fictitious, and fabricated activity. It is illogical to assert that the calibration of instruments could be validated when the sample in question is substandard on physical grounds which makes no relevance to the use of any instruments. This further demonstrates that no investigation into the firm's appeal was conducted in accordance with the principles of a fair trial and due process and that there was a failure to fulfill the duties as mandated by the Drug Act of 1976.

c. The conclusion drawn by the committee member, stating that 'the government analyst has fulfilled all test protocol requirements as outlined in the USP" and testing according to international standards' is indicative of a flawed, fictitious, and baseless investigation. The USP contains no protocol for determining the taste (sweetness/bitterness) of a product, nor does it provide a method for classifying a product as a suspension, liquid solution, or syrup. The further underscores that the firm's appeal was not investigated in accordance with the principles of a fair trial and due process and that there was a failure to uphold the duties prescribed under the Drug Act of 1976.

d. Firm's claim & appeal regarding presence of sweetener or sweetness of suspension could only be verified if the samples will be sent to NIII. Islamabad for the conclusive report however same has not been done as per the impugned order by the committee POCB.

e. Firm's claim & appeal regarding Parapol being "suspension" against government analyst claim "Liquid" could only be verified if the samples will be went to NIIL, Islamabad for re-testing so as to get conclusive report POD has already sent 42 cases of Parapol suspension to NIH Islamabad for the conclusive result while samples were initially declared substandard on similar rounds government analyst claimed that sample

is not being suspension conclusive result while samples were initially declared substandard on similar grounds Le government analyst claimed that sample is not being suspension. However, in this case, committee PQCB turned down appeal for re-testing and issued contradictory decision "impugned order"

2. As per point no 6 (Form 7) of all substandard reports by DTL Faisalabad, USP specs were applied for complete testing which is contrary to the statement of government analyst in which manufacturer's method of analysis was taken into consideration for conclusion of results.

3. The government analyst has stated that the samples of Parapol suspension are "bitter" in taste but has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitt bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs, committer PQCB relied solely on the personal observation of analyst which just not creates an avenue for potential misuse but also enable DTLs to unfairly targets and victimize product in an illegal manner for future analysis. The foregoing infirmity makes the report invalid and baseless.

4. The government analyst has wrongfully claimed the Products to be a "liquid" despite the same being a suspension. It is pertinent to highlight that PQCB already investigated this case and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst holding that Parapol is a "Biphasic liquid like suspension having translucent appearance due to of presence of particles (copy of findings of expert committer attached).

It is also important to highlight that USP on the basis of which samples were declared substandard has only the definition of suspension but no specific method or procedure to determine product is suspension, solution of syrup. Name has been confirmed in letters by Fill, Islamabad dated 6-6-2024 and 29-8-2024 as below.

Latter dated 6 June 2014 Its pertinent to inform that USP monograph for Acetaminophen oral suspension does not mention any such test on the basis of which the samples are declared Substandard by DILs et Punjab.

Latter dated 27 August 2024 It is once again informed that USP monograph for Acetaminophen oral suspension have different texts, including test from the general chapter is performance test conformity of dosage units 903, deliverable volume 698, impurities (4 Aminophenol in Acetaminophen containing Deng Products 2770 specific test tell (91) etc. These different tests from the General chapters.

5. Government analyst has mentioned in form 7 "S. No # 6" that he / she has applied Spec. USP 2024. However, it is pertinent to highlight that USP 2024 does not provide any test to determine sweetness / bitterness of suspension and also does not provide test to check presence or absence of solid particles to declare product as suspension / solution/ syrup. Therefore, Product "Parapol" have been declared as substandard on the basis of the extraneous grounds and the personal whims of the government analyst.

6. Government analyst has fraudulently declared samples substandard on the basis of physical characteristics using reference of In-House specs as our firm vide letter dated 03-11-2023 (copy attached) categorically informed in advance to the government analyst of DTL Faisalabad that the applicable specifications are USP and hence the only tests that could be performed on the Products were those prescribed in the applicable specifications. Therefore, the statement of the government analyst vis-à-vis the manufacturer claim of the Products being "sweet" is factually incorrect and the reliance, if any placed on any previous in-house specs, is invalid and incorrect.

7. The test reports do not shed any light on the testing method and protocol that was employed to ascertain the presence or absence of sweetener and presence or absence of solid particles in samples. Such illegality renders the reports as illegal and unlawful since it was incumbent upon the government analyst to have provided the entire method that was employed to reach such conclusion. Same fact was stated in NIH letter dated 29-8-2024:

“It is inform you that the Federal Drug Laboratory has to mention the detail of results of tests or analysis (with protocol of test) as desired in Form 6 (Rule 16 of Drugs (Faders! Drug inspectors, Federal Drug Laboratories. Federal Government analyst) Rules, 1976)”

In this regard, committee PQCB was duty bound to consider the foregoing fact whilst allegedly scrutinizing the DTL Reports however same has not been done and the Impugned Decision has been taken in a slipshod manner as undue reliance has been placed on inadmissible DTL Reports.

8. The action of the government analyst in declaring the samples of the Product to be of substandard quality while applying "In-house/others specs" along with USP specs is in contradiction with the DRAP Circular dated 07-02-2022 (copy attached) wherein a direction was given by the Drug Regulatory Authority of Pakistan with respect to the strict adoption and implementation of the pharmacopeial specifications. Since the firm exclusively claims USP specifications only and therefore any reliance on In house/other specifications' renders the report invalid and inaccurate.

9. Since Parapol suspension was being declared of standard quality by DTL Faisalabad till 06-10-2023 this proves that till this date, as per analysts of DTL Faisalabad, our product complied USP specs and last available In-House specs submitted by the firm. So, Definitely. DTL Faisalabad must have received a revised and new method of analysis from the firm after 06-10-2023 having different claim regarding physical characteristics on the basis of which government analyst all of a sudden found non-compliance on physical characteristics. However, such revised in-house specs has never been provided by the firm after 06-10-2023 which proves malice intention and act of victimization by government analyst.

10. Although the firm has not made any claim regarding the term 'sweet on the packaging material of Parapol suspension and has only cited 'USP specifications, if the government analyst wished to test for the presence of a sweetener, they should have requested the standard & testing method for such sweeteners from the firm for proper chemical analysis. Declaring the sample substandard based on personal observation is inappropriate as the perception of sweetness and its intensity can vary from individual to individual, making personal observations unreliable for 1 awing conclusions. No such request or chemical analysis was made, and the product was instead declared substandard based solely on personal observation (bitter taste) without conducting or verifying any formal test.

Additionally, we would like to highlight grounds comprehensively which have already been discussed in difference committee meeting that further supports our stance in said case:

1. The malafide intentions of the Government Analysts and Director DTL Faisalabad are evinced by the fact that all batches of Parapol suspension either declared standard or substandard by DTL Bahawalpur has been manufactured by the firm using the same formulation and all supplied batches exhibited identical physical characteristics. Over the last six financial years, there have been 479 standard reports on Parapol suspension issued by DTLs in Punjab, with DTL Bahawalpur contributing 62 of those reports. A comparison between the batches deemed standard and those deemed sub-standard reveals they share same physical characteristics and description Similar kind of comparison has been done by the experts committee of pharmaceutical experts constituted by PQCB in which they categorically stated in their findings that they found no difference in batches deemed standard and those deemed sub-standard.

2. Since, product "Parapol suspension" claims USP specs, it is to be noted that USP does not prescribe/ instruct to conduct test for determination of the taste of the products, test to check dispersed particles in a suspension or test for determination of concentration of propylene glycol in a finished product. Therefore, the findings of the government analyst are illegal and not backed by any pharmacopical testing.

3. Honorable High court Lahore in its decision (127 of 1989) has categorically motioned that "it is an admitted fact that the question reports in this case clearly reveal that the samples taken conform to the specification chemically and therefore it is obvious and clear, the sample of the drugs do not fall within the definition of the substandard drugs" However, in our case, government analyst has shown her/his malice intention by declaring samples substandard on the basis of physical characteristics while sample complied to stated specification chemically.

PRAYER:

In view of the foregoing, it is most respectfully prayed that this Honorable Board may graciously be pleased to accept the instant review petition and:

i. Set aside the Impugned Decision (Dated 27-6-2024) in which request for re-testing has been turned down.

ii. Pass an order for the samples of suspension Parapol Batch No. 048-24 to be sent to the National Institute of Health, Islamabad for conclusive report on physical characteristic.

iii. Direct the government analyst of the Drug Testing Laboratory, Faisalabad to bring the method and protocols of the test employed to determine the taste along with the protocol to declare sample "Liquid" on record.

iv. Permanently restrain the Provincial Inspector of Drugs, District Mandi Bahauddin from taking any adverse and/or coercive action against our firm "Petitioner Company" and its officials along with final report based on the Impugned Decision. We hope that learned board will give us chance of fair trial and accept our review petition.

7. Personal hearing notice(s) issued to accused person(s) dated 02-01-2025.

PERVIOUS PROCEEDINGS & DECISION BY THE BOARD:

8. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, vice-chairperson PQCB. Ms. Uzma Mazhar Secretary DQCB Mandi Bahauddin attended the meeting online via zoom link. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. He stated that government analyst has mentioned in the DTL report that the samples of Parapol suspension are "bitter" in taste but there is no pharmacopoeil test to check the taste of the product and furthermore Govt. analyst has not specified the acceptable level of sweetness required to meet standard quality. We respectfully question and challenge the standards and validated criteria used by the analyst to classify a product as bitter or sweet in taste. Despite the fact that there being no validated criteria or acceptable limits for taste profile either in USP or in-house specs. They further stated that taste sense may vary individual to individual basis and there will be no toxicity or adverse effects due to bitter taste
ii. We are confident that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension”.
iii. As far as declaring our samples substandard declaring them to be “free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iv. He further reiterated firm’s request to send the subject drug sample to Appellate Laboratory, National Institute of Health Islamabad for retesting.

9. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample of Parapol Suspension (Each 5ml contains: Paracetamol USP…120mg), Batch No. 048-24, has been declared substandard by the Drugs Testing Laboratory, Faisalabad on the basis of physical characeristics i.e., Pinkish red viscous liquid having bitter taste, whereas, manufacturer specifies, “Pinkish Red Sweet Suspension” in its method of analysis. The Board also observed that the firm’s retesting request was also turned down in 41st committee meeting dated 27-06-2024. This is also in context to mention that Board in its 279th meeting dated 24-04-2024 sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976. Hence, the Board unanimously decided to **Turn Down** the subject review petition regarding retesting request and **upheld the previous decision** as taken in its **41st Committee meeting** held on **27-06-2024** as the firm did not provide any satisfactory argument in their review petition to the question regarding the physical characteristics and bitter taste of the subject sample.

10. Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The Board firmly opined that determining the nature of the liquid pharmaceutical formulation, whether it is suspension/syrup/liquid/solution etc., is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation.

11. Keeping in view the case record and correspondence between NIH & PQCB, the Board remarked that the sample in question was declared substandard by DTL Faisalabad on the basis of physical description of suspension as per General Chapter <1151> of the USP and upon bitter taste as well. The firm claims the product as “Suspension” on its label, but the formulation is free from any dispersed solid particles as per DTL report, thus refuting the basic principle of pharmaceutical sciences as reported by the DTL Faisalabad. The Board was certain/ convinced that it is the legal binding of the Appellate Laboratory to issue the test/ analysis reports as conclusive evidence in the light of clarification/ justification already submitted

by the DRAP vide letter no. 13-22/2024-QC dated 15-11-2024, email by the USP and replies of PQCB dated 21-08-2024 & 20-09-2024.

12. The Board disagreed with the point of view of Chief, DC & TMD, NIH Islamabad as conveyed to PQCB vide letter no. F.No.1-20/17-Misc/2021-DC&TMD dated 04-12-2024 recommending the PQCB to *"consider withdrawing the retesting request for all samples based on physical description"* as there is no such provision in the prevailing Drugs Act and Rules which encourages withdrawal of samples/ retesting request sent to Appellate Laboratory. Hence, taking into account all aspects of the subject cases and arguments pleaded by the firm's representatives, the Board was of the unanimous opinion that the Appellate Laboratory (NIH) should furnish the test report in the form of certificate of analysis on its prescribed Form-6 under sub-section (1) of Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976 as the Drugs Control & Traditional Medicines Division (DC&TMD), National Institute of Health (NIH) serves as a laboratory specified by the Federal Government vide notification No. F.2-12/76-QCA dated, the 10th September, 1976 & SRO No. 542 (1)/92 dated 19th May, 1992 for the purpose of sub-section (5) of section 22 of the Drugs Act, 1976. The Board after due deliberation and detailed discussion, unanimously decided to **pend the case.**

Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

Summary of the case:

- **Mfg. date: 07-2023**
- **Exp. Date: 07-2025**
- **Sampling date (Form 4): 07-03-2024**
- **Sent to DTL (Form 6): 08-03-2024**
- **Date of receipt in DTL: 11-03-2024**
- **DTL Report Date (Form 7): 08-05-2024**
- **DI 1st intimation to firm: 14-05-2024**
- **Retesting request if any: 14-05-2024**
- **Fate of Retesting: Turned Down in 41st Committee meeting dated 27-06-2024**
- **Investigation report Dated: 22-08-2024**
- **Permission of SCN: 285th meeting dated 26-09-2024**
- **SCN Issued: 27-09-2024**
- **Reply of the firm: Yes dated 30-10-2024**
- **History (2021 onwards): Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 8

PQCB/MSS-177698,177699/2023

Tehsil & District Khushab

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F. B. Industrial Area, Karachi** through its Managing Director, M. Muzammil Nazar. 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/Warrantor of M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil & District Khushab reported that: -

i. The then drug Inspector, on 05-10-2023 inspected the medicine store of CEO Health office Khushab, took 3 different drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 177698 & 177699 dated 05-10-2023.
ii. Following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Sr no.	Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
1	Suspension Parapol 120ml (Paracetamol 120 mg/5ml) Mfg date: 07-2023 Exp Date: 07-2025	056-24	M/S Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA 75007771 /DTL dated 12-12-2023	**Specification applied; USP 2023** **PHYSICAL DESCRIPTION** Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton. **As per USP <1151> Pharmaceutical Dosage Forms; *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution. (DOES NOT COMPLY)** **PH:** Observed:5.43 (Complies the test)

					Limit: 4.0 – 6.9 **IDENTIFICATION:** Paracetamol Identified. (Complies the test) **ASSAY:** Stated: 120 mg / 5mL Determined:122.924 mg / 5mL Percentage: 102.44 % (Complies the test) Limit: 90 % - 110 % **RESULT: The above sample is "Substandard" on the basis of physical description as per USP.**
2	Suspension Parapol 120ml (Paracetamol 120 mg/5ml) Mfg date: 07-2023 Exp Date: 07-2025	057-24	M/S Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA 01-75007767 DTL dated 12-12-2023	**Specification applied; USP 2023** **PHYSICAL DESCRIPTION** Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton. **As per USP <1151> Pharmaceutical Dosage Forms; *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution. (DOES NOT COMPLY)** **PH:** Observed: 5.42 (Complies the test) Limit: 4.0 – 6.9 **IDENTIFICATION:** Paracetamol Identified. (Complies the test) **ASSAY:** Stated: 120 mg / 5mL Determined: 125.192 mg / 5mL Percentage: 104.33 % (Complies the test) Limit: 90 % - 110 %

					RESULT: The above sample is "Substandard" on the basis of physical description as per USP.

iii. Storekeeper medicine store of CEO Health office Khushab, provided invoice/warranty No. 000185 dated 12-09-2023 issued by M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.
iv. Warrantor Portions of subject batches of the subject samples were sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.
v. Copies of Test/ Analysis reports were sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi and they were directed to provide requisite information in this regard.

Previous Proceedings & Decision by the Board: (Regarding Retesting Request of both batches)

32nd Committee Meeting held on 25-01-2024

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **32nd meeting** held on 25-01-2024 under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. Haji Javed, Quality Control Manager of M/S Lisko Pakistan (Pvt.) appeared before the committee to plead the case.

3. The Secretary PQCB apprised the Committee that the Manufacturer requested for retesting vide letter Reference No. Nil dated 19-12-2023. The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. MSS-177699, 176662, 178849, 178850, 177698/23 dated 16-01-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard).

4. The representative of the firm appeared before the committee and submitted withdrawal request vide letter no Nil dated 24-01-2024. The committee after due deliberation and discussion unanimously decided to accept the firm's request for **withdrawal of the retesting request** of the drug samples and the Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under by the way of: -

a. Manufacture for sale/sale of the Substandard drugs

b.Issuance of false warranty

3. Show cause Notice (s) issued to the accused person(s) Dated 22-11-2024.

Reply of show cause notice dated 16-12-2024

With reference to your letter no# 177698/2023 and 177699/2023 received on 14-12-2024 regarding show cause notice for batch no# 056-24 and 057-24 of Parapol suspension 120mg/5ml which was supplied to DHA Khushab, we would like inform you that PQCB has already constituted special committee for findings and opinions on "Physical description issue of Parapol suspension" (report attached). By the grace of Almighty, findings clearly state that **Parapol is a "Biphasic liquid like suspension'" having translucent appearance due to of presence of particles.** On this premise, samples of 42 batches of Parapol suspension were sent to NIH, Islamabad for re-testing purpose. However, firm withdrew from re- testing request on later stages but board decided to send samples to NIH, Islamabad for conclusive report. We tried our level best to settle

down case at PQCB stage after favorable report from special committee but PQCB decided to send samples to appellate lab for conclusive report. In the same manner, both samples of batch no# 056-24 and 057-24 have been declared substandard by DTL Rawalpindi on invalid premise “physical description";

Batch no#	**Station**	**TRA No**	**Report Date**
056-24	KHUSHAB	01-75007771	12/12/2023
057-24	KHUSHAB	01-75007767	12/12/2023

We already have presented our stance comprehensively that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension", In the light of foregoing, we request P¿CB to decide case in the light of findings of special committee and send samples of both batches 056-24 and 057-24 to NIH, Islamabad similar to those 42 batches which were sent for re-testing earlier.

As informed earlier, following persons were responsible for manufacturing, QC analysis and distribution:

Details of Managing Director

M. Muzammil Nazar

Add: House No 693, DOHS, Phase 1, Malir Cantt., Karachi

CNIC No# 42101-9965280-7

Details of Production Manager

Mr. Ghulam Nabi Khoso

Add: House No: 47-A, Sindhi Para, Shanti Nagar, Dalmia, Karachi

CNIC No# 42201-7504385-7

Details of QC Manager+ Warrantor

Mrs. Naima Khanam

Add: House No. 407-A, Block 1, U.C-5, Gulshan-e-Iqbal Karachi

CNIC No# 42201-1930079-6

We request honorable PQCB to give us chance of fair trial and send sample to NIH, Islamabad on urgent basis so that we may get conclusive reports appellate lab before expiry of stock (July 2025).

Firm submitted vide letter dated 28-10-2024 and 21-10-2024

Most respectfully, with reference to our previously submitted letter dated 2|-10-24, we would like to bring in your kind knowledge that below mentioned samples of Parapol suspension 120mg/5ml have been declared sub-standard on the basis of physical description by DTL Rawalpindi and case were already discussed in committee meeting of 25-1-2024. Details are as below:

Batch no #	Station	TRA No	DTL	Reason for being sub-standard	Last PQCB Meeting
056-24	KHUSHAB	01-75007771	Rawalpindi	Physical description	25-01-2024
057-24	KHUSHAB	01-75007767	Rawalpindi		

Despite of lapse of more than l1 months, we have not been issued personal hearing notice for the above cases result of which we are deprived of our right of justice. Please note that P¿CB has already constituted committee on physical description issue against 42 similar cases and on the basis of findings of expert committee, PQCB sent samples of 42 batches of Parapol suspension to NIH, Islamabad by their own in which re-testing request was withdrawn initially as suggested by PQCB. In the same manner, re-testing request was withdrawn initially in above mentioned cases and but now **we request P¿CB to send above mentioned batches to NIH, Islamabad for re-testing purpose as the cases are exactly same as of 42 previous cases of physical description issue**.

Expiry of all above batches of Parapol susp is July 2025 and we therefore request you to kindly place above cases in forthcoming PQCB meeting and allow retesting of above samples from NIH, Islamabad without any further delay so that conclusive report may be obtained through fair and transparent process.

We hope that no further act of delay will be observed from the **honorable board and samples will be sent to NIH, Islamabad for re-testing in the same manner as those 42 cases were sent for conclusive** report.

We shall remain thankful for your prompt response in this regard

7. Personal Hearing notice(s) issued to accused person(s) dated 01-01-2025

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD

The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the Chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB, Primary & Secondary Healthcare Department Punjab. Mr. Ahmad Khan Secretary DQCB Khushab attended the meeting online via zoom link and Mr. M. Anwar Provincial Inspector of drugs Tehsil & District Khushab was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. We are confident that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension”.
ii. As far as declaring our samples substandard declaring them to be “free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iii. He further reiterated firm’s request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting on the same analogy as learned Board on its own motion already sent forty-two (42) samples to NIH of the same product.

6. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11

(5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 056-24 & 057-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Rawalpindi on the basis of physical description as *"Pinkish Red coloured liquid"* further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 19-12-2023 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was willingly withdrawn during the hearing of 32nd Committee meeting of the Board held on 25-01-2024, which was accepted by the Board. Whereas, the re-submitted retesting request by the firm in its letters dated 21-10-2024 & 28-10-2024 cannot be accepted and hence, is turned down. This is also in context to mention that Board in its 279th meeting dated 24-04-2024 sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976.

7. However, Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The observations/ recommendations in letters submitted by NIH were discussed by the Board and pointwise response is as under:

i. The section 3 (z) of the Drugs Act, 1976 defines specifications as:
    a. Such specifications as may be prescribed;
    b. when the specifications are not prescribed, the specifications as contained in the most recent edition any of the Pharmacopeial publications (USP in the instant case).
    c. If no specifications are either prescribed or contained in any of the publications referred above, the specification approved for the purpose of registration under this act.

The Drugs Regulatory Authority of Pakistan ("**DRAP**") has prescribed/ registered Suspension Paracetamol 120 mg/ 5ml of M/s Lisko Pakistan (Pvt.) Limited as **Suspension.** Finished product specifications of Parapol Suspension 120 mg of M/s Lisko Pakistan (Pvt.) Limited describes appearance of the questioned product as "Pinkish Red Sweet Suspension". Hence, dosage form & physical characteristics are part of specifications. General Chapters of USP <1151> defines the dosage forms. The identification/ determination of dosage form is primary prerequisite of physical testing and same cannot be determined through HPLCs/ or any other analytical technique. DRAP issues registration certificates for different categories of drugs like Syrups/ Suspensions/ Solution, Tablet (enteric, film or sugar coated)/ Capsules/ Lozenges/ Pills and Lotions/ Ointments/ Creams/ Emulsions etc. Regulatory laboratory while issuing test/ analysis report ascertain the dosage form of a drug as per its label claim. Otherwise testing laboratory cannot question/ fail a product having tablet but claiming capsules or otherwise as method of differentiation of tablet/ capsule has not been specified in the monographs. Non utilization of General Chapters and manufacturer specifications will undermine entire regulatory regime and manufacturer will be at liberty to provide syrups in place of suspension and tablets in place of capsules. Similarly, testing laboratories fail a liquid product on appearance of crystals, discoloration/ caking, taste or bad smell etc. but same has not been specified in the monographs. The manufacturer at the time of registration submits all manufacturing procedures & stability data regarding the dosage form of product. Hence, non-identification of dosage form will undermine the registration certificates issued by DRAP.

ii. The Board after due deliberation and detailed discussion, unanimously decided that it is legal binding on the Chief, Appellate Laboratory NIH, Islamabad to issue conclusive report as required undersection 22(5) of the Drugs Act 1976 to PQCB and same should be furnished in the form of certificate of analysis on its prescribed Form-6 under sub-section (1) of Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976. It is reiterated that DTLs failed the questioned product on the basis of physical appearance as per guidelines provided by USP through electronic mail i.e., visual inspection & filtration. Besides visual inspection, membrane filter of 0.45 micrometer was used for filtration by DTLs.
iii. DTLs tested product as per specifications. Moreover, DRAP endorses that NIH being appellate laboratory to take decision for the purpose of test/analysis of drugs. Hence, it is required to issue a conclusive report after complete testing of all batches of the questioned product.
iv. The Board disagreed withdrawing the retesting request as there is no such provision in the prevailing Drugs Act/Rules and NIH has

already taken cognizance over the matter and now it is mandatory under the law to issue the test/ analysis report being the only appellate forum in this regard. Moreover, a period of 10 months has already been lapsed from the date of sending of samples and remaining shelf life of these samples is limited.

v. The section 3 (zz) of the Drugs Act, 1976 defines the "Substandard drug" means a drug which is not of specifications. According to manufacturer specification, the said drug is not of specification on physical ground which is contrary to Registration letter (R. no.002772) approved by DRAP as suspension.

8. The Board firmly opined that determining the nature of liquid pharmaceutical formulations, whether it is suspension/ syrup/ liquid/ solution etc. is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation. The Board after due deliberation and detailed discussion, unanimously decided to **pend the case** till response from NIH and same may be conveyed to Appellate Lab (NIH) in response to their letter no. F.No.1-20/17-Mis/2021-DC&TDM, dated 25-10-2024, F.No.1/20/17-Mis/2021-DC&TDM dated 04-12-2024 and F.No.1/20/17-Misc/2021-DC&TDM dated 30-12-2024 with the request to furnish conclusive test report as above endorsed by DRAP & under section 22 (5) of the Drugs Act 1976, at earliest in order to avoid further delay in the proceedings of the subject cases.

SUMMARY OF THE CASE		
1	**Sampling Date: (Form 4)**	05.10.2023
2	**Sent to DTL (Form 6):**	05-10-2023
3	**Date of receipt in DTL**	25-10-2023 (After 21 days)
4	**DTL Report date**	12-12-2023 (49days)
5	**Time extension granted**	Not time barred
6	**1ST DI Communication with firm**	12-03-2024
7	**Retesting Request of Firm**	Yes (19-12-2023)
8	**Fate of Retesting Request**	Withdrawal request of firm accepted in 32nd CM dated 25-01-2024
9	**Investigation Report of DI**	27-10-2024 received in PQCB dated 06-11-2024
10	**SCN permission**	287-M dated 08-01-2025
11	**Show cause dated**	22-11-2024
12	**Reply of show cause notice**	16-12-2024 (again requesting to send subject batches to NIH)
13	**Firm History:**	Firm: 110

		Product: 87

Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025

Case is placed before the Board for Decision

PROCEEDINGS & DECISION BY THE BOARD

PQCB/MSS-177698,177699/2023

Tehsil & District Khushab

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F. B. Industrial Area, Karachi** through its Managing Director, M. Muzammil Nazar. 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/Warrantor of M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil & District Khushab reported that: -

i. The then drug Inspector, on 05-10-2023 inspected the medicine store of CEO Health office Khushab, took 3 different drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 177698 & 177699 dated 05-10-2023.
ii. Following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Sr no.	Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
1	Suspension Parapol 120ml (Paracetamol 120 mg/5ml)	056-24	M/S Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas	TRA 75007771 /DTL dated 12-12-2023	**Specification applied; USP 2023** **PHYSICAL DESCRIPTION** Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton.

	Mfg date: 07-2023 Exp Date: 07-2025		Road Federal B Industrial Area, Karachi, Pakistan		**As per USP <1151> Pharmaceutical Dosage Forms; *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution. (DOES NOT COMPLY)** **PH:** Observed:5.43 (Complies the test) Limit: 4.0 – 6.9 **IDENTIFICATION:** Paracetamol Identified. (Complies the test) **ASSAY:** Stated: 120 mg / 5mL Determined:122.924 mg / 5mL Percentage: 102.44 % (Complies the test) Limit: 90 % - 110 % **RESULT: The above sample is "Substandard" on the basis of physical description as per USP.**
2	Suspension Parapol 120ml (Paracetamol 120 mg/5ml) Mfg date: 07-2023 Exp Date: 07-2025	057-24	M/S Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA 01-75007767 DTL dated 12-12-2023	**Specification applied; USP 2023** **PHYSICAL DESCRIPTION** Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton. **As per USP <1151> Pharmaceutical Dosage Forms; *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution. (DOES NOT COMPLY)** **PH:** Observed: 5.42 (Complies the test) Limit: 4.0 – 6.9 **IDENTIFICATION:** Paracetamol Identified. (Complies the test)

					ASSAY: Stated: 120 mg / 5mL Determined: 125.192 mg / 5mL Percentage: 104.33 % (Complies the test) Limit: 90 % - 110 % **RESULT: The above sample is "Substandard" on the basis of physical description as per USP.**

iii. Storekeeper medicine store of CEO Health office Khushab, provided invoice/warranty No. 000185 dated 12-09-2023 issued by M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.

iv. Warrantor Portions of subject batches of the subject samples were sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.

v. Copies of Test/ Analysis reports were sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi and they were directed to provide requisite information in this regard.

Previous Proceedings & Decision by the Board: (Regarding Retesting Request of both batches)

32nd Committee Meeting held on 25-01-2024

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **32nd meeting** held on 25-01-2024 under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. Haji Javed, Quality Control Manager of M/S Lisko Pakistan (Pvt.) appeared before the committee to plead the case.

3. The Secretary PQCB apprised the Committee that the Manufacturer requested for retesting vide letter Reference No. Nil dated 19-12-2023. The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. MSS-177699, 176662, 178849, 178850, 177698/23 dated 16-01-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard).

4. The representative of the firm appeared before the committee and submitted withdrawal request vide letter no Nil dated 24-01-2024. The committee after due deliberation and discussion unanimously decided to accept the firm's request for **withdrawal of the retesting request** of the drug samples and the Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under by the way of: -

a. Manufacture for sale/sale of the Substandard drugs

b.Issuance of false warranty

3. Show cause Notice (s) issued to the accused person(s) Dated 22-11-2024.

Reply of show cause notice dated 16-12-2024

With reference to your letter no# 177698/2023 and 177699/2023 received on 14-12-2024 regarding show cause notice for batch no# 056-24 and 057-24 of Parapol suspension 120mg/5ml which was supplied to DHA Khushab, we would like inform you that PQCB has already constituted special committee for findings and opinions on "Physical description issue of Parapol suspension" (report attached). By the grace of Almighty, findings clearly state that **Parapol is a "Biphasic liquid like suspension'" having translucent appearance due to of presence of particles.** On this premise, samples of 42 batches of Parapol suspension were sent to NIH, Islamabad for re-testing purpose. However, firm withdrew from re- testing request on later stages but board decided to send samples to NIH, Islamabad for conclusive report. We tried our level best to settle down case at PQCB stage after favorable report from special committee but PQCB decided to send samples to appellate lab for conclusive report. In the same manner, both samples of batch no# 056-24 and 057-24 have been declared substandard by DTL Rawalpindi on invalid premise “physical description";

Batch no#	**Station**	**TRA No**	**Report Date**
056-24	KHUSHAB	01-75007771	12/12/2023
057-24	KHUSHAB	01-75007767	12/12/2023

We already have presented our stance comprehensively that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension", In the light of foregoing, we request P¿CB to decide case in the light of findings of special committee and send samples of both batches 056-24 and 057-24 to NIH, Islamabad similar to those 42 batches which were sent for re-testing earlier.

As informed earlier, following persons were responsible for manufacturing, QC analysis and distribution:

Details of Managing Director

M. Muzammil Nazar

Add: House No 693, DOHS, Phase 1, Malir Cantt., Karachi

CNIC No# 42101-9965280-7

Details of Production Manager

Mr. Ghulam Nabi Khoso

Add: House No: 47-A, Sindhi Para, Shanti Nagar, Dalmia, Karachi

CNIC No# 42201-7504385-7

Details of QC Manager+ Warrantor

Mrs. Naima Khanam

Add: House No. 407-A, Block 1, U.C-5, Gulshan-e-Iqbal Karachi

CNIC No# 42201-1930079-6

We request honorable PQCB to give us chance of fair trial and send sample to NIH, Islamabad on urgent basis so that

we may get conclusive reports appellate lab before expiry of stock (July 2025).

Firm submitted vide letter dated 28-10-2024 and 21-10-2024

Most respectfully, with reference to our previously submitted letter dated 2|-10-24, we would like to bring in your kind knowledge that below mentioned samples of Parapol suspension 120mg/5ml have been declared sub-standard on the basis of physical description by DTL Rawalpindi and case were already discussed in committee meeting of 25-1-2024. Details are as below:

Batch no #	Station	TRA No	DTL	Reason for being sub-standard	Last PQCB Meeting
056-24	KHUSHAB	01-75007771	Rawalpindi	Physical description	25-01-2024
057-24	KHUSHAB	01-75007767	Rawalpindi		

Despite of lapse of more than l1 months, we have not been issued personal hearing notice for the above cases result of which we are deprived of our right of justice. Please note that P¿CB has already constituted committee on physical description issue against 42 similar cases and on the basis of findings of expert committee, PQCB sent samples of 42 batches of Parapol suspension to NIH, Islamabad by their own in which re-testing request was withdrawn initially as suggested by PQCB. In the same manner, re-testing request was withdrawn initially in above mentioned cases and but now **we request P¿CB to send above mentioned batches to NIH, Islamabad for re-testing purpose as the cases are exactly same as of 42 previous cases of physical description issue**.

Expiry of all above batches of Parapol susp is July 2025 and we therefore request you to kindly place above cases in forthcoming PQCB meeting and allow retesting of above samples from NIH, Islamabad without any further delay so that conclusive report may be obtained through fair and transparent process.

We hope that no further act of delay will be observed from the **honorable board and samples will be sent to NIH, Islamabad for re-testing in the same manner as those 42 cases were sent for conclusive** report.

We shall remain thankful for your prompt response in this regard

7. Personal Hearing notice(s) issued to accused person(s) dated 01-01-2025

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD

The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the Chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB, Primary & Secondary Healthcare Department Punjab. Mr. Ahmad Khan Secretary DQCB Khushab attended the meeting online via zoom link and Mr. M. Anwar Provincial Inspector of drugs Tehsil & District Khushab was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. We are confident that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension”.
ii. As far as declaring our samples substandard declaring them to be “free from any dispersed solid

particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.

iii. He further reiterated firm's request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting on the same analogy as learned Board on its own motion already sent forty-two (42) samples to NIH of the same product.

6. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 056-24 & 057-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Rawalpindi on the basis of physical description as *"Pinkish Red coloured liquid"* further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 19-12-2023 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was willingly withdrawn during the hearing of 32nd Committee meeting of the Board held on 25-01-2024, which was accepted by the Board. Whereas, the re-submitted retesting request by the firm in its letters dated 21-10-2024 & 28-10-2024 cannot be accepted and hence, is turned down. This is also in context to mention that Board in its 279th meeting dated 24-04-2024 sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976.

7. However, Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The observations/ recommendations in letters submitted by NIH were discussed by the Board and pointwise response is as under:

i. The section 3 (z) of the Drugs Act, 1976 defines specifications as:
   a. Such specifications as may be prescribed;
   b. when the specifications are not prescribed, the specifications as contained in the most recent edition any of the Pharmacopeial publications (USP in the instant case).
   c. If no specifications are either prescribed or contained in any of the publications referred above, the specification approved for the purpose of registration under this act.

The Drugs Regulatory Authority of Pakistan ("**DRAP**") has prescribed/ registered Suspension Paracetamol 120 mg/ 5ml of M/s Lisko Pakistan (Pvt.) Limited as **Suspension.** Finished product specifications of Parapol Suspension 120 mg of M/s Lisko Pakistan (Pvt.) Limited describes appearance of the questioned product as "Pinkish Red Sweet Suspension". Hence, dosage form & physical characteristics are part of specifications. General Chapters of USP <1151> defines the dosage forms. The identification/ determination of dosage form is primary prerequisite of physical testing and same cannot be determined through HPLCs/ or any other analytical technique. DRAP issues registration certificates for different categories of drugs like Syrups/ Suspensions/ Solution, Tablet (enteric, film or sugar coated)/ Capsules/ Lozenges/ Pills and Lotions/ Ointments/ Creams/ Emulsions etc. Regulatory laboratory while issuing test/ analysis report ascertain the dosage form of a drug as per its label claim. Otherwise testing laboratory cannot question/ fail a product having tablet but claiming capsules or otherwise as method of differentiation of tablet/ capsule has not been specified in the monographs. Non utilization of General Chapters and manufacturer specifications will undermine entire regulatory regime and manufacturer will be at liberty to provide syrups in place of suspension and tablets in place of capsules. Similarly, testing laboratories fail a liquid product on appearance of crystals, discoloration/ caking, taste or bad smell etc. but same has not been specified in the monographs. The manufacturer at the time of registration submits all manufacturing procedures & stability data regarding the dosage form of product. Hence, non-identification of dosage form will undermine the registration certificates issued by DRAP.

ii. The Board after due deliberation and detailed discussion, unanimously decided that it is legal binding on the Chief,

Appellate Laboratory NIH, Islamabad to issue conclusive report as required undersection 22(5) of the Drugs Act 1976 to PQCB and same should be furnished in the form of certificate of analysis on its prescribed Form-6 under sub-section (1) of Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976. It is reiterated that DTLs failed the questioned product on the basis of physical appearance as per guidelines provided by USP through electronic mail i.e., visual inspection & filtration. Besides visual inspection, membrane filter of 0.45 micrometer was used for filtration by DTLs.

iii. DTLs tested product as per specifications. Moreover, DRAP endorses that NIH being appellate laboratory to take decision for the purpose of test/analysis of drugs. Hence, it is required to issue a conclusive report after complete testing of all batches of the questioned product.

iv. The Board disagreed withdrawing the retesting request as there is no such provision in the prevailing Drugs Act/Rules and NIH has already taken cognizance over the matter and now it is mandatory under the law to issue the test/ analysis report being the only appellate forum in this regard. Moreover, a period of 10 months has already been lapsed from the date of sending of samples and remaining shelf life of these samples is limited.

v. The section 3 (zz) of the Drugs Act, 1976 defines the "Substandard drug" means a drug which is not of specifications. According to manufacturer specification, the said drug is not of specification on physical ground which is contrary to Registration letter (R. no.002772) approved by DRAP as suspension.

8. The Board firmly opined that determining the nature of liquid pharmaceutical formulations, whether it is suspension/ syrup/ liquid/ solution etc. is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation. The Board after due deliberation and detailed discussion, unanimously decided to **pend the case** till response from NIH and same may be conveyed to Appellate Lab (NIH) in response to their letter no. F.No.1-20/17-Mis/2021-DC&TDM, dated 25-10-2024, F.No.1/20/17-Mis/2021-DC&TDM dated 04-12-2024 and F.No.1/20/17-Misc/2021-DC&TDM dated 30-12-2024 with the request to furnish conclusive test report as above endorsed by DRAP & under section 22 (5) of the Drugs Act 1976, at earliest in order to avoid further delay in the proceedings of the subject cases.

SUMMARY OF THE CASE		
1	**Sampling Date: (Form 4)**	05.10.2023
2	**Sent to DTL (Form 6):**	05-10-2023
3	**Date of receipt in DTL**	25-10-2023 (After 21 days)
4	**DTL Report date**	12-12-2023 (49days)
5	**Time extension granted**	Not time barred
6	**1ST DI Communication with firm**	12-03-2024
7	**Retesting Request of Firm**	Yes (19-12-2023)
8	**Fate of Retesting Request**	Withdrawal request of firm accepted in 32nd CM dated 25-01-2024
9	**Investigation Report of DI**	27-10-2024 received in PQCB dated 06-11-2024

10	**SCN permission**	287-M dated 08-01-2025
11	**Show cause dated**	22-11-2024
12	**Reply of show cause notice**	16-12-2024 (again requesting to send subject batches to NIH)
13	**Firm History:**	Firm: 110 Product: 87

Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025

Case is placed before the Board for Decision

PROCEEDINGS & DECISION BY THE BOARD

Case No. 9

PQCB/MSS-178849,178850/2023

Tehsil & District Sargodha

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi** through its Managing Director, M. Muzammil Nazar. 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor of M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil & District Sargodha reported that: -

i. He, on 17.10.2023, inspected the premises of Main Medicine Store, situated at CEO (DHA) Office Sargodha and took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No. 178849 and 178850, dated 17.10.2023.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Rawalpindi, as detailed below:

Sr.	Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
01	Suspension Parapol 120mL (Paracetamol: 120mg/5ml) **Mfg Date: Exp Date: Registration No.** 07.2023 07.2025 002772	054-24	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-75007807/DTL Dated. 12.12.2023
	DTL Test Report Result **Specification applied:** USP 2023 **Physical Description:** Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton. **As per USP<1151> Pharmaceuticals Dosage Forms; "A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase" while in actual the sample is clear viscous solution. (Does not comply)**			

pH:

observed 5.41 Complies

limit: 4.0-6.9

Identification: Paracetamol identified

Assay:

Stated: 120mg/5ml

Determined 121.797mg/5ml

Percentage: 101.50% Complies

Limit 90-110%

RESULT: The above sample is **SUB-STANDARD** on the basis of **Physical Description as per USP.**

02	Suspension Parapol 120mL (Paracetamol: 120mg/5ml) **Mfg Date: Exp Date: Registration No.** 07.2023 07.2025 002772	058-24	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-75007808/DTL Dated. 12.12.2023

DTL Test Report Result

Specification applied: USP 2023

Physical Description: Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton.

As per USP<1151> Pharmaceuticals Dosage Forms; "A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase" while in actual the sample is clear viscous solution. (Does not comply)

observed 5.46 Complies

limit: 4.0-6.9

Identification: Paracetamol identified

Assay:

Stated: 120mg/5ml

Determined 123.538mg/5ml

Percentage: 102.95% Complies the test

Limit 90-110%

RESULT: The above sample is **SUB-STANDARD** on the basis of **Physical Description as per USP.**

iii. Store Keeper, Main Medicine Store, situated at CEO (DHA) Office Sargodha provided delivery challan/ Invoice/warranty No. 000163, dated 09.09.2023 issued by M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi as a proof of its purchase.
iv. Warrantor portion of drug sample was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi as a proof of its purchase.
v. Copies of test/analysis reports were sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard.

Previous Proceedings & Decision Regarding Retesting Request) (For both batches)

32nd Committee Meeting held on 25-01-2024

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **32nd meeting** held on 25-01-2024 under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. Haji Javed, Quality Control Manager of M/S Lisko Pakistan (Pvt.) appeared before the committee to plead the case.

3. The Secretary PQCB apprised the Committee that the Manufacturer requested for retesting vide letter Reference No. Nil dated 19-12-2023. The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. MSS-177699, 176662, 178849, 178850, 177698/23 dated 16-01-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard).

4. The representative of the firm appeared before the committee and submitted withdrawal request vide letter no Nil dated 24-01-2024. The committee after due deliberation and discussion unanimously decided to accept the firm's request for **withdrawal** of the retesting request of the drug samples and the Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

5. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended)/DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacture for sale/sale of the Substandard drugs**
b. **Issuance of false warranty**

6. Show cause Notice (s) issued to the accused person(s) Dated 20-06-2024.

Note: Firm AGAIN requested for retesting of the subject drug samples vide letter addressed to Drug Inspector dated 06-06-2024, as follows:

Subject: PROVISION OF DETAILS OF TECHNICAL STAFF & VERIFICATION OF INVOICES AGAINST SUPPLIED BATCH NO 054-24 & 058-24 OF PARAPOL SUSPENSION 120MG/5ML

With reference to your letter no# 137/DI/SLW in which you have informed us that DTL Rawalpindi has declared batch no# 054-24 & 058-24 of Parapol susp 120mg/5ml as sub-standard on the basis of **physical description,** we would like to bring in your kind knowledge that we have already **contested and challenged all reports by DTL Rawalpindi in PQCB and we have requested PQCB to send our samples to NIH, Islamabad for conclusive report** as DTL Rawalpindi has declared our batches sub-standard on the basis of non-pharmacopeia test whereas product complies 100% against all USP test.

As requisite, we are submitting documents and verify all invoices against supplied stock (batch no 054-24 & 058-24) to DHA Sargodha:

1. DML and renewal challan attached

2. Following persons were responsible for manufacturing, QC analysis and distribution:

Details of Managing Director

M. Muzammil Nazar

Add: House No 693, DOHS, Phase 1, Malir Cantt., Karachi

CNIC No# 42101-9965280-7

Details of Production Manager

Mr. Ghulam Nabi Khoso

Add: House No: 47-A, Sindhi Para, Shanti Nagar, Dalmia, Karachi

CNIC No# 42201-7504385-7

Details of QC Manager+ Warrantor

Mrs. Naima Khanam

Add: House No. 407-A, Block 1, U.C-5, Gulshan-e-Iqbal Karachi

CNIC No# 42201-1930079-6

We request you to kindly submit complete investigation report to honourable PQCB so that **PQCB send samples of said batches for retesting by appellate lab i.e NIH, Islamabad.**

7. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024

PROCEEDINGS & DECISION BY THE BOARD:

8. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **284th** meeting held on **05-09-2024** under the chairmanship of Secretary Primary & Secondary Healthcare Department, chairperson PQCB. Mr. Amir Mehmood Secretary DQCB Sargodha attended meeting via zoom link and Mr. Zeeshan Haider Kazmi Provincial Inspector of drugs Tehsil & District Sargodha was present along with original case record. No one among the nominated accused person was present. However, Dr Sarfraz (Business Unit & Technical Operations Head) of firm M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and reiterated to send the sample of said batches for retesting from NIH, Islamabad as PQCB already sent other batches of subject drug to NIH for retesting on the same aspect.

9. The Board after due deliberation and discussion unanimously decided to **pend** the case as on the same aspect the report of Appellate Lab is pending from NIH Islamabad and provide another opportunity of hearing to the firm in the best interest of justice.

Firm again requested to send samples of Parapol to NIH supplied to DHA Sargodha to NIH Islamabad for Retesting purpose vide letter dated 16-12-2024

With reference to PQCB meeting (284) held on 5-9-2024 regarding personal hearing for batch nof 052-24, 054-24 and 058-24 of Parapol suspension 120mng/5ml which was supplied to DHA Sargodha, in which we request honorable PQCB to send all three samples to NIH, Islamabad for re-testing purpose but till date no samples have been sent to NIH, Islamabad and case has not yet decided by POCB.

As discussed earlier, PQCB has already constituted special committee for findings and opinions on "Physical description issue of Parapol suspension" (report attached). By the grace of Almighty, findings clearly state that Parapol is a "Biphasic liquid like suspension"' having translucent appearance due to of presence of particles. On this premise, samples of 42 batches of Parapol suspension were sent to NIH, Islamabad for re-testing purpose. However, firm withdrew from re-testing request on later stages but board decided to send samples to NIH, Islamabad for conclusive report. We tried our level best to settle down case at POCB stage after favorable report from special committee but P¿CB decided to send samples to appellate lab as to get conclusive report.

In the same manner, samples of batch no# 052-24, 054-24 and 058-24 have been declared substandard by DTL Rawalpindi on invalid premise "physical description":

Batch no#	**Station**	**TRA No**	**Report Date**
056224	Sargodha	01-75007737	12/12/2023
054-24	Sargodha	01-75007807	12/12/2023
058-24	Sargodha	01-75007808	12-12-2023

We already have presented our stance comprehensively that **our product is suspension and complies all applicable test of USP monograph acetaminophen oral suspension". In the light of foregoing, we request POCB to urgently send above samples to NIH, Islamabad** in the same manner as PQCB did for 42 cases earlier.

We request honourable board to give us chance of fair trial and send samples to NIH Islamabad on urgent basis so that we may get conclusive reports appellate lab before expiry of stock (July 2025),

We shall remain thankful for your prompt response in this regard.

10. Personal Hearing notice(s) issued to accused person(s) dated 31-12-2024

PERVIOUS PROCEEDINGS & DECISION BY THE BOARD:

8. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the Chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB, Primary & Secondary Healthcare Department Punjab. Mr. Ahmad Khan Secretary DQCB Khushab attended the meeting online via zoom link and Mr. M. Anwar Provincial Inspector of drugs Tehsil & District Khushab was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. We are confident that our product is suspension and complies all applicable test of USP monograph

"acetaminophen oral suspension".

ii. As far as declaring our samples substandard declaring them to be "free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.

iii. He further reiterated firm's request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting on the same analogy as learned Board on its own motion already sent forty-two (42) samples to NIH of the same product.

6. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 054-24 & 058-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Rawalpindi on the basis of physical description as *"Pinkish Red coloured liquid"* further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 19-12-2023 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was willingly withdrawn during the hearing of 32nd Committee meeting of the Board held on 25-01-2024, which was accepted by the Board. Whereas, the re-submitted retesting request of batch no. 054-24 by the firm in its letter dated 16-12-2024 cannot be accepted and hence, is turned down. This is also in context to mention that Board in its 279th meeting dated 24-04-2024 sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976 along with the Batch No. 058-24 (under-consideration) has already been sent to NIH for testing on 25-04-2024.

7. However, Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The observations/ recommendations in letters submitted by NIH were discussed by the Board and pointwise response is as under:

i. The section 3 (z) of the Drugs Act, 1976 defines specifications as:
   a. Such specifications as may be prescribed;
   b. when the specifications are not prescribed, the specifications as contained in the most recent edition any of the Pharmacopeial publications (USP in the instant case).
   c. If no specifications are either prescribed or contained in any of the publications referred above, the specification approved for the purpose of registration under this act.

The Drugs Regulatory Authority of Pakistan ("**DRAP**") has prescribed/ registered Suspension Paracetamol 120 mg/ 5ml of M/s Lisko Pakistan (Pvt.) Limited as **Suspension.** Finished product specifications of Parapol Suspension 120 mg of M/s Lisko Pakistan (Pvt.) Limited describes appearance of the questioned product as "Pinkish Red Sweet Suspension". Hence, dosage form & physical characteristics are part of specifications. General Chapters of USP <1151> defines the dosage forms. The identification/ determination of dosage form is primary prerequisite of physical testing and same cannot be determined through HPLCs/ or any other analytical technique. DRAP issues registration certificates for different categories of drugs like Syrups/ Suspensions/ Solution, Tablet (enteric, film or sugar coated)/ Capsules/ Lozenges/ Pills and Lotions/ Ointments/ Creams/ Emulsions etc. Regulatory laboratory while issuing test/ analysis report ascertain the dosage form of a drug as per its label claim. Otherwise testing laboratory cannot question/ fail a product having tablet but claiming capsules or otherwise as method of differentiation of tablet/ capsule has not been specified in the monographs. Non utilization of General Chapters and manufacturer specifications will undermine entire regulatory regime and manufacturer will be at liberty to provide syrups in place of suspension and tablets in place of capsules. Similarly, testing laboratories fail a liquid product on appearance of crystals, discoloration/ caking, taste or bad smell etc. but same has not been specified in the monographs. The manufacturer at the time of registration submits all manufacturing procedures & stability data regarding the dosage form of product. Hence, non-identification

of dosage form will undermine the registration certificates issued by DRAP.

ii. The Board after due deliberation and detailed discussion, unanimously decided that it is legal binding on the Chief, Appellate Laboratory NIH, Islamabad to issue conclusive report as required undersection 22(5) of the Drugs Act 1976 to PQCB and same should be furnished in the form of certificate of analysis on its prescribed Form-6 under sub-section (1) of Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976. It is reiterated that DTLs failed the questioned product on the basis of physical appearance as per guidelines provided by USP through electronic mail i.e., visual inspection & filtration. Besides visual inspection, membrane filter of 0.45 micrometer was used for filtration by DTLs.

iii. DTLs tested product as per specifications. Moreover, DRAP endorses that NIH being appellate laboratory to take decision for the purpose of test/analysis of drugs. Hence, it is required to issue a conclusive report after complete testing of all batches of the questioned product.

iv. The Board disagreed withdrawing the retesting request as there is no such provision in the prevailing Drugs Act/Rules and NIH has already taken cognizance over the matter and now it is mandatory under the law to issue the test/ analysis report being the only appellate forum in this regard. Moreover, a period of 10 months has already been lapsed from the date of sending of samples and remaining shelf life of these samples is limited.

v. The section 3 (zz) of the Drugs Act, 1976 defines the "Substandard drug" means a drug which is not of specifications. According to manufacturer specification, the said drug is not of specification on physical ground which is contrary to Registration letter (R. no.002772) approved by DRAP as suspension.

8. The Board firmly opined that determining the nature of liquid pharmaceutical formulations, whether it is suspension/ syrup/ liquid/ solution etc. is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation. The Board after due deliberation and detailed discussion, unanimously decided to **pend the case** till response from NIH and same may be conveyed to Appellate Lab (NIH) in response to their letter no. F.No.1-20/17-Mis/2021-DC&TDM, dated 25-10-2024, F.No.1/20/17-Mis/2021-DC&TDM dated 04-12-2024 and F.No.1/20/17-Misc/2021-DC&TDM dated 30-12-2024 with the request to furnish conclusive test report as above endorsed by DRAP & under section 22 (5) of the Drugs Act 1976, at earliest in order

SUMMARY OF THE CASE		
1	**Sampling Date: (Form 4)**	17.10.2023
2	**Sent to DTL (Form 6):**	17.10.2023
3	**Date of receipt in DTL**	25-10-2023(after 9 days)
4	**DTL Report date**	12-12-2023
5	**Time extension granted**	Not Time Barred
6	**1ST DI Communication with firm**	15-12-2023
7	**Retesting Request of Firm**	Yes (19-12-2023)
8	**Fate of Retesting Request**	Withdrawal request of firm accepted in 32nd CM dated 25-01-2024

11	**Investigation Report of DI**	13-05-2024
12	**SCN permission**	281-M dated 06-06-2024
13	**Show cause issued**	20-06-2024
14	**Firm History: (3 years)**	Firm: 110 Product: 87

Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025

Case is placed before the Board for Decision

PROCEEDINGS & DECISION BY THE BOARD

PQCB/MSS-178849,178850/2023

Tehsil & District Sargodha

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi** through its Managing Director, M. Muzammil Nazar. 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor of M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil & District Sargodha reported that: -

i. He, on 17.10.2023, inspected the premises of Main Medicine Store, situated at CEO (DHA) Office Sargodha and took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No. 178849 and 178850, dated 17.10.2023.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Rawalpindi, as detailed below:

Sr.	**Name of Drug**	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**

01	Suspension Parapol 120mL (Paracetamol: 120mg/5ml) **Mfg Date: Exp Date: Registration No.** 07.2023 07.2025 002772	054-24	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-75007807/DTL Dated. 12.12.2023

DTL Test Report Result

Specification applied: USP 2023

Physical Description: Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton.

As per USP<1151> Pharmaceuticals Dosage Forms; "A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase" while in actual the sample is clear viscous solution. (Does not comply)

pH:

observed 5.41 Complies

limit: 4.0-6.9

Identification: Paracetamol identified

Assay:

Stated: 120mg/5ml

Determined 121.797mg/5ml

Percentage: 101.50% Complies

Limit 90-110%

RESULT: The above sample is **SUB-STANDARD** on the basis of **Physical Description as per USP.**

02	Suspension Parapol 120mL (Paracetamol: 120mg/5ml) **Mfg Date: Exp Date: Registration No.** 07.2023 07.2025 002772	058-24	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-75007808/DTL Dated. 12.12.2023

DTL Test Report Result

Specification applied: USP 2023

Physical Description: Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton.

As per USP<1151> Pharmaceuticals Dosage Forms; "A suspension is a biphasic preparation consisting of solid particles

dispersed throughout a liquid phase" while in actual the sample is clear viscous solution. (Does not comply)

observed 5.46 Complies

limit: 4.0-6.9

Identification: Paracetamol identified

Assay:

Stated: 120mg/5ml

Determined 123.538mg/5ml

Percentage: 102.95% Complies the test

Limit 90-110%

RESULT: The above sample is **SUB-STANDARD** on the basis of **Physical Description as per USP.**

iii. Store Keeper, Main Medicine Store, situated at CEO (DHA) Office Sargodha provided delivery challan/ Invoice/warranty No. 000163, dated 09.09.2023 issued by M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi as a proof of its purchase.

v. Copies of test/analysis reports were sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard.

Previous Proceedings & Decision Regarding Retesting Request) (For both batches)

32nd Committee Meeting held on 25-01-2024

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **32nd meeting** held on 25-01-2024 under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. Haji Javed, Quality Control Manager of M/S Lisko Pakistan (Pvt.) appeared before the committee to plead the case.

3. The Secretary PQCB apprised the Committee that the Manufacturer requested for retesting vide letter Reference No. Nil dated 19-12-2023. The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. MSS-177699, 176662, 178849, 178850, 177698/23 dated 16-01-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard).

4. The representative of the firm appeared before the committee and submitted withdrawal request vide letter no Nil dated 24-01-2024. The committee after due deliberation and discussion unanimously decided to accept the firm's request for **withdrawal** of the retesting request of the drug samples and the Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

5. Drug Inspector requested for grant of permission for prosecution against the above-mentioned

accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended)/DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacture for sale/sale of the Substandard drugs**
b. **Issuance of false warranty**

6. Show cause Notice (s) issued to the accused person(s) Dated 20-06-2024.

Note: Firm AGAIN requested for retesting of the subject drug samples vide letter addressed to Drug Inspector dated 06-06-2024, as follows:

Subject: PROVISION OF DETAILS OF TECHNICAL STAFF & VERIFICATION OF INVOICES AGAINST SUPPLIED BATCH NO 054-24 & 058-24 OF PARAPOL SUSPENSION 120MG/5ML

With reference to your letter no# 137/DI/SLW in which you have informed us that DTL Rawalpindi has declared batch no# 054-24 & 058-24 of Parapol susp 120mg/5ml as sub-standard on the basis of **physical description,** we would like to bring in your kind knowledge that we have already **contested and challenged all reports by DTL Rawalpindi in PQCB and we have requested PQCB to send our samples to NIH, Islamabad for conclusive report** as DTL Rawalpindi has declared our batches sub-standard on the basis of non-pharmacopeia test whereas product complies 100% against all USP test.

As requisite, we are submitting documents and verify all invoices against supplied stock (batch no 054-24 & 058-24) to DHA Sargodha:

1. DML and renewal challan attached

2. Following persons were responsible for manufacturing, QC analysis and distribution:

Details of Managing Director

M. Muzammil Nazar

Add: House No 693, DOHS, Phase 1, Malir Cantt., Karachi

CNIC No# 42101-9965280-7

Details of Production Manager

Mr. Ghulam Nabi Khoso

Add: House No: 47-A, Sindhi Para, Shanti Nagar, Dalmia, Karachi

CNIC No# 42201-7504385-7

Details of QC Manager+ Warrantor

Mrs. Naima Khanam

Add: House No. 407-A, Block 1, U.C-5, Gulshan-e-Iqbal Karachi

CNIC No# 42201-1930079-6

We request you to kindly submit complete investigation report to honourable PQCB so that **PQCB send samples of said batches for retesting by appellate lab i.e NIH, Islamabad.**

7. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024

PROCEEDINGS & DECISION BY THE BOARD:

8. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **284th** meeting held on **05-09-2024** under the chairmanship of Secretary Primary & Secondary Healthcare Department, chairperson PQCB. Mr. Amir Mehmood Secretary DQCB Sargodha attended meeting via zoom link and Mr. Zeeshan Haider Kazmi Provincial Inspector of drugs Tehsil & District Sargodha was present along with original case record. No one among the nominated accused person was present. However, Dr Sarfraz (Business Unit & Technical Operations Head) of firm M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and reiterated to send the sample of said batches for retesting from NIH, Islamabad as PQCB already sent other batches of subject drug to NIH for retesting on the same aspect.

9. The Board after due deliberation and discussion unanimously decided to **pend** the case as on the same aspect the report of Appellate Lab is pending from NIH Islamabad and provide another opportunity of hearing to the firm in the best interest of justice.

Firm again requested to send samples of Parapol to NIH supplied to DHA Sargodha to NIH Islamabad for Retesting purpose vide letter dated 16-12-2024

With reference to PQCB meeting (284) held on 5-9-2024 regarding personal hearing for batch nof 052-24, 054-24 and 058-24 of Parapol suspension 120mng/5ml which was supplied to DHA Sargodha, in which we request honorable PQCB to send all three samples to NIH, Islamabad for re-testing purpose but till date no samples have been sent to NIH, Islamabad and case has not yet decided by POCB.

As discussed earlier, PQCB has already constituted special committee for findings and opinions on "Physical description issue of Parapol suspension" (report attached). By the grace of Almighty, findings clearly state that Parapol is a "Biphasic liquid like suspension'" having translucent appearance due to of presence of particles. On this premise, samples of 42 batches of Parapol suspension were sent to NIH, Islamabad for re-testing purpose. However, firm withdrew from re-testing request on later stages but board decided to send samples to NIH, Islamabad for conclusive report. We tried our level best to settle down case at POCB stage after favorable report from special committee but P¿CB decided to send samples to appellate lab as to get conclusive report.

In the same manner, samples of batch no# 052-24, 054-24 and 058-24 have been declared substandard by DTL Rawalpindi on invalid premise "physical description":

Batch no#	Station	TRA No	Report Date
056224	Sargodha	01-75007737	12/12/2023
054-24	Sargodha	01-75007807	12/12/2023
058-24	Sargodha	01-75007808	12-12-2023

We already have presented our stance comprehensively that **our product is suspension and complies all applicable test of USP monograph acetaminophen oral suspension". In the light of foregoing, we request POCB to urgently send above samples to NIH, Islamabad** in the same manner as PQCB did for 42 cases

earlier.

We request honourable board to give us chance of fair trial and send samples to NIH Islamabad on urgent basis so that we may get conclusive reports appellate lab before expiry of stock (July 2025),

We shall remain thankful for your prompt response in this regard.

10. Personal Hearing notice(s) issued to accused person(s) dated 31-12-2024

PERVIOUS PROCEEDINGS & DECISION BY THE BOARD:

8. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the Chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB, Primary & Secondary Healthcare Department Punjab. Mr. Ahmad Khan Secretary DQCB Khushab attended the meeting online via zoom link and Mr. M. Anwar Provincial Inspector of drugs Tehsil & District Khushab was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. We are confident that our product is suspension and complies all applicable test of USP monograph "acetaminophen oral suspension".
ii. As far as declaring our samples substandard declaring them to be "free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iii. He further reiterated firm's request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting on the same analogy as learned Board on its own motion already sent forty-two (42) samples to NIH of the same product.

6. The Board after thoroughly examining the case record and scrutiny of DTL reports under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batches 054-24 & 058-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Rawalpindi on the basis of physical description as *"Pinkish Red coloured liquid"* further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 19-12-2023 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was willingly withdrawn during the hearing of 32nd Committee meeting of the Board held on 25-01-2024, which was accepted by the Board. Whereas, the re-submitted retesting request of batch no. 054-24 by the firm in its letter dated 16-12-2024 cannot be accepted and hence, is turned down. This is also in context to mention that Board in its 279th meeting dated 24-04-2024 sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976 along with the Batch No. 058-24 (under-consideration) has already been sent to NIH for testing on 25-04-2024.

7. However, Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The observations/ recommendations in letters submitted by NIH were discussed by the Board and pointwise response is as under:

i. The section 3 (z) of the Drugs Act, 1976 defines specifications as:

a. Such specifications as may be prescribed;
b. when the specifications are not prescribed, the specifications as contained in the most recent edition any of the Pharmacopeial publications (USP in the instant case).
c. If no specifications are either prescribed or contained in any of the publications referred above, the specification approved for the purpose of registration under this act.

The Drugs Regulatory Authority of Pakistan ("**DRAP**") has prescribed/ registered Suspension Paracetamol 120 mg/ 5ml of M/s Lisko Pakistan (Pvt.) Limited as **Suspension.** Finished product specifications of Parapol Suspension 120 mg of M/s Lisko Pakistan (Pvt.) Limited describes appearance of the questioned product as "Pinkish Red Sweet Suspension". Hence, dosage form & physical characteristics are part of specifications. General Chapters of USP <1151> defines the dosage forms. The identification/ determination of dosage form is primary prerequisite of physical testing and same cannot be determined through HPLCs/ or any other analytical technique. DRAP issues registration certificates for different categories of drugs like Syrups/ Suspensions/ Solution, Tablet (enteric, film or sugar coated)/ Capsules/ Lozenges/ Pills and Lotions/ Ointments/ Creams/ Emulsions etc. Regulatory laboratory while issuing test/ analysis report ascertain the dosage form of a drug as per its label claim. Otherwise testing laboratory cannot question/ fail a product having tablet but claiming capsules or otherwise as method of differentiation of tablet/ capsule has not been specified in the monographs. Non utilization of General Chapters and manufacturer specifications will undermine entire regulatory regime and manufacturer will be at liberty to provide syrups in place of suspension and tablets in place of capsules. Similarly, testing laboratories fail a liquid product on appearance of crystals, discoloration/ caking, taste or bad smell etc. but same has not been specified in the monographs. The manufacturer at the time of registration submits all manufacturing procedures & stability data regarding the dosage form of product. Hence, non-identification of dosage form will undermine the registration certificates issued by DRAP.

ii. The Board after due deliberation and detailed discussion, unanimously decided that it is legal binding on the Chief, Appellate Laboratory NIH, Islamabad to issue conclusive report as required undersection 22(5) of the Drugs Act 1976 to PQCB and same should be furnished in the form of certificate of analysis on its prescribed Form-6 under sub-section (1) of Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976. It is reiterated that DTLs failed the questioned product on the basis of physical appearance as per guidelines provided by USP through electronic mail i.e., visual inspection & filtration. Besides visual inspection, membrane filter of 0.45 micrometer was used for filtration by DTLs.
iii. DTLs tested product as per specifications. Moreover, DRAP endorses that NIH being appellate laboratory to take decision for the purpose of test/analysis of drugs. Hence, it is required to issue a conclusive report after complete testing of all batches of the questioned product.
iv. The Board disagreed withdrawing the retesting request as there is no such provision in the prevailing Drugs Act/Rules and NIH has already taken cognizance over the matter and now it is mandatory under the law to issue the test/ analysis report being the only appellate forum in this regard. Moreover, a period of 10 months has already been lapsed from the date of sending of samples and remaining shelf life of these samples is limited.
v. The section 3 (zz) of the Drugs Act, 1976 defines the "Substandard drug" means a drug which is not of specifications. According to manufacturer specification, the said drug is not of specification on physical ground which is contrary to Registration letter (R. no.002772) approved by DRAP as suspension.

8. The Board firmly opined that determining the nature of liquid pharmaceutical formulations, whether it is suspension/ syrup/ liquid/ solution etc. is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation. The Board after due deliberation and detailed discussion, unanimously decided to **pend the case** till response from NIH and same may be conveyed to Appellate Lab (NIH) in response to their letter no. F.No.1-20/17-Mis/2021-DC&TDM, dated 25-10-2024, F.No.1/20/17-Mis/2021-DC&TDM dated 04-12-2024 and F.No.1/20/17-Misc/2021-DC&TDM dated 30-12-2024 with the request to furnish conclusive test report as above endorsed by DRAP & under section 22 (5) of the Drugs Act 1976, at earliest in order

SUMMARY OF THE CASE		
1	**Sampling Date: (Form 4)**	17.10.2023
2	**Sent to DTL (Form 6):**	17.10.2023

3	**Date of receipt in DTL**	25-10-2023(after 9 days)
4	**DTL Report date**	12-12-2023
5	**Time extension granted**	Not Time Barred
6	**1ST DI Communication with firm**	15-12-2023
7	**Retesting Request of Firm**	Yes (19-12-2023)
8	**Fate of Retesting Request**	Withdrawal request of firm accepted in 32nd CM dated 25-01-2024
11	**Investigation Report of DI**	13-05-2024
12	**SCN permission**	281-M dated 06-06-2024
13	**Show cause issued**	20-06-2024
14	**Firm History: (3 years)**	Firm: 110 Product: 87

Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025

Case is placed before the Board for Decision

PROCEEDINGS & DECISION BY THE BOARD

Case No. 10

MSS-176662/2023

THQ Hospital Sillanwali, District Sargodha

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi** through its Chief Executive Officer/ Managing Director, M. Muzammil Nazar. 2. M. Muzammil Nazar Chief Executive Officer/ Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor of M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, THQ Hospital Sillanwali reported that: -

i. She, on 28.09.2023, inspected the premises of Main Medicine Store, THQH Sillanwali situated at Kachahri Road, Sillanwali, District Sargodha and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No. 176662, dated 20.10.2023.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Rawalpindi, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**
Suspension Parapol 120mL (Paracetamol: 120mg/5ml) **Mfg Date: Exp Date: Registration No.** 07.2023 07.2025 002772	052-24	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-75007737/DTL Dated. 12.12.2023

Specs Applied: USP 2024/Others/In house

COMPOSITION: Each 5ml contains:

Paracetamol USP…. 120mg

PHYSICAL CHARACTERISTICS:

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles,

filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9

Determined: 5.4 @ 23.4ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml

Determined 122.50 mg/5ml (102.08%)

Limit 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected

Diethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected

Propylene Glycol

Determined: 10.815%

iii. Store Keeper, Main Medicine Store, THQH Sillanwali situated at Kachahri Road, Sillanwali, District Sargodha provided delivery challan/ Invoice/warranty No. 000172, dated 09.09.2023 issued by M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal “B” Industrial Area, Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi as a proof of its purchase.

v. A copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed

Rashid Minhas Road, Federal "B" Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard.

Previous Proceedings & Decision by the Board: (Regarding Retesting Request)

32nd Committee Meeting held on 25-01-2024

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **32nd meeting** held on 25-01-2024 under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. Haji Javed, Quality Control Manager of M/S Lisko Pakistan (Pvt.) appeared before the committee to plead the case.

3. The Secretary PQCB apprised the Committee that the Manufacturer requested for retesting vide letter Reference No. Nil dated 19-12-2023. The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. MSS-177699, 176662, 178849, 178850, 177698/23 dated 16-01-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard).

4. The representative of the firm appeared before the committee and submitted withdrawal request vide letter no Nil dated 24-01-2024. The committee after due deliberation and discussion unanimously **decided to accept the firm's request for withdrawal of the retesting request** of the drug samples and the Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board

5. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacture for sale/sale of the Substandard drug**
b. **Issuance of false warranty**

6. Show cause Notice (s) issued to the accused person(s) Dated 20-06-2024.

Note: Firm AGAIN requested for retesting of the subject drug samples vide letter addressed to Drug Inspector dated 06-06-2024, as follows:

Subject: PROVISION OF DETAILS OF TECHNICAL STAFF & VERIFICATION OF INVOICES AGAINST SUPPLIED BATCH NO 052-24 OF PARAPOL SUSPENSION 120MG/5ML

With reference to your letter no# 137/DI/SLW in which you have informed us that DTL Rawalpindi has declared batch no# 052-24 of Parapol susp 120mg/5ml as sub-standard on the basis of **physical description,** we would like to bring in your kind knowledge that we have already **contested and challenged all reports by DTL Rawalpindi in PQCB and we have requested PQCB to send our samples to NIH, Islamabad for conclusive report** as DTL Rawalpindi has declared our batches sub-standard on the basis of non-pharmacopeia test whereas product complies 100% against all USP test.

As requisite, we are submitting documents and verify all invoices against supplied stock (batch no 052-24) to THQ Hospital Silanwali:

1. DML and renewal challan attached

2. Following persons were responsible for manufacturing, QC analysis and distribution:

Details of Managing Director

M. Muzammil Nazar

Add: House No 693, DOHS, Phase 1, Malir Cantt., Karachi

CNIC No# 42101-9965280-7

Details of Production Manager

Mr. Ghulam Nabi Khoso

Add: House No: 47-A, Sindhi Para, Shanti Nagar, Dalmia, Karachi

CNIC No# 42201-7504385-7

Details of QC Manager+ Warrantor

Mrs. Naima Khanam

Add: House No. 407-A, Block 1, U.C-5, Gulshan-e-Iqbal Karachi

CNIC No# 42201-1930079-6

We request you to kindly submit complete investigation report to honourable PQCB so that **PQCB send samples of said batches for retesting by appellate lab i.e NIH, Islamabad.**

7. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024

PROCEEDINGS & DECISION BY THE BOARD:

8 The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **284th** meeting held on **05-09-2024** under the chairmanship of Secretary Primary & Secondary Healthcare Department, chairperson PQCB. Mr. Amir Mehmood Secretary DQCB Sargodha attended meeting via zoom link and Mst Bushra Maryam Provincial Inspector of drugs THQ Hospital Sillanwali was present along with original case record. No one among the nominated accused person was present. However, Dr Sarfraz (Business Unit & Technical Operations Head) of firm M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and reiterated to send the sample for retesting from NIH, Islamabad as PQCB already sent other batches of subject drug to NIH for retesting.

9. The Board after due deliberation and discussion unanimously decided to **pend** the case as on the same aspect the report of Appellate Lab is pending from NIH Islamabad and provide another opportunity of hearing to the firm in the best interest of justice.

Firm again requested to send samples of Parapol to NIH supplied to DHA Sargodha to NIH Islamabad for Retesting purpose vide letter dated 16-12-2024

With reference to PQCB meeting (284) held on 5-9-2024 regarding personal hearing for batch nof 052-24, 054-24 and 058-24 of Parapol suspension 120mng/5ml which was supplied to DHA Sargodha, in which we request honorable PQCB to send all three samples to NIH, Islamabad for re-testing purpose but till date no samples have been sent to NIH, Islamabad and case has not yet decided by POCB.

As discussed earlier, PQCB has already constituted special committee for findings and opinions on "Physical description

issue of Parapol suspension" (report attached). By the grace of Almighty, findings clearly state that Parapol is a "Biphasic liquid like suspension"' having translucent appearance due to of presence of particles. On this premise, samples of 42 batches of Parapol suspension were sent to NIH, Islamabad for re-testing purpose. However, firm withdrew from re-testing request on later stages but board decided to send samples to NIH, Islamabad for conclusive report. We tried our level best to settle down case at POCB stage after favorable report from special committee but P¿CB decided to send samples to appellate lab as to get conclusive report.

In the same manner, samples of batch no# 052-24, 054-24 and 058-24 have been declared substandard by DTL Rawalpindi on invalid premise "physical description":

Batch no#	**Station**	**TRA No**	**Report Date**
056224	Sargodha	01-75007737	12/12/2023
054-24	Sargodha	01-75007807	12/12/2023
058-24	Sargodha	01-75007808	12-12-2023

We already have presented our stance comprehensively that **our product is suspension and complies all applicable test of USP monograph acetaminophen oral suspension". In the light of foregoing, we request PQCB to urgently send above samples to NIH, Islamabad** in the same manner as PQCB did for 42 cases earlier.

We request honourable board to give us chance of fair trial and send samples to NIH Islamabad on urgent basis so that we may get conclusive reports appellate lab before expiry of stock (July 2025). We shall remain thankful for your prompt response in this regard.

10. Personal Hearing notice(s) issued to accused person(s) dated 31-12-2024

Case is placed before the Board for Decision

PERVIOUS PROCEEEDINGS & DECISION BY THE BOARD:

11. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the Chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB, Primary & Secondary Healthcare Department Punjab. Mr. Ahmad Khan Secretary DQCB Khushab attended the meeting online via zoom link and Mr. M. Anwar Provincial Inspector of drugs Tehsil & District Khushab was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. We are confident that our product is suspension and complies all applicable test of USP monograph “acetaminophen oral suspension”.
ii. As far as declaring our samples substandard declaring them to be “free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent

to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.

iii. He further reiterated firm's request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting on the same analogy

as learned Board on its own motion already sent forty-two (42) samples to NIH of the same product.

12. The Board after thoroughly examining the case record and scrutiny of DTL report under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batch 052-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Rawalpindi on the basis of physical description as *"Pinkish Red coloured liquid"* further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 19-12-2023 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was willingly withdrawn during the hearing of 32nd Committee meeting of the Board held on 25-01-2024, which was accepted by the Board. Whereas, the re-submitted retesting request of the subject batch number 052-24 by the firm in its letter dated 16-12-2024 cannot be accepted and hence, is turned down This is also in context to mention that Board in its 279th meeting dated 24-04-2024 sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976.

13. However, Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The observations/ recommendations in letters submitted by NIH were discussed by the Board and pointwise response is as under:

i. The section 3 (z) of the Drugs Act, 1976 defines specifications as:
   a. Such specifications as may be prescribed;
   b. when the specifications are not prescribed, the specifications as contained in the most recent edition any of the Pharmacopeial publications (USP in the instant case).
   c. If no specifications are either prescribed or contained in any of the publications referred above, the specification approved for the purpose of registration under this act.

The Drugs Regulatory Authority of Pakistan ("**DRAP**") has prescribed/ registered Suspension Paracetamol 120 mg/ 5ml of M/s Lisko Pakistan (Pvt.) Limited as **Suspension.** Finished product specifications of Parapol Suspension 120 mg of M/s Lisko Pakistan (Pvt.) Limited describes appearance of the questioned product as "Pinkish Red Sweet Suspension". Hence, dosage form & physical characteristics are part of specifications. General Chapters of USP <1151> defines the dosage forms. The identification/ determination of dosage form is primary prerequisite of physical testing and same cannot be determined through HPLCs/ or any other analytical technique. DRAP issues registration certificates for different categories of drugs like Syrups/ Suspensions/ Solution, Tablet (enteric, film or sugar coated)/ Capsules/ Lozenges/ Pills and Lotions/ Ointments/ Creams/ Emulsions etc. Regulatory laboratory while issuing test/ analysis report ascertain the dosage form of a drug as per its label claim. Otherwise testing laboratory cannot question/ fail a product having tablet but claiming capsules or otherwise as method of differentiation of tablet/ capsule has not been specified in the monographs. Non utilization of General Chapters and manufacturer specifications will undermine entire regulatory regime and manufacturer will be at liberty to provide syrups in place of suspension and tablets in place of capsules. Similarly, testing laboratories fail a liquid product on appearance of crystals, discoloration/ caking, taste or bad smell etc. but same has not been specified in the monographs. The manufacturer at the time of registration submits all manufacturing procedures & stability data regarding the dosage form of product. Hence, non-identification of dosage form will undermine the registration certificates issued by DRAP.

ii. The Board after due deliberation and detailed discussion, unanimously decided that it is legal binding on the Chief, Appellate Laboratory NIH, Islamabad to issue conclusive report as required undersection 22(5) of the Drugs Act 1976 to PQCB and same should be furnished in the form of certificate of analysis on its prescribed Form-6 under sub-section (1) of Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976. It is reiterated that DTLs failed the questioned product on the basis of physical appearance as per guidelines provided by USP through electronic mail i.e., visual inspection & filtration. Besides visual inspection, membrane filter of 0.45 micrometre was used for filtration by DTLs.

iii. DTLs tested product as per specifications. Moreover, DRAP endorses that NIH being appellate laboratory to take decision for the purpose of test/analysis of drugs. Hence, it is required to issue a conclusive report after complete testing of all batches of the questioned product.

iv. The Board disagreed withdrawing the retesting request as there is no such provision in the prevailing Drugs Act/Rules and NIH has already taken cognizance over the matter and now it is mandatory under the law to issue the test/ analysis report being the only appellate forum in this regard. Moreover, a period of 10 months has already been lapsed from the date of sending of samples and remaining shelf life of these samples is limited.

v. The section 3 (zz) of the Drugs Act, 1976 defines the "Substandard drug" means a drug which is not of specifications. According to manufacturer specification, the said drug is not of specification on physical ground which is contrary to Registration letter (R. no.002772) approved by DRAP as suspension.

14. The Board firmly opined that determining the nature of liquid pharmaceutical formulations, whether it is suspension/ syrup/ liquid/ solution etc. is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation. The Board after due deliberation and detailed discussion, unanimously decided to **pend the case** till response from NIH and same may be conveyed to Appellate Lab (NIH) in response to their letter no. F.No.1-20/17-Mis/2021-DC&TDM, dated 25-10-2024, F.No.1/20/17-Mis/2021-DC&TDM dated 04-12-2024 and F.No.1/20/17-Misc/2021-DC&TDM dated 30-12-2024 with the request to furnish conclusive test report at earliest as above endorsed by DRAP & under section 22 (5) of the Drugs Act 1976, in order to avoid further delay in the proceedings of the subject cases.

Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025

SUMMARY OF THE CASE		
1	**Sampling Date: (Form 4)**	28.09.2023
2	**Sent to DTL (Form 6):**	28-09-2023 (20-10-2023 as per DTL)
3	**Date of receipt in DTL**	23-10-2023 (After approx. 22 days from Form-4)
4	**DTL Report date**	12-12-2023
5	**Time extension granted**	Not Time Barred
6	**1ST DI Communication with firm**	12-03-2024
7	**Retesting Request of Firm**	Yes (19-12-2023)
8	**Fate of Retesting Request**	Withdrawal request of firm accepted in 32nd CM dated 25-01-2024

11	**Investigation Report of DI**	13-05-2024
12	**SCN permission**	281-M dated 06-06-2024
13	**Show cause issued**	20-06-2024
14	**Firm History: (3 years)**	Firm: 110 Product: 87

Case is placed before the Board for Descion

PROCEEEDINGS & DECISION BY THE BOARD

MSS-176662/2023

THQ Hospital Sillanwali, District Sargodha

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi** through its Chief Executive Officer/ Managing Director, M. Muzammil Nazar. 2. M. Muzammil Nazar Chief Executive Officer/ Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor of M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, THQ Hospital Sillanwali reported that: -

i. She, on 28.09.2023, inspected the premises of Main Medicine Store, THQH Sillanwali situated at Kachahri Road, Sillanwali, District Sargodha and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No. 176662, dated 20.10.2023.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Rawalpindi, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date

Suspension Parapol 120mL (Paracetamol: 120mg/5ml) **Mfg Date: Exp Date: Registration No.** 07.2023 07.2025 002772	052-24	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-75007737/DTL Dated. 12.12.2023

Specs Applied: USP 2024/Others/In house

COMPOSITION: Each 5ml contains:

Paracetamol USP…. 120mg

PHYSICAL CHARACTERISTICS:

Stated: Pinkish red sweet suspension.

Determined: Parapol is a pinkish red, bitter viscous liquid and free from any dispersed solid particles, filled in an amber plastic bottle, sealed with a white screw cap, further packed in a labeled outer carton.

As per USP <1151> Pharmaceutical Dosage Forms "A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

pH:

Limit: 4.0-6.9

Determined: 5.4 @ 23.4ºC

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml

Determined 122.50 mg/5ml (102.08%)

Limit 90.0-110.0%

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected

Diethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected

Propylene Glycol

Determined: 10.815%

iii. Store Keeper, Main Medicine Store, THQH Sillanwali situated at Kachahri Road, Sillanwali, District Sargodha provided delivery challan/ Invoice/warranty No. 000172, dated 09.09.2023 issued by M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi as a proof of its purchase.

v. A copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard.

Previous Proceedings & Decision by the Board: (Regarding Retesting Request)

32nd Committee Meeting held on 25-01-2024

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **32nd meeting** held on 25-01-2024 under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. Haji Javed, Quality Control Manager of M/S Lisko Pakistan (Pvt.) appeared before the committee to plead the case.

3. The Secretary PQCB apprised the Committee that the Manufacturer requested for retesting vide letter Reference No. Nil dated 19-12-2023. The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. MSS-177699, 176662, 178849, 178850, 177698/23 dated 16-01-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard).

4. The representative of the firm appeared before the committee and submitted withdrawal request vide letter no Nil dated 24-01-2024. The committee after due deliberation and discussion unanimously **decided to accept the firm's request for withdrawal of the retesting request** of the drug samples and the Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board

5. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacture for sale/sale of the Substandard drug**

b. **Issuance of false warranty**

6. Show cause Notice (s) issued to the accused person(s) Dated 20-06-2024.

Note: Firm AGAIN requested for retesting of the subject drug samples vide letter addressed to Drug Inspector dated 06-06-2024, as follows:

Subject: PROVISION OF DETAILS OF TECHNICAL STAFF & VERIFICATION OF INVOICES AGAINST SUPPLIED BATCH NO 052-24 OF PARAPOL SUSPENSION 120MG/5ML

With reference to your letter no# 137/DI/SLW in which you have informed us that DTL Rawalpindi has declared batch no# 052-24 of Parapol susp 120mg/5ml as sub-standard on the basis of **physical description,** we would like to bring in your kind knowledge that we have already **contested and challenged all reports by DTL Rawalpindi in PQCB and we have requested PQCB to send our samples to NIH, Islamabad for conclusive report** as DTL Rawalpindi has declared our batches sub-standard on the basis of non-pharmacopeia test whereas product complies 100% against all USP test.

As requisite, we are submitting documents and verify all invoices against supplied stock (batch no 052-24) to THQ Hospital Silanwali:

1. DML and renewal challan attached

2. Following persons were responsible for manufacturing, QC analysis and distribution:

Details of Managing Director

M. Muzammil Nazar

Add: House No 693, DOHS, Phase 1, Malir Cantt., Karachi

CNIC No# 42101-9965280-7

Details of Production Manager

Mr. Ghulam Nabi Khoso

Add: House No: 47-A, Sindhi Para, Shanti Nagar, Dalmia, Karachi

CNIC No# 42201-7504385-7

Details of QC Manager+ Warrantor

Mrs. Naima Khanam

Add: House No. 407-A, Block 1, U.C-5, Gulshan-e-Iqbal Karachi

CNIC No# 42201-1930079-6

We request you to kindly submit complete investigation report to honourable PQCB so that **PQCB send samples of said batches for retesting by appellate lab i.e NIH, Islamabad.**

7. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024

PROCEEDINGS & DECISION BY THE BOARD:

8 The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **284th** meeting held on **05-09-2024** under the chairmanship of Secretary Primary & Secondary Healthcare Department, chairperson PQCB. Mr. Amir Mehmood Secretary DQCB Sargodha attended meeting via zoom link

and Mst Bushra Maryam Provincial Inspector of drugs THQ Hospital Sillanwali was present along with original case record. No one among the nominated accused person was present. However, Dr Sarfraz (Business Unit & Technical Operations Head) of firm M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and reiterated to send the sample for retesting from NIH, Islamabad as PQCB already sent other batches of subject drug to NIH for retesting.

9. The Board after due deliberation and discussion unanimously decided to **pend** the case as on the same aspect the report of Appellate Lab is pending from NIH Islamabad and provide another opportunity of hearing to the firm in the best interest of justice.

Firm again requested to send samples of Parapol to NIH supplied to DHA Sargodha to NIH Islamabad for Retesting purpose vide letter dated 16-12-2024

With reference to PQCB meeting (284) held on 5-9-2024 regarding personal hearing for batch nof 052-24, 054-24 and 058-24 of Parapol suspension 120mng/5ml which was supplied to DHA Sargodha, in which we request honorable PQCB to send all three samples to NIH, Islamabad for re-testing purpose but till date no samples have been sent to NIH, Islamabad and case has not yet decided by POCB.

As discussed earlier, PQCB has already constituted special committee for findings and opinions on "Physical description issue of Parapol suspension" (report attached). By the grace of Almighty, findings clearly state that Parapol is a "Biphasic liquid like suspension'" having translucent appearance due to of presence of particles. On this premise, samples of 42 batches of Parapol suspension were sent to NIH, Islamabad for re-testing purpose. However, firm withdrew from re-testing request on later stages but board decided to send samples to NIH, Islamabad for conclusive report. We tried our level best to settle down case at POCB stage after favorable report from special committee but P¿CB decided to send samples to appellate lab as to get conclusive report.

In the same manner, samples of batch no# 052-24, 054-24 and 058-24 have been declared substandard by DTL Rawalpindi on invalid premise "physical description":

Batch no#	**Station**	**TRA No**	**Report Date**
056224	Sargodha	01-75007737	12/12/2023
054-24	Sargodha	01-75007807	12/12/2023
058-24	Sargodha	01-75007808	12-12-2023

We already have presented our stance comprehensively that **our product is suspension and complies all applicable test of USP monograph acetaminophen oral suspension". In the light of foregoing, we request PQCB to urgently send above samples to NIH, Islamabad** in the same manner as PQCB did for 42 cases earlier.

We request honourable board to give us chance of fair trial and send samples to NIH Islamabad on urgent basis so that we may get conclusive reports appellate lab before expiry of stock (July 2025). We shall remain thankful for your prompt response in this regard.

10. Personal Hearing notice(s) issued to accused person(s) dated 31-12-2024

Case is placed before the Board for Decision

PERVIOUS PROCEEEDINGS & DECISION BY THE BOARD:

11. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **287th** meeting held on **08-01-2025** under the Chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB, Primary & Secondary Healthcare Department Punjab. Mr. Ahmad Khan Secretary DQCB Khushab attended the meeting online via zoom link and Mr. M. Anwar Provincial Inspector of drugs Tehsil & District Khushab was present along with original case record. Among the nominated accused persons, M. Muzammil (Director) of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi appeared before the Board and presented following grounds:

i. We are confident that our product is suspension and complies all applicable test of USP monograph "acetaminophen oral suspension".
ii. As far as declaring our samples substandard declaring them to be "free from any dispersed solid particles" by quoting USP General Chapter <1151> in the DTL report is concerned, it is pertinent to highlight that PQCB has already investigated similar cases in this regard and constituted a special committee of pharmaceutical experts which concluded its findings in our favor whilst concluding that Parapol is a "Biphasic liquid like suspension" having translucent appearance due to presence of particles.
iii. He further reiterated firm's request to send the subject drug samples to Appellate Laboratory, National Institute of Health Islamabad for retesting on the same analogy

as learned Board on its own motion already sent forty-two (42) samples to NIH of the same product.

12. The Board after thoroughly examining the case record and scrutiny of DTL report under section 11 (5) (b) of The Drugs Act 1976 & the Rules framed thereunder, observed that the subject batch 052-24 of the drug sample Parapol Suspension [Each 5ml contains: Paracetamol USP…120mg], , have been declared substandard by the Drugs Testing Laboratory, Rawalpindi on the basis of physical description as *"Pinkish Red coloured liquid"* further reporting that "As per USP <1151> Pharmaceutical Dosage Forms; "*A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*" while in actual the sample is clear viscous solution". Upon perusal of the case record, Board further observed that the firm applied for retesting of their subject drug samples on 19-12-2023 from the Appellate Laboratory under Section 22 (4) of The Drugs Act 1976. However, the same was willingly withdrawn during the hearing of 32nd Committee meeting of the Board held on 25-01-2024, which was accepted by the Board. Whereas, the re-submitted retesting request of the subject batch number 052-24 by the firm in its letter dated 16-12-2024 cannot be accepted and hence, is turned down This is also in context to mention that Board in its 279th meeting dated 24-04-2024 sent forty-two (42) such kind of substandard samples to the Appellate Laboratory (NIH) on its own motion as empowered under Section 22(5) of The Drugs Act 1976.

13. However, Secretary PQCB apprised the Board that the Appellate Laboratory (NIH) has not issued report till to date of the already sent samples even after a lapse of eight (08) months on the prescribed Form-6 under Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976, even on clarification by the PQCB to NIH after detailed discussion in 283rd & 284th meeting of the Board, wherein the Board endorsed the version of the Government Analyst and reply of the email to USP. The Board further deliberated on the inability of the Appellate Laboratory (NIH) to differentiate between the formulations as suspension and viscous liquid. The observations/ recommendations in letters submitted by NIH were discussed by the Board and pointwise response is as under:

i. The section 3 (z) of the Drugs Act, 1976 defines specifications as:
    a. Such specifications as may be prescribed;
    b. when the specifications are not prescribed, the specifications as contained in the most recent edition any of the Pharmacopeial publications (USP in the instant case).

c. If no specifications are either prescribed or contained in any of the publications referred above, the specification approved for the purpose of registration under this act.

The Drugs Regulatory Authority of Pakistan ("**DRAP**") has prescribed/ registered Suspension Paracetamol 120 mg/ 5ml of M/s Lisko Pakistan (Pvt.) Limited as **Suspension.** Finished product specifications of Parapol Suspension 120 mg of M/s Lisko Pakistan (Pvt.) Limited describes appearance of the questioned product as "Pinkish Red Sweet Suspension". Hence, dosage form & physical characteristics are part of specifications. General Chapters of USP <1151> defines the dosage forms. The identification/ determination of dosage form is primary prerequisite of physical testing and same cannot be determined through HPLCs/ or any other analytical technique. DRAP issues registration certificates for different categories of drugs like Syrups/ Suspensions/ Solution, Tablet (enteric, film or sugar coated)/ Capsules/ Lozenges/ Pills and Lotions/ Ointments/ Creams/ Emulsions etc. Regulatory laboratory while issuing test/ analysis report ascertain the dosage form of a drug as per its label claim. Otherwise testing laboratory cannot question/ fail a product having tablet but claiming capsules or otherwise as method of differentiation of tablet/ capsule has not been specified in the monographs. Non utilization of General Chapters and manufacturer specifications will undermine entire regulatory regime and manufacturer will be at liberty to provide syrups in place of suspension and tablets in place of capsules. Similarly, testing laboratories fail a liquid product on appearance of crystals, discoloration/ caking, taste or bad smell etc. but same has not been specified in the monographs. The manufacturer at the time of registration submits all manufacturing procedures & stability data regarding the dosage form of product. Hence, non-identification of dosage form will undermine the registration certificates issued by DRAP.

ii. The Board after due deliberation and detailed discussion, unanimously decided that it is legal binding on the Chief, Appellate Laboratory NIH, Islamabad to issue conclusive report as required undersection 22(5) of the Drugs Act 1976 to PQCB and same should be furnished in the form of certificate of analysis on its prescribed Form-6 under sub-section (1) of Rule 16 of The Drugs (Federal inspector, Federal Drug Laboratory and Federal Government Analyst) Rules 1976. It is reiterated that DTLs failed the questioned product on the basis of physical appearance as per guidelines provided by USP through electronic mail i.e., visual inspection & filtration. Besides visual inspection, membrane filter of 0.45 micrometre was used for filtration by DTLs.

iii. DTLs tested product as per specifications. Moreover, DRAP endorses that NIH being appellate laboratory to take decision for the purpose of test/analysis of drugs. Hence, it is required to issue a conclusive report after complete testing of all batches of the questioned product.

iv. The Board disagreed withdrawing the retesting request as there is no such provision in the prevailing Drugs Act/Rules and NIH has already taken cognizance over the matter and now it is mandatory under the law to issue the test/ analysis report being the only appellate forum in this regard. Moreover, a period of 10 months has already been lapsed from the date of sending of samples and remaining shelf life of these samples is limited.

v. The section 3 (zz) of the Drugs Act, 1976 defines the "Substandard drug" means a drug which is not of specifications. According to manufacturer specification, the said drug is not of specification on physical ground which is contrary to Registration letter (R. no.002772) approved by DRAP as suspension.

14. The Board firmly opined that determining the nature of liquid pharmaceutical formulations, whether it is suspension/ syrup/ liquid/ solution etc. is the exclusive scope or legal mandate of any regulatory Drug Testing Laboratory, to give declaration as per label claim of any formulation. The Board after due deliberation and detailed discussion, unanimously decided to **pend the case** till response from NIH and same may be conveyed to Appellate Lab (NIH) in response to their letter no. F.No.1-20/17-Mis/2021-DC&TDM, dated 25-10-2024, F.No.1/20/17-Mis/2021-DC&TDM dated 04-12-2024 and F.No.1/20/17-Misc/2021-DC&TDM dated 30-12-2024 with the request to furnish conclusive test report at earliest as above endorsed by DRAP & under section 22 (5) of the Drugs Act 1976, in order to avoid further delay in the proceedings of the subject cases.

Personal Hearing notice(s) issued to accused person(s) dated 20-03-2025

SUMMARY OF THE CASE		
1	**Sampling Date: (Form 4)**	28.09.2023

2	**Sent to DTL (Form 6):**	28-09-2023 (20-10-2023 as per DTL)
3	**Date of receipt in DTL**	23-10-2023 (After approx. 22 days from Form-4)
4	**DTL Report date**	12-12-2023
5	**Time extension granted**	Not Time Barred
6	**1ST DI Communication with firm**	12-03-2024
7	**Retesting Request of Firm**	Yes (19-12-2023)
8	**Fate of Retesting Request**	Withdrawal request of firm accepted in 32nd CM dated 25-01-2024
11	**Investigation Report of DI**	13-05-2024
12	**SCN permission**	281-M dated 06-06-2024
13	**Show cause issued**	20-06-2024
14	**Firm History: (3 years)**	Firm: 110 Product: 87

Case is placed before the Board for Descion

PROCEEEDINGS & DECISION BY THE BOARD

Case No. 11

PQCB/MSS-185879/2024

(Tehsil Safdarabad District Sheikhupura)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi** through its Managing Director, M. Muzammil Nazar. 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Safdarabad District Sheikhupura reported that: -

i. He, on 14.12.2023, inspected the manufacturing premises of M/s Main Medicine Store (M.S.D.) situated inside Tehsil Head Quarter (T.H.Q.) Hospital, Safdarabad, Tehsil Safdarabad District Sheikhupura and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 185879 dated 14.12.2023.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Lahore, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Syrup Fulliron (Iron III Hydroxide Polymaltose Complex eq. to Elemental Iron: 50mg/5mL) **Mfg. Date: Exp. Date: Registration No.** 07.2022 07.2024 086915	005-23	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-10193000465/DTL Dated. 14.02.2024

DTL Test Report Result

Specification applied: MS

Physical Characteristics: Brown colored liquid in amber glass bottle having label pasted on it, sealed with white aluminium screw cap. **Solid mass was found in the bottom of the bottle which does not dissolve upon vigorous shaking. Upon standing the liquid separates into two phases while label claims it to be syrup. (Does not comply)**

IDENTIFICATION: Iron is identified.

ASSAY: Stated: 50mg/5mL, **Determined: 8.57mg/5mL, Percentage: 17.14%,** Limit: 80-120% of the stated amount **(Does not Comply)**

RESULT: The above sample is **Substandard** on the basis of **"Physical Description and Assay Tests"** as per The Drugs Act 1976, {3(zz)}.

iii. Pharmacy Manager, Main Medicine Store (M.S.D.) situated inside Tehsil Head Quarter (T.H.Q.) Hospital, Safdarabad, Tehsil Safdarabad District Sheikhupura provided invoice/ warranty no. 000156 dated 03.09.2022 issued by M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.
iv. The Provincial Inspector of Drugs ordered the Store keeper and pharmacy manager, not to dispose of stock in their possession vide Form-3 dated 14.12.2023
v. Warrantor portion of drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.
vi. A copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

i. **Manufacture for sale/sale of Substandard Drug**
ii. **Issuance of false warranty**
iii. **Disobey the Lawful Authority**

3. The Show-Cause/ Personal Hearing Notice was issued to the accused person (s) on 11.09.2024.

4. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 07.2022

Expiry Date: 07.2024

Sampling Date (Form 4): 14.12.2023

Sent to DTL (Form 6): 14.12.2023

Date of receipt in DTL: 19.12.2023

DTL Report Date (Form 7): 14.02.2024

Time Extension: N/A

1ST DI Communication with firm on dated: 19.02.2024

Date of Retesting Request of Firm: N/A

Fate of Retesting: N/A

Investigation Report Dated: 20.05.2024

Permission of SCN: 282-M

SC/PHN issued: 11.09.2024

Reply of firm:

History of Lisko (Last 03 Years): Product: 04 reported case including subject case, Firm: 111 cases reported.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-185879/2024

(Tehsil Safdarabad District Sheikhupura)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi** through its Managing Director, M. Muzammil Nazar. 2. M. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Safdarabad District Sheikhupura reported that: -

i. He, on 14.12.2023, inspected the manufacturing premises of M/s Main Medicine Store (M.S.D.) situated inside Tehsil Head Quarter (T.H.Q.) Hospital, Safdarabad, Tehsil Safdarabad District Sheikhupura and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 185879 dated 14.12.2023.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Lahore, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Syrup Fulliron (Iron III Hydroxide Polymaltose Complex eq. to Elemental Iron: 50mg/5mL) **Mfg. Date: Exp. Date: Registration No.** 07.2022 07.2024 086915	005-23	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-10193000465/DTL Dated. 14.02.2024

DTL Test Report Result

Specification applied: MS

Physical Characteristics: Brown colored liquid in amber glass bottle having label pasted on it, sealed with white aluminium screw cap. **Solid mass was found in the bottom of the bottle which does not dissolve upon vigorous shaking. Upon standing the liquid separates into two phases while label claims it to be syrup. (Does not comply)**

IDENTIFICATION: Iron is identified.

ASSAY: Stated: 50mg/5mL, **Determined: 8.57mg/5mL, Percentage: 17.14%,** Limit: 80-120% of the stated amount **(Does not Comply)**

RESULT: The above sample is **Substandard** on the basis of **"Physical Description and Assay Tests"** as per The Drugs Act 1976, {3(zz)}.

iii. Pharmacy Manager, Main Medicine Store (M.S.D.) situated inside Tehsil Head Quarter (T.H.Q.) Hospital, Safdarabad, Tehsil Safdarabad District Sheikhupura provided invoice/ warranty no. 000156 dated 03.09.2022 issued by M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.
iv. The Provincial Inspector of Drugs ordered the Store keeper and pharmacy manager, not to dispose of stock in their possession vide Form-3 dated 14.12.2023
v. Warrantor portion of drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi.
vi. A copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

i. **Manufacture for sale/sale of Substandard Drug**
ii. **Issuance of false warranty**
iii. **Disobey the Lawful Authority**

3. The Show-Cause/ Personal Hearing Notice was issued to the accused person (s) on 11.09.2024.

4. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 07.2022

Expiry Date: 07.2024

Sampling Date (Form 4): 14.12.2023

Sent to DTL (Form 6): 14.12.2023

Date of receipt in DTL: 19.12.2023

DTL Report Date (Form 7): 14.02.2024

Time Extension: N/A

1ST DI Communication with firm on dated: 19.02.2024

Date of Retesting Request of Firm: N/A

Fate of Retesting: N/A

Investigation Report Dated: 20.05.2024

Permission of SCN: 282-M

SC/PHN issued: 11.09.2024

Reply of firm:

History of Lisko (Last 03 Years): Product: 04 reported case including subject case, Firm: 111 cases reported.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 12

PQCB/MSS-193304/2024

(Govt. Teaching Hospital Shahdra, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore-Pakistan** through its Managing Partner, Kashif Liaqat Ali 2. Kashif Liaqat Ali — Managing Partner 3. Abdul Rauf — Production Incharge/Warrantor 4. Junaid Zafar — Quality Control Manager of M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore- Pakistan.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Govt. Teaching Hospital Shahdara, Lahore reported that: -

i. He, on 26-02-2024 inspected the premises of Main Medicine Store of Govt. Teaching Hospital Shahdara, Lahore, took different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Lahore vide memorandum no. 193304 dated 26-02-2024.
ii. The subject drug sample, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Powder for injection Fymezole 40mg (Omeprazole Sodium equivalent to Omeprazole 40mg) **Mfg. Date**: Jan-2024 **Exp. Date**:	F-394	M/S Fynk Pharmaceuticals 19 KM GT Road Kalashah Kaku, Lahore, Pakistan	01-10200000685/DTL dated 22-04-2024	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION:** White powder for injection in amber glass vial having label pasted on it with rubber stopper, aluminum seal and blue flip off cover. **pH:** Determined: 10.49 AT 25ºC Limit: 9.0-12.0 AT 25º C **IDENTIFICATION OF OMEPRAZOLE:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Omeprazole identified).

Jan-2026 **Regn**. **No**: 081266				**ASSAY OF OMEPRAZOLE:** Stated: 40 mg/vial Determined: 45.91mg/vial Percentage: 114.77% Limit: 90.0-120.0% of the labeled amount **STERILITY TEST:** The sample is **non-sterile.** **(DOES NOT COMPLY)** **RESULT:** The above sample is **SUB-STANDARD**, on the basis of Sterility test performed as per Manufacturer provided method of analysis.

iii. The Storekeeper, Main Medicine Store, Govt. Teaching Hospital Shahdara, Lahore provided Invoice/Warranty bearing No. T-20791 dated 14-02-2024 issued by M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore- Pakistan as a proof of its purchase.
iv. Warrantor portion of the drug sample was sent M/s Fynk Pharmaceuticals, 175-M, Near Naseerabad Station, Gulberg-III Lahore.
v. A copy of test/analysis report was sent to M/s Fynk Pharmaceuticals, 175-M, Near Naseerabad Station, Gulberg-III Lahore with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the subject drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
vi. Pursuant to firm's request, the Provincial Quality Control Board in its 40th committee meeting held on 13-06-2024, after due deliberation and discussion unanimously decide to turn down the firm's request for retesting of the subject drug sample.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

i. **Manufacture for sale/sale of Substandard Drug**
ii. **Issuance of false warranty**

3. Show Cause Notice issued to the accused dated 07.02.2025.

Reply of Show Cause Notice:

This is with reference to your letter bearing no. PQCB/MSS-193304/2024 dated 07-02-2025 received at our office on 17-02-2025 wherein we were directed to explain our position and provide certain information/documents regarding the product **Injection Fymezole bearing batch no. F-394** declared substandard by Government Analyst Drug Testing Laboratory Lahore vide TRA No. 01-10200000685/DTL dated 22-04-2024 (hereafter referred as The Impugned DTL report) on the basis of sterility.

In this regard, it is humbly submitted that:

1- M/S Fynk Pharmaceuticals (The Manufacturer) is one of the leading and trusted national companies, best known for its high quality products, which is fully compliant with Drugs Act 1976 and rules framed there under. Its firm commitment to quality and adherence to high standards/ CGMP guidelines is the hallmark of The Manufacturer to meet the high expectations of the patients as well as Health care providers.

2- Regarding quality of Injection Fymezole bearing batch no. F-394, please be noted that the product in question contains sterile Omeprazole Sodium powder batch no. OSM-1023032 which was filled in sterile amber colored sealed vial. The sterile Omeprazole Sodium powder batch no. OSM-1023032 was imported by The Manufacturer from its manufacturer Vartika Chemicals & Pharmaceuticals (P) Ltd. relying on certificate of analysis issued by him declaring it sterile. While vials were autoclaved and rubber stopper of the vials were pre-sterilized before their usage for filling.

Copy of the Certificate of Analysis of sterile Omeprazole Sodium powder batch no. OSM-1023032, depyrogenation sheet and pre-sterilization sheet is attached herewith as Annexure A, A1 & A2 respectively.

3- It is pertinent to mention here that after filling of sterile Omeprazole Sodium powder batch no. OSM-1023032 in sterile amber colored sealed vial, the quality control department of The Manufacturer tested all the required quality parameters including sterility of the product in question i.e. Injection Fymezole batch no. F-394 and found them satisfactory and compliant as per Fynk specifications.

Copy of the Certificate of Analysis of finished product along with sterility test report is attached herewith as Annexure B & B1 respectively.

4- Upon the issuance of medicine recall notice dated 25-04-2024 by Directorate of Drugs Control Punjab, the quality control department of The Manufacturer even retested retained sample of the same batch Le. F-394 of Injection Fymezole kept under prescribed conditions in its well-equipped state of art quality control Laboratory and found the results of all parameters including sterility as standard quality complying with Fynk specifications

Copy of the Certificate of Analysis of retesting test of retained sample is attached herewith as Annexure C

5- It is also not out of place to mention here that The Monufacturer got retested the retained sample of the same batch ie. F-394 of Injection Fymezole kept from Pakistan Drugs Testing and Research Centre which also found and declared the results of sterility parameter as standard one complying with Fynk specifications.

Copy of the test report of of retained somple issued by Pokiston Drugs Testing and Research Centre is attached herewith as Annexure D

6- It is also pertinent to mention here that The Impugned DTL report doesn't meet the mandatory statutory requirement of Form-7 Rule (11)(1) of Punjab Drug Rules, 2007 as it does not provide **details** of the result of test/analysis performed in the prescribed format for determining procedural fairness of testing. Since The Impugned DTL report in its clause 7 under the heading of "**details of the result of test/analysis**" (the clause/heading which was inserted by Notification no. SO (DC) 814/2003(A-97)(P), dated 20-01-2014) discloses only results and its specifications (test range) which are actually the contents of clause 6 read as " **results of the test/analysis with specification applied”** (the clause/heading which was already the part of form-7 before insertion of clouse 7 in 2014) and does not disclose the **detail** including results/observations of negative control (Medium Control) positive control (Cultural Control), sample control which are integral parts of the Sterility Test and even otherwise The Impugned DTL report does not transpire the no, of containers used for sample control, without which the result stated in The Impugned DTL report are not valid and reliable. This non conformity nature of The Impugned DTL report makes The Impugned DTL report illegal and unlawful and offending to principles of natural justice since it cannot be ascertained from The Impugned DTL report how the government analyst performed the test and reached to the conclusion and which also raises serious doubts on the sanctity and authenticity of The Impugned DTL report.

7. It is pertinent to mention here that The Manufacturer Le. M/s Fynk Pharmaceuticals has supplied approx.

21 lakh vials of Inj. Fymezole during last 9-10 months across Punjab. Out of 21 lakh vials of Inj. Fymezole, 1,85,000 vials were supplied in Shahdra Hospital Lahore and out of 1,85,000 vials of Inj Fymezole supplied to Shahdra Hospital Lahore, only batch # F-394 of Inj Fymezole comprising of 14000 vials was declared allegedly substandard. While remaining whole 21 lakh stock of aforesaid drug was declared passed the sterility parameter.

8. Therefore the alleged anomaly pointed out in The Impugned DTL report vide TRA No. 01-10200000685/DTL dated 22-04-2024 is prima facie based on any of erroneous mistakes and non-observance of mandatory protocol by Govt Analyst as discussed below:

I- Performance of sterility test by government analyst on number of containers less than that of numbers required by Fynk Specifications as mentioned in the method of analysis submitted by The Manufacturer to the Drug Testing Laboratory Lahore.

II- Performance of sterility test under septic conditions. *The test of sterility must be carried out under oseptic conditions. In order to achieve such conditions, the test environment has to be adopted to the way in which sterility test is performed.*

Any deviance from this precaution by the government analyst might have affected the results of test. As government analyst didn't mention the details of test applied so it raises questions on the validity of the test. These deviances by government analyst may include:

- Improper functioning of LAF and HEPA filters at sterility room
- Non conformity to proper disinfection of hands by analyst before performing sterility test
- Usage of non sterile membrane filter by analyst for conducting sterility test
- Usage of non sterile filtration apparatus or opening of filtration without applying LAF
- Contamination of any surface of filtration unit by touch
- Delayed performance of the test on the filtration unit resulting contamination,
- Touch of filter paper to any surface causing contamination resulting into test failure.
- Whether negative control test was applied or not.

9. The Impugned DTL Report also doesn't meet the mandatory statutory requirement of section 16 of the Drugs Act 1976 for the appointment of the government analyst who prepared and signed The Impugned DTL Report in respect of sampled drugs or such class of drugs or such area of jurisdiction. So The Impugned DTL Report is unauthentic, without lawful authority and jurisdiction and inadmissible against the manufacturer due to non appointment of government analyst who prepared and signed The Impugned DTL Report within the meaning of the Drugs Act 1976.

10-Even otherwise the PQCB order declining the company's retesting request is NON SPEAKING order which is based on speculations as follows:

A. That PQCB while passing the order dated 013-06-2024 issued on 30-07-2024 for turning down the request to send the sample of the captioned Product to federal drug testing laboratory didn't discuss how PQCB by way of scrutiny satisfied itself scientifically that government analyst performed the test correctly i.e.

- What were the results/observations of negative control (Medium Control),
- What were the results/observations of positive control (Cultural Control)
- What were the results/observations of sample control
- What were the no, of containers used for sample control

All these are integral parts of the Sterility Test but The impugned DTL report does not transpire these results rendering itself faulty and inadmissible.

The PQCB order is completely silent about all these parameters/aspects of The Impugned DTL Report which clearly manifests that the report of government analyst/The Impugned DTL Report was not even scrutinized

by PQCB and resultantly PQCB declined the retesting request of the petitioner in capricious and hasty manner in sheer violation of Section 11(5)(b) of The Drugs Act 1976.

B. The PQCB has averred in the retesting declining order that

"that the committee advised the representative of the firm to get their HVAC system validated and to monitor the source materials to minimize the chances of contamination of products."

Whereas this observation of PQCB is contrary to actual facts as follows:

- The Manufacturer had already submitted the HVAC system validation report as evidence in PQCB vide its letter FY/13135/24 dated 24-10-2024.

  Copy of HVAC system validation report is attached herewith as Annexure E.

- The Manufacturer had also submitted environmental control microbiological report both at working condition and non working condition as part of batch manufacturing record (BMR).

  Copy of BMR is attached herewith as Annexure F.

11- It is also not out of place to mention here that The Manufacturer despite being confident about the quality of the captioned product have also provided replacement stock vide delivery challan T-20791-R dated 12-06-2024 for the sake of betterment of ailing community and the said replacement stock has also been declared of standard quality vide DTL report TRA #01-10194008159.

Copy of delivery challan T-20791-R dated 12-06-2024 and DTL report TRA # 01-10194008159 is attached herewith as Annexure G & G1 respectively.

12-Furthermore, without prejudice to all aforementioned arguments another important aspect to be kept in mind is that the storage of any pharmaceutical product at appropriate storage condition is critically important to maintain its physico-chemical properties. It is imperative to discuss here that no one from the premises, from where the product was allegedly sampled, tendered any evidence that the product was kept stored by them in the same state as it was acquired/purchased by them from The Manufacturer nor any notice to The Manufacturer/warrantor was served by them in this regard as required under The Drugs Act 1976. So the improper storage at the place of sampling and/or improper transportation condition after sampling may also be the cause of compromised sterility. Therefore The Manufacturer cannot be held liable regarding the quality of the product stored at improper storage conditions at other places and all above mentioned scenarios provide the protection to The Company under section 32(3) (b) of the Drug Act 1976 and thus makes the case liable to be dropped against The Manufacturer.

13-**That PARA 2 of SCN alleges that**

"In this way you have contravened the section 23/27 of the Drug Act 1976 (as amended)/DRAP act 2012 and Rules framed thereunder by way of:

i- Manufacturing for sale/sale of Substandard drug

ii- Issuance of false warranty

Comments/Explanation:

I. The allegation of Manufacturing for sale/sale of Sub standard drug has been dealt and defended in detail in supra paragraphs and may also kindly be considered as reply to this allegation as well.

II- As far as allegation of issuance of false warranty is concerned, it is groundless and based upon misreading of relevant law. The warranty was issued after release of standard quality report by Quality Control Department of The Monufacturer which was good and sufficient reason available at the time of sale of the product and issuance of warranty for believing the product of standard quality. So the offence of issuance of false warranty has been added just to manipulate the scenario.

Section 27(2)(b) is reproduced below:

27 (2) whoever himself or by any other person on his behalf (o) or

(b) gives to the purchaser a false warranty in respect of any drug sold by him that the drug does not in any way contravene the provisions of section 23 and is not able to prove that, when he gave the warranty, he had good and sufficient reason to believe the same to be true.

14. **That PARA 3 of SCN alleges that**

"You are therefore required under Section (11) of the Drugs Act, 1976 and Rules (5) Of the Punjab Drug Rules 2007 (as amended) to show cause as to why:

i. You should not be prosecuted for committing above said contravention si in the Drug Court.
ii. The licensing Authority/Drug Registration Authority should not be recommended for cancellation / suspension of your Drug Manufacturing/Sale License and Drug Registration.
iii. Other suitable legal action [s] should not be taken against you.

Comments/Explanation

1- It is respectfully repeated/reiterated that The Impugned DTL Report which forms the basis of this show cause notice is itself illegal and non conformity to section 16, section 22 of Drugs Act 1976 and clause 7 of form-7 of Punjab Drug Rules 2007 and as discussed in detail in supra paragraphs.

II- The prosecution would be unlawful because it would be based upon illegal and invalid Report which cannot be used as evidence in any criminal trial.

III- Furthermore, mandatory provisions of Drugs Act 1976 have been ignored by the Drug Inspector which creates serious doubts in the whole story and would adversely affect the prosecution culminating into a futile exercise which would ultimately lead to acquittal of the accused.

IV-Even otherwise The Show Cause Notice under reply bearing no. PQCB/MSS-193304/2024 dated 07-02-2025 issued by the secretary Provincial Quality Control Board Punjab is also without lawful jurisdiction & authority ie. **CORAM NON JUDICE** and in sheer violation of rule 5(3) of Punjab Drug Rules 2007.

The statutory language of rule 5(3) of Punjab Drug Rules 2007 is reproduced here below:

> *"the Provincial and the District Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under this Act or the rules, issue a show couse notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or concellation of his license to the licensing authority",*

Whereas in this case, The Show Cause Notice under reply was not issued by Provincial Quality Control Board Punjab as required by the law but by the secretary who is just a member of the Board under rule 3(2) of Punjab Dugs Rules 2007 and he issued The Show Cause Notice in excess of its jurisdiction. Therefore The Show Cause Notice issued by the secretary is illegal, without jurisdiction & lawful authority ie. CORAM NON JUDICE and in sheer violation of rule 5(3) of Punjab Drug Rules 2007.

15. Please also find the relevant person's contact no.0301-4528260, Manager Regulatory Affairs.

16. That in addition to above, The Manufacturer reserves its right to submit further assistance/arguments/contradictory evidence to any honorable forum at personal hearing stage if happened.

17.

We do hereby verify the following information as required by you

Sr. #	Designation	Name	Address
1	Managing Partner	Kashif Liaqat Ali	19-KM G.T. Road, Kala Shah Kaku, Lahore.
2	Production Incharge	Abdul Rauf	19-KM G.T. Road, Kala Shah Kaku, Lahore.
3	Quality Control Incharge	Junaid Zafar	19-KM G.T. Road, Kala Shah Kaku, Lahore.
4	Warrantor	Junaid Zafar	19-KM G.T. Road, Kala Shah Kaku, Lahore.

Copy of Drug Manufacturing License

Copy of Drug Registration Certificate

Copy of CNICs of Managing Partner, Quality Control Incharge, Production Incharge & Warrantor

attached as Annexure H

attached as Annexure J

Enclosed as Annexure K

NOTE: Please also note that Mr. Junaid Zafar Control Incharge has left his jobs from The Manufacturer. So his SHOW CAUSE NOTICE be kindly considered as UNSERVED and are being sent back to your kind office along with this reply.

So based on the above discussion, The Impugned DTL report has no substance and no legs to stand upon and should be rejected and deemed a nullity in essence and spirit. Therefore, the entire proceedings/actions/Show Cause Notice based on this faulty and inconclusive Impugned DTL report are void ab initio and are unlawful and this case deserves to be dropped.

Submitted for further action and record.

4. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 01.2024

Expiry Date: 01.2026

Sampling Date (Form 4): 26.02.2024

Sent to DTL (Form 6): 26.02.2024

Date of receipt in DTL: 28.02.2024

DTL Report Date (Form 7): 22.04.2024

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 18.05.2024

Retesting Request of Firm: 25.05.2024

Fate of Firm's Retest Request: Turn Down in 40th-CM dated 13.06.2024

Investigation Report Dated: 08.10.2024

SCN: 07.02.2025

Reply SCN: 20.02.2025

History (Last 03 Years): Product: 02 including subject reported case, Firm: 14 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-193304/2024

(Govt. Teaching Hospital Shahdra, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore-Pakistan** through its Managing Partner, Kashif Liaqat Ali 2. Kashif Liaqat Ali — Managing Partner 3. Abdul Rauf — Production Incharge/Warrantor 4. Junaid Zafar — Quality Control Manager of M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore- Pakistan.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Govt. Teaching Hospital Shahdara, Lahore reported that: -

i. He, on 26-02-2024 inspected the premises of Main Medicine Store of Govt. Teaching Hospital Shahdara, Lahore, took different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Lahore vide memorandum no. 193304 dated 26-02-2024.
ii. The subject drug sample, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Powder for injection Fymezole 40mg (Omeprazole Sodium equivalent to Omeprazole 40mg) **Mfg**. **Date**: Jan-2024 **Exp**. **Date**: Jan-2026 **Regn**. **No**: 081266	F-394	M/S Fynk Pharmaceuticals 19 KM GT Road Kalashah Kaku, Lahore, Pakistan	01-10200000685/DTL dated 22-04-2024	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION:** White powder for injection in amber glass vial having label pasted on it with rubber stopper, aluminum seal and blue flip off cover. **pH:** Determined: 10.49 AT 25ºC Limit: 9.0-12.0 AT 25º C **IDENTIFICATION OF OMEPRAZOLE:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Omeprazole identified). **ASSAY OF OMEPRAZOLE:** Stated: 40 mg/vial Determined: 45.91mg/vial Percentage: 114.77% Limit: 90.0-120.0% of the labeled amount **STERILITY TEST:** The sample is **non-sterile.** **(DOES NOT COMPLY)** **RESULT:** The above sample is **SUB-STANDARD**, on the basis of Sterility test performed as per Manufacturer provided

				method of analysis.

iii. The Storekeeper, Main Medicine Store, Govt. Teaching Hospital Shahdara, Lahore provided Invoice/Warranty bearing No. T-20791 dated 14-02-2024 issued by M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore- Pakistan as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent M/s Fynk Pharmaceuticals, 175-M, Near Naseerabad Station, Gulberg-III Lahore.

v. A copy of test/analysis report was sent to M/s Fynk Pharmaceuticals, 175-M, Near Naseerabad Station, Gulberg-III Lahore with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the subject drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to firm's request, the Provincial Quality Control Board in its 40th committee meeting held on 13-06-2024, after due deliberation and discussion unanimously decide to turn down the firm's request for retesting of the subject drug sample.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

i. **Manufacture for sale/sale of Substandard Drug**
ii. **Issuance of false warranty**

3. Show Cause Notice issued to the accused dated 07.02.2025.

Reply of Show Cause Notice:

This is with reference to your letter bearing no. PQCB/MSS-193304/2024 dated 07-02-2025 received at our office on 17-02-2025 wherein we were directed to explain our position and provide certain information/documents regarding the product **Injection Fymezole bearing batch no. F-394** declared substandard by Government Analyst Drug Testing Laboratory Lahore vide TRA No. 01-10200000685/DTL dated 22-04-2024 (hereafter referred as The Impugned DTL report) on the basis of sterility.

In this regard, it is humbly submitted that:

1- M/S Fynk Pharmaceuticals (The Manufacturer) is one of the leading and trusted national companies, best known for its high quality products, which is fully compliant with Drugs Act 1976 and rules framed there under. Its firm commitment to quality and adherence to high standards/ CGMP guidelines is the hallmark of The Manufacturer to meet the high expectations of the patients as well as Health care providers.

2- Regarding quality of Injection Fymezole bearing batch no. F-394, please be noted that the product in question contains sterile Omeprazole Sodium powder batch no. OSM-1023032 which was filled in sterile amber colored sealed vial. The sterile Omeprazole Sodium powder batch no. OSM-1023032 was imported by The Manufacturer from its manufacturer Vartika Chemicals & Pharmaceuticals (P) Ltd. relying on certificate of analysis issued by him declaring it sterile. While vials were autoclaved and rubber stopper of the vials were pre-sterilized before their usage for filling.

Copy of the Certificate of Analysis of sterile Omeprazole Sodium powder batch no. OSM-1023032, depyrogenation sheet and pre-sterilization sheet is attached herewith as Annexure A, A1 & A2 respectively.

3- It is pertinent to mention here that after filling of sterile Omeprazole Sodium powder batch no. OSM-1023032 in sterile amber colored sealed vial, the quality control department of The Manufacturer tested all the required quality parameters including sterility of the product in question i.e. Injection Fymezole batch no.

F-394 and found them satisfactory and compliant as per Fynk specifications.

Copy of the Certificate of Analysis of finished product along with sterility test report is attached herewith as Annexure B & B1 respectively.

4- Upon the issuance of medicine recall notice dated 25-04-2024 by Directorate of Drugs Control Punjab, the quality control department of The Manufacturer even retested retained sample of the same batch Le. F-394 of Injection Fymezole kept under prescribed conditions in its well-equipped state of art quality control Laboratory and found the results of all parameters including sterility as standard quality complying with Fynk specifications

Copy of the Certificate of Analysis of retesting test of retained sample is attached herewith as Annexure C

5- It is also not out of place to mention here that The Monufacturer got retested the retained sample of the same batch ie. F-394 of Injection Fymezole kept from Pakistan Drugs Testing and Research Centre which also found and declared the results of sterility parameter as standard one complying with Fynk specifications.

Copy of the test report of of retained somple issued by Pokiston Drugs Testing and Research Centre is attached herewith as Annexure D

6- It is also pertinent to mention here that The Impugned DTL report doesn't meet the mandatory statutory requirement of Form-7 Rule (11)(1) of Punjab Drug Rules, 2007 as it does not provide **details** of the result of test/analysis performed in the prescribed format for determining procedural fairness of testing. Since The Impugned DTL report in its clause 7 under the heading of "**details of the result of test/analysis**" (the clause/heading which was inserted by Notification no. SO (DC) 814/2003(A-97)(P), dated 20-01-2014) discloses only results and its specifications (test range) which are actually the contents of clause 6 read as " **results of the test/analysis with specification applied"** (the clause/heading which was already the part of form-7 before insertion of clouse 7 in 2014) and does not disclose the **detail** including results/observations of negative control (Medium Control) positive control (Cultural Control), sample control which are integral parts of the Sterility Test and even otherwise The Impugned DTL report does not transpire the no, of containers used for sample control, without which the result stated in The Impugned DTL report are not valid and reliable. This non conformity nature of The Impugned DTL report makes The Impugned DTL report illegal and unlawful and offending to principles of natural justice since it cannot be ascertained from The Impugned DTL report how the government analyst performed the test and reached to the conclusion and which also raises serious doubts on the sanctity and authenticity of The Impugned DTL report.

7. It is pertinent to mention here that The Manufacturer Le. M/s Fynk Pharmaceuticals has supplied approx. 21 lakh vials of Inj. Fymezole during last 9-10 months across Punjab. Out of 21 lakh vials of Inj. Fymezole, 1,85,000 vials were supplied in Shahdra Hospital Lahore and out of 1,85,000 vials of Inj Fymezole supplied to Shahdra Hospital Lahore, only batch # F-394 of Inj Fymezole comprising of 14000 vials was declared allegedly substandard. While remaining whole 21 lakh stock of aforesaid drug was declared passed the sterility parameter.

8. Therefore the alleged anomaly pointed out in The Impugned DTL report vide TRA No. 01-10200000685/DTL dated 22-04-2024 is prima facie based on any of erroneous mistakes and non-observance of mandatory protocol by Govt Analyst as discussed below:

I- Performance of sterility test by government analyst on number of containers less than that of numbers required by Fynk Specifications as mentioned in the method of analysis submitted by The Manufacturer to the Drug Testing Laboratory Lahore.

II- Performance of sterility test under septic conditions. *The test of sterility must be carried out under oseptic conditions. In order to achieve such conditions, the test environment has to be adopted to the way in which sterility test is performed.*

Any deviance from this precaution by the government analyst might have affected the results of test. As government analyst didn't mention the details of test applied so it raises questions on the validity of the test. These deviances by government analyst may include:

- Improper functioning of LAF and HEPA filters at sterility room
- Non conformity to proper disinfection of hands by analyst before performing sterility test
- Usage of non sterile membrane filter by analyst for conducting sterility test
- Usage of non sterile filtration apparatus or opening of filtration without applying LAF
- Contamination of any surface of filtration unit by touch
- Delayed performance of the test on the filtration unit resulting contamination,
- Touch of filter paper to any surface causing contamination resulting into test failure.
- Whether negative control test was applied or not.

9. The Impugned DTL Report also doesn't meet the mandatory statutory requirement of section 16 of the Drugs Act 1976 for the appointment of the government analyst who prepared and signed The Impugned DTL Report in respect of sampled drugs or such class of drugs or such area of jurisdiction. So The Impugned DTL Report is unauthentic, without lawful authority and jurisdiction and inadmissible against the manufacturer due to non appointment of government analyst who prepared and signed The Impugned DTL Report within the meaning of the Drugs Act 1976.

10-Even otherwise the PQCB order declining the company's retesting request is NON SPEAKING order which is based on speculations as follows:

A. That PQCB while passing the order dated 013-06-2024 issued on 30-07-2024 for turning down the request to send the sample of the captioned Product to federal drug testing laboratory didn't discuss how PQCB by way of scrutiny satisfied itself scientifically that government analyst performed the test correctly i.e.

- What were the results/observations of negative control (Medium Control),
- What were the results/observations of positive control (Cultural Control)
- What were the results/observations of sample control
- What were the no, of containers used for sample control

All these are integral parts of the Sterility Test but The impugned DTL report does not transpire these results rendering itself faulty and inadmissible.

The PQCB order is completely silent about all these parameters/aspects of The Impugned DTL Report which clearly manifests that the report of government analyst/The Impugned DTL Report was not even scrutinized by PQCB and resultantly PQCB declined the retesting request of the petitioner in capricious and hasty manner in sheer violation of Section 11(5)(b) of The Drugs Act 1976.

B. The PQCB has averred in the retesting declining order that

"that the committee advised the representative of the firm to get their HVAC system validated and to monitor the source materials to minimize the chances of contamination of products."

Whereas this observation of PQCB is contrary to actual facts as follows:

- The Manufacturer had already submitted the HVAC system validation report as evidence in PQCB vide its letter FY/13135/24 dated 24-10-2024.

  Copy of HVAC system validation report is attached herewith as Annexure E.

- The Manufacturer had also submitted environmental control microbiological report both at

working condition and non working condition as part of batch manufacturing record (BMR).

Copy of BMR is attached herewith as Annexure F.

11- It is also not out of place to mention here that The Manufacturer despite being confident about the quality of the captioned product have also provided replacement stock vide delivery challan T-20791-R dated 12-06-2024 for the sake of betterment of ailing community and the said replacement stock has also been declared of standard quality vide DTL report TRA #01-10194008159.

Copy of delivery challan T-20791-R dated 12-06-2024 and DTL report TRA # 01-10194008159 is attached herewith as Annexure G & G1 respectively.

12-Furthermore, without prejudice to all aforementioned arguments another important aspect to be kept in mind is that the storage of any pharmaceutical product at appropriate storage condition is critically important to maintain its physico-chemical properties. It is imperative to discuss here that no one from the premises, from where the product was allegedly sampled, tendered any evidence that the product was kept stored by them in the same state as it was acquired/purchased by them from The Manufacturer nor any notice to The Manufacturer/warrantor was served by them in this regard as required under The Drugs Act 1976. So the improper storage at the place of sampling and/or improper transportation condition after sampling may also be the cause of compromised sterility. Therefore The Manufacturer cannot be held liable regarding the quality of the product stored at improper storage conditions at other places and all above mentioned scenarios provide the protection to The Company under section 32(3) (b) of the Drug Act 1976 and thus makes the case liable to be dropped against The Manufacturer.

13-**That PARA 2 of SCN alleges that**

"In this way you have contravened the section 23/27 of the Drug Act 1976 (as amended)/DRAP act 2012 and Rules framed thereunder by way of:

i- Manufacturing for sale/sale of Substandard drug

ii- Issuance of false warranty

Comments/Explanation:

I. The allegation of Manufacturing for sale/sale of Sub standard drug has been dealt and defended in detail in supra paragraphs and may also kindly be considered as reply to this allegation as well.

II- As far as allegation of issuance of false warranty is concerned, it is groundless and based upon misreading of relevant law. The warranty was issued after release of standard quality report by Quality Control Department of The Monufacturer which was good and sufficient reason available at the time of sale of the product and issuance of warranty for believing the product of standard quality. So the offence of issuance of false warranty has been added just to manipulate the scenario.

Section 27(2)(b) is reproduced below:

27 (2) whoever himself or by any other person on his behalf (o) or

(b) gives to the purchaser a false warranty in respect of any drug sold by him that the drug does not in any way contravene the provisions of section 23 and is not able to prove that, when he gave the warranty, he had good and sufficient reason to believe the same to be true.

14. **That PARA 3 of SCN alleges that**

"You are therefore required under Section (11) of the Drugs Act, 1976 and Rules (5) Of the Punjab Drug Rules 2007 (as amended) to show cause as to why:

i. You should not be prosecuted for committing above said contravention si in the Drug Court.
ii. The licensing Authority/Drug Registration Authority should not be recommended for cancellation / suspension of your Drug Manufacturing/Sale License and Drug Registration.
iii. Other suitable legal action [s] should not be taken against you.

Comments/Explanation

1- It is respectfully repeated/reiterated that The Impugned DTL Report which forms the basis of this show cause notice is itself illegal and non conformity to section 16, section 22 of Drugs Act 1976 and clause 7 of form-7 of Punjab Drug Rules 2007 and as discussed in detail in supra paragraphs.

II- The prosecution would be unlawful because it would be based upon illegal and invalid Report which cannot be used as evidence in any criminal trial.

III- Furthermore, mandatory provisions of Drugs Act 1976 have been ignored by the Drug Inspector which creates serious doubts in the whole story and would adversely affect the prosecution culminating into a futile exercise which would ultimately lead to acquittal of the accused.

IV-Even otherwise The Show Cause Notice under reply bearing no. PQCB/MSS-193304/2024 dated 07-02-2025 issued by the secretary Provincial Quality Control Board Punjab is also without lawful jurisdiction & authority ie. **CORAM NON JUDICE** and in sheer violation of rule 5(3) of Punjab Drug Rules 2007.

The statutory language of rule 5(3) of Punjab Drug Rules 2007 is reproduced here below:

> *"the Provincial and the District Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under this Act or the rules, issue a show couse notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or concellation of his license to the licensing authority",*

Whereas in this case, The Show Cause Notice under reply was not issued by Provincial Quality Control Board Punjab as required by the law but by the secretary who is just a member of the Board under rule 3(2) of Punjab Dugs Rules 2007 and he issued The Show Cause Notice in excess of its jurisdiction. Therefore The Show Cause Notice issued by the secretary is illegal, without jurisdiction & lawful authority ie. CORAM NON JUDICE and in sheer violation of rule 5(3) of Punjab Drug Rules 2007.

15. Please also find the relevant person's contact no.0301-4528260, Manager Regulatory Affairs.

16. That in addition to above, The Manufacturer reserves its right to submit further assistance/arguments/contradictory evidence to any honorable forum at personal hearing stage if happened.

17.

We do hereby verify the following information as required by you

Sr. #	Designation	Name	Address
1	Managing Partner	Kashif Liaqat Ali	19-KM G.T. Road, Kala Shah Kaku, Lahore.
2	Production Incharge	Abdul Rauf	19-KM G.T. Road, Kala Shah Kaku,

			Lahore.
3	Quality Control Incharge	Junaid Zafar	19-KM G.T. Road, Kala Shah Kaku, Lahore.
4	Warrantor	Junaid Zafar	19-KM G.T. Road, Kala Shah Kaku, Lahore.

Copy of Drug Manufacturing License

Copy of Drug Registration Certificate

Copy of CNICs of Managing Partner, Quality Control Incharge, Production Incharge & Warrantor

attached as Annexure H

attached as Annexure J

Enclosed as Annexure K

NOTE: Please also note that Mr. Junaid Zafar Control Incharge has left his jobs from The Manufacturer. So his SHOW CAUSE NOTICE be kindly considered as UNSERVED and are being sent back to your kind office along with this reply.

So based on the above discussion, The Impugned DTL report has no substance and no legs to stand upon and should be rejected and deemed a nullity in essence and spirit. Therefore, the entire proceedings/actions/Show Cause Notice based on this faulty and inconclusive Impugned DTL report are void ab initio and are unlawful and this case deserves to be dropped.

Submitted for further action and record.

4. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 01.2024

Expiry Date: 01.2026

Sampling Date (Form 4): 26.02.2024

Sent to DTL (Form 6): 26.02.2024

Date of receipt in DTL: 28.02.2024

DTL Report Date (Form 7): 22.04.2024

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 18.05.2024

Retesting Request of Firm: 25.05.2024

Fate of Firm's Retest Request: Turn Down in 40th-CM dated 13.06.2024

Investigation Report Dated: 08.10.2024

SCN: 07.02.2025

Reply SCN: 20.02.2025

History (Last 03 Years): Product: 02 including subject reported case, Firm: 14 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 13

PQCB/MSS-212454/2024

(Services Hospital, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore** through its Managing Director, Muhammad Ali. 2. Muhammad Ali — Managing Director 3. Huma Fajar Din — Production Incharge 4. Tajammal Hussain — Quality Control Incharge/ Warrantor **of M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Services Hospital, Lahore reported that: -

i. He, on 07.12.2024, inspected the premises of Main Surgical Store situated at Services Hospital, Jail Road, Lahore and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 212454 dated 07.12.2024.
ii. Following Drug samples after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Lahore, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Surgee Bandages (Bandages 6.5cm*6m) **Mfg. Date: Exp. Date: Registration No.** 11.2024 10.2027 030774	B1124	M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore	01-141001192DTL Dated. 31.12.2024

DTL Test Report Result

Specification applied: BPC

Description: Cotton cloth of plain weave, bleached, it is clean and free from weaving defects leaf and shell. Claimed size = 6.5cm x 6m.

Warps: Limit: 15.45-18.75/cm, Determined: **14.44/cm (Does not Comply)**

Wefts: Limit: 9.95-11.45/cm, Determined: **7.34/cm (Does not Comply)**

Weight Per Unit Area: Limit: 63.5-78.5g/ m^2, Determined: **35.3g/m^2 (Does not Comply)**

Length: Limit: 6.13M, Label: 6M

Width: Limit: 6.5CM, Label: 6.5CM

Result: The above sample is **Substandard** on the basis of **Threads per Stated Length and Weight per Unit Area** as per BPC.

ii. Store Keeper, Main Surgical Store situated at Services Hospital, Jail Road, Lahore provided Invoice/ Delivery Challan/ warranty No. RR02429 dated 03.12.2024 issued by M/s Roys & Roys International, 1st floor, Rehamn Centre-2, Service Lane Ring Road, Near Askari-11 Gate No. 3, Lahore as proof of its purchase.
iii. M/s Roys & Roys International, 1st floor, Rehamn Centre-2, Service Lane Ring Road, Near Askari-11 Gate No. 3, Lahore provided Invoice/ Delivery Challan/ warranty No. RRSTX-031224, dated 03.12.2024 issued by M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore as a proof of its purchase.
iv. Manufacturer & Warrantor portion of drug sample was sent to M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore.
v. A copy of test/analysis report was sent to M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore and they were directed to explain their position and to provide the requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

i. **Manufacture for sale/sale of Substandard Drug**
ii. **Issuance of false warranty**

3. Show Cause/ Personal Hearing Notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 11.2024

Expiry Date: 10.2027

Sampling Date (Form 4): 07.12.2024

Sent to DTL (Form 6): 07.12.2024

Date of receipt in DTL: 09.12.2024

DTL Report Date (Form 7): 31.12.2024

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 04.01.2025

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 17.02.2025

SC-PHN: 20.03.2025

History (Last 03 Years): Firm: 20 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-212455/2024

(Services Hospital, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore** through its Managing Director, Muhammad Ali. 2. Muhammad Ali Managing Director 3. Huma Fajar Din Production Incharge 4. Tajammal Hussain Quality Control Incharge/ Warrantor **of M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Services Hospital, Lahore reported that: -

i. He, on 07.12.2024, inspected the premises of Main Surgical Store situated at Services Hospital, Jail Road, Lahore and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 212455 dated 07.12.2024.
ii. Following Drug samples after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Lahore, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**
Surgee Bandages (Bandages 15cm*6m) **Mfg. Date: Exp. Date: Registration No.** 11.2024 10.2027 030774	B1124	M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore	01-141001193DTL Dated. 31.12.2024
DTL Test Report Result			

Specification applied: BPC

Description: Cotton cloth of plain weave, bleached, it is clean and free from weaving defects leaf and shell. Claimed size = 15cm x 6m.

Warps: Limit: 15.45-18.75/cm, Determined: **14.96/cm (Does not Comply)**

Wefts: Limit: 9.95-11.45/cm, Determined: **7.87/cm (Does not Comply)**

Weight Per Unit Area: Limit: 63.5-78.5g/ m^2, Determined: **38.5g/m^2 (Does not Comply)**

Length: Limit: 6.3M, Label: 6M

Width: Limit: 15CM, Label: 15CM

Result: The above sample is **Substandard** on the basis of **Threads per Stated Length and Weight per Unit Area** as per BPC.

ii. Store Keeper, Main Surgical Store situated at Services Hospital, Jail Road, Lahore provided Invoice/ Delivery Challan/ warranty No. RR02428 dated 03.12.2024 issued by M/s Roys & Roys International, 1st floor, Rehamn Centre-2, Service Lane Ring Road, Near Askari-11 Gate No. 3, Lahore as proof of its purchase.
iii. M/s Roys & Roys International, 1st floor, Rehamn Centre-2, Service Lane Ring Road, Near Askari-11 Gate No. 3, Lahore provided Invoice/ Delivery Challan/ warranty No. RRSTX-041224, dated 03.12.2024 issued by M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore as a proof of its purchase.
iv. Manufacturer & Warrantor portion of drug sample was sent to M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.
v. A copy of test/analysis report was sent to M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore and they were directed to explain their position and to provide the requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

i. **Manufacture for sale/sale of Substandard Drug**
ii. **Issuance of false warranty**

3. Show Cause/ Personal Hearing Notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 11.2024

Expiry Date: 10.2027

Sampling Date (Form 4): 07.12.2024

Sent to DTL (Form 6): 07.12.2024

Date of receipt in DTL: 09.12.2024

DTL Report Date (Form 7): 31.12.2024

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 04.01.2025

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 17.02.2025

SC-PHN: 20.03.2025

History (Last 03 Years): Firm: 20 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-212454/2024

(Services Hospital, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore** through its Managing Director, Muhammad Ali. 2. Muhammad Ali — Managing Director 3. Huma Fajar Din — Production Incharge 4. Tajammal Hussain — Quality Control Incharge/ Warrantor **of M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Services Hospital, Lahore reported that: -

1. He, on 07.12.2024, inspected the premises of Main Surgical Store situated at Services Hospital, Jail Road, Lahore and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 212454 dated 07.12.2024.
2. Following Drug samples after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Lahore, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date

Surgee Bandages (Bandages 6.5cm*6m) **Mfg. Date: Exp. Date: Registration No.** 11.2024 10.2027 030774	B1124	M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore	01-141001192DTL Dated. 31.12.2024

DTL Test Report Result

Specification applied: BPC

Description: Cotton cloth of plain weave, bleached, it is clean and free from weaving defects leaf and shell. Claimed size = 6.5cm x 6m.

Warps: Limit: 15.45-18.75/cm, Determined: **14.44/cm (Does not Comply)**

Wefts: Limit: 9.95-11.45/cm, Determined: **7.34/cm (Does not Comply)**

Weight Per Unit Area: Limit: 63.5-78.5g/ m^2, Determined: **35.3g/m^2 (Does not Comply)**

Length: Limit: 6.13M, Label: 6M

Width: Limit: 6.5CM, Label: 6.5CM

Result: The above sample is **Substandard** on the basis of **Threads per Stated Length and Weight per Unit Area** as per BPC.

ii. Store Keeper, Main Surgical Store situated at Services Hospital, Jail Road, Lahore provided Invoice/ Delivery Challan/ warranty No. RR02429 dated 03.12.2024 issued by M/s Roys & Roys International, 1st floor, Rehamn Centre-2, Service Lane Ring Road, Near Askari-11 Gate No. 3, Lahore as proof of its purchase.
iii. M/s Roys & Roys International, 1st floor, Rehamn Centre-2, Service Lane Ring Road, Near Askari-11 Gate No. 3, Lahore provided Invoice/ Delivery Challan/ warranty No. RRSTX-031224, dated 03.12.2024 issued by M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore as a proof of its purchase.
iv. Manufacturer & Warrantor portion of drug sample was sent to M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore.
v. A copy of test/analysis report was sent to M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore and they were directed to explain their position and to provide the requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

i. **Manufacture for sale/sale of Substandard Drug**
ii. **Issuance of false warranty**

3. Show Cause/ Personal Hearing Notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 11.2024

Expiry Date: 10.2027

Sampling Date (Form 4): 07.12.2024

Sent to DTL (Form 6): 07.12.2024

Date of receipt in DTL: 09.12.2024

DTL Report Date (Form 7): 31.12.2024

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 04.01.2025

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 17.02.2025

SC-PHN: 20.03.2025

History (Last 03 Years): Firm: 20 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-212455/2024

(Services Hospital, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore** through its Managing Director, Muhammad Ali. 2. Muhammad Ali — Managing Director 3. Huma Fajar Din — Production Incharge 4. Tajammal Hussain — Quality Control Incharge/ Warrantor **of M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Services Hospital, Lahore reported that: -

1. He, on 07.12.2024, inspected the premises of Main Surgical Store situated at Services Hospital, Jail Road, Lahore and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 212455 dated 07.12.2024.
2. Following Drug samples after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Lahore, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**
Surgee Bandages (Bandages 15cm*6m) **Mfg. Date: Exp. Date: Registration No.** 11.2024 10.2027 030774	B1124	M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore	01-141001193DTL Dated. 31.12.2024

DTL Test Report Result

Specification applied: BPC

Description: Cotton cloth of plain weave, bleached, it is clean and free from weaving defects leaf and shell. Claimed size = 15cm x 6m.

Warps: Limit: 15.45-18.75/cm, Determined: **14.96/cm (Does not Comply)**

Wefts: Limit: 9.95-11.45/cm, Determined: **7.87/cm (Does not Comply)**

Weight Per Unit Area: Limit: 63.5-78.5g/ m^2, Determined: **38.5g/m^2 (Does not Comply)**

Length: Limit: 6.3M, Label: 6M

Width: Limit: 15CM, Label: 15CM

Result: The above sample is **Substandard** on the basis of **Threads per Stated Length and Weight per Unit Area** as per BPC.

ii. Store Keeper, Main Surgical Store situated at Services Hospital, Jail Road, Lahore provided Invoice/ Delivery Challan/ warranty No. RR02428 dated 03.12.2024 issued by M/s Roys & Roys International, 1st floor, Rehamn Centre-2, Service Lane Ring Road, Near Askari-11 Gate No. 3, Lahore as proof of its purchase.
iii. M/s Roys & Roys International, 1st floor, Rehamn Centre-2, Service Lane Ring Road, Near Askari-11 Gate No. 3, Lahore provided Invoice/ Delivery Challan/ warranty No. RRSTX-041224, dated 03.12.2024 issued by M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore as a proof of its purchase.
iv. Manufacturer & Warrantor portion of drug sample was sent to M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.
v. A copy of test/analysis report was sent to M/S Rehman Rainbow (Pvt.) Ltd., 82-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore and they were directed to explain their position and to provide the requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

i. **Manufacture for sale/sale of Substandard Drug**
ii. **Issuance of false warranty**

3. Show Cause/ Personal Hearing Notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 11.2024

Expiry Date: 10.2027

Sampling Date (Form 4): 07.12.2024

Sent to DTL (Form 6): 07.12.2024

Date of receipt in DTL: 09.12.2024

DTL Report Date (Form 7): 31.12.2024

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 04.01.2025

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 17.02.2025

SC-PHN: 20.03.2025

History (Last 03 Years): Firm: 20 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 14

PQCB/SM-03-04/2021

(Tehsil Ferozewala District Sheikhupura)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Muhammad Bilal 2. Muhammad Bilal S/o Liaqat Ali Butt Chief Executive Officer 3. Shehzad Mamoon S/o Muhammad Ashraf Production Incharge 4. Saleem Shahid S/o Jan Muhammad Quality Control Incharge/ Warrantor of **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. His Predecessor, on 15-03-2021, along-with other team members inspected the manufacturing premises of M/S B J Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API/ material on Form 5:

Serial No.	Name of drug	Batch No.	Name of Manufacturer	Quantity	Reason of seizure
1.	Paracetamol (Active)	Nil	Carry for Pharmaceuticals	24 Kg	**1-Misbranded drug (Batch no., expiry date, Mfg. date not mentioned)** **2-Without Warranty (Inactive)**
2.	Ciprofloxacin (Active)	Nil	Carry for Pharmaceuticals	0. g	**1-Misbranded drug (Batch no., expiry date , Mfg. date not mentioned)** **2-Without Warranty (Inactive)**
3.	Sulfamethoxazole	Nil	Carry for Pharmaceuticals	25.00 Kg	**1-Misbranded drug (Batch no., expiry date, Mfg. date not mentioned)** **2-Without Warranty (Inactive)**

4.	Tablet Chloroquine 250 mg(jar packed0	005	BJ Pharmaceuticals	1500 tablets	**Expired medicines (12-2020)**
5.	Tablet Chloroquine 250 mg	006	BJ Pharmaceuticals	300 tablets	**Expired medicines (12-2020)**
6.	Tablet Entagyl 400 mg	001	BJ Pharmaceuticals	400 tablets	**Expired medicines(04-2020)**
7.	Tablet Bellfen	578	BJ Pharmaceuticals	200 tablets	**Expired medicines (12-2020)**
8.	Tablet Trezine 10 mg	021	BJ Pharmaceuticals	100 tablets	**Over pricing** **Approved rate Rs. 42 and printed rate Rs. 60.**

ii. The factory was sealed under the provision of 18(1) of The Drugs Act 1976 (as amended) and the rules framed thereunder.

2. In this way You have contravened the provisions of Section 23/27 of the Drugs Act, 1976 (as amended)/DRAP Act, 2012 and Rules framed there under by the way of :-

a. **Manufacturing for sale/ sale of Misbranded drugs.**

b. **Stocking of APIs without warranties**

c. **Stocking of expired drugs.**

d. **Overpricing of drugs.**

3. The Show-Cause Notice was issued to the accused person (s).

Reply of Show-Cause Notice:

With reference to your letter No. PQCB/SM-03-04/2021, R-686, 687/2021 dated 21-02- 2023, which we received on 27-02-2023. The Government Analyst, drug Testing Laboratory, Lahore had declared the Tab Doxycycline 100mg vide test report TRA No. 01-166000598/DTL dated: 05-05-2021 SUB-STANDARD on the basis of Assay, Dissolution and Uniformity of Dosage Units and Tab film coated Trezine 10mg sample vide test report TRA No. 01-166000599/DTL dated: 05-05-2021 "SUB-STANDARD" on the basis of dissolution, We did not receive DTL testing repot of both products above mentioned.

So, you are requested to provide us the testing report (Test/Analysis by Government Analyst, Lahore) as soon as possible. So we may proceed it according to the procedure and able to give complete and comprehensive answer according the reports.

5. Personal hearing notice(s) issued to accused person(s) dated 30.07.2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **283rd meeting** held on **08.08.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice-Chairperson PQCB. Dr. Asma, Secretary DQCB District Sheikhupura attended the meeting online via zoom link along with original case record. No one appeared before the Board on the behalf of M/s BJ Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.
7. The Board decided to adjourn the case on written request of firm and also decided to provide another opportunity of personal hearing in best interest of justice.
8. Personal hearing notice(s) issued to accused person(s) dated 20.03.2025.

Summary:

Seizure Date (Form 5): 15.03.2021

Investigation Report Dated: 16.12.2022

Permission of SCN:

SCN issued: 21.02.2023

Reply of firm: 01.03.2023

History (Last 03 Years): Firm: 13 cases reported.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/SM-03-04/2021

(Tehsil Ferozewala District Sheikhupura)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Muhammad Bilal 2. Muhammad Bilal S/o Liaqat Ali Butt Chief Executive Officer 3. Shehzad Mamoon S/o Muhammad Ashraf Production Incharge 4. Saleem Shahid S/o Jan Muhammad Quality Control Incharge/ Warrantor of **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. His Predecessor, on 15-03-2021, along-with other team members inspected the manufacturing premises of M/S B J Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API/ material on Form 5:

Serial No.	**Name of drug**	**Batch No.**	**Name of Manufacturer**	**Quantity**	**Reason of seizure**
1.	Paracetamol (Active)	Nil	Carry for Pharmaceuticals	24 Kg	**1-Misbranded drug (Batch no., expiry date, Mfg. date not mentioned)** **2-Without Warranty (Inactive)**
2.	Ciprofloxacin (Active)	Nil	Carry for Pharmaceuticals	0. g	**1-Misbranded drug (Batch no., expiry date , Mfg. date not mentioned)** **2-Without Warranty (Inactive)**
3.	Sulfamethoxazole	Nil	Carry for Pharmaceuticals	25.00 Kg	**1-Misbranded drug (Batch no., expiry date, Mfg. date not mentioned)** **2-Without Warranty (Inactive)**
4.	Tablet Chloroquine 250 mg(jar packed0	005	BJ Pharmaceuticals	1500 tablets	**Expired medicines (12-2020)**
5.	Tablet Chloroquine 250 mg	006	BJ Pharmaceuticals	300 tablets	**Expired medicines (12-2020)**
6.	Tablet Entagyl 400 mg	001	BJ Pharmaceuticals	400 tablets	**Expired medicines(04-2020)**
7.	Tablet Bellfen	578	BJ Pharmaceuticals	200 tablets	**Expired medicines (12-2020)**
8.	Tablet Trezine 10 mg	021	BJ Pharmaceuticals	100 tablets	**Over pricing** **Approved rate Rs. 42 and**

					printed rate Rs. 60.

ii. The factory was sealed under the provision of 18(1) of The Drugs Act 1976 (as amended) and the rules framed thereunder.

2. In this way You have contravened the provisions of Section 23/27 of the Drugs Act, 1976 (as amended)/DRAP Act, 2012 and Rules framed there under by the way of :-

a. **Manufacturing for sale/ sale of Misbranded drugs.**

b. **Stocking of APIs without warranties**

c. **Stocking of expired drugs.**

d. **Overpricing of drugs.**

3. The Show-Cause Notice was issued to the accused person (s).

Reply of Show-Cause Notice:

With reference to your letter No. PQCB/SM-03-04/2021, R-686, 687/2021 dated 21-02- 2023, which we received on 27-02-2023. The Government Analyst, drug Testing Laboratory, Lahore had declared the Tab Doxycycline 100mg vide test report TRA No. 01-166000598/DTL dated: 05-05-2021 SUB-STANDARD on the basis of Assay, Dissolution and Uniformity of Dosage Units and Tab film coated Trezine 10mg sample vide test report TRA No. 01-166000599/DTL dated: 05-05-2021 "SUB-STANDARD" on the basis of dissolution, We did not receive DTL testing repot of both products above mentioned.

So, you are requested to provide us the testing report (Test/Analysis by Government Analyst, Lahore) as soon as possible. So we may proceed it according to the procedure and able to give complete and comprehensive answer according the reports.

5. Personal hearing notice(s) issued to accused person(s) dated 30.07.2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **283rd meeting** held on **08.08.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice-Chairperson PQCB. Dr. Asma, Secretary DQCB District Sheikhupura attended the meeting online via zoom link along with original case record. No one appeared before the Board on the behalf of M/s BJ Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.
7. The Board decided to adjourn the case on written request of firm and also decided to provide another opportunity of personal hearing in best interest of justice.
8. Personal hearing notice(s) issued to accused person(s) dated 20.03.2025.

Summary:

Seizure Date (Form 5): 15.03.2021

Investigation Report Dated: 16.12.2022

Permission of SCN:

SCN issued: 21.02.2023

Reply of firm: 01.03.2023

History (Last 03 Years): Firm: 13 cases reported.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 15

PQCB/R-687/2021

(Tehsil Ferozewala District Sheikhupura)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Muhammad Bilal 2. Muhammad Bilal S/o Liaqat Ali Butt Chief Executive Officer 3. Shehzad Mamoon S/o Muhammad Ashraf Production Incharge 4. Saleem Shahid S/o Jan Muhammad Quality Control Incharge/ Warrantor of **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. His Predecessor, on 15-03-2021, along-with other team members inspected the manufacturing premises of M/S B J Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.
ii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis and send to Drug Testing Laboratory Lahore vide memo number 87213 dated 16-03-2021. These samples were declared of substandard quality from Drug Testing Laboratory, Lahore as detailed below:
iii. A copy of test reports were sent to M/s B J Pharmaceuticals 18-km, Mandiali Stop Lahore-Sheikhupura Road, Lahore with directions to provide requisite information in this regard.

Name of drug	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Film-coated Tablet, TREZINE [Cetirizine 2HCl…10 MG] **Mfg. Date 03-2021** **Expiry Date: 03-2023** **Reg No. 082782**	036	M/s B J Pharmaceuticals 18-km, Mandiali Stop Lahore-Sheikhupura Road, Lahore.	TRA No. 01-166000599/DTL Dated: 05-05-2021	**Analysis with specifications applied:** USP 2020 **Physical Characteristics:** Blue colored oval shaped tablet with line of bisection on one side in transparent blister p **Identification:** The retention time of the major peak in the sample chromatogram corresponds to the re major peak in standard chromatogram (CETIRIZINE DIHYDROCHLORIDE IDENTIF **Assay of Cetirizine Dihydrochloride:** Stated: 10 mg/tab Determined: 9.34 mg/tab

Percentage: 93.39%

Limit: 90-110% of Label Claim.

Dissolution Test: Does not comply with the USP Specifications as detailed below:

Tolerance Limit: NLT 80% (Q) of the labelled amount is dissolved in 30 minutes.

For S2: Average of 12 units (S1 + S2) is equal or greater than Q, and no unit is less tha

FOR S3: Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2
Q-15%, and no unit is less than Q-25%.

Level	**Number tested**	**Acceptance Criteria**					
S1	6	Each individual unit should NLT 80% Q					
		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Un
Determined		**45.69%**	**46.21%**	**51.16%**	**45.16%**	**53.55%**	61.

The sample fails to comply at S1 stage, as 5 out of 6 units release is below the limit of Q

RESULT:

The above sample is Substandard, on the basis of DISSOLUTION TEST performed as p

2. In this way You have contravened the provisions of Section 23/27 of the Drugs Act, 1976 (as amended)/DRAP Act, 2012 and Rules framed there under by the way of :-

a. **Manufacturing for sale/ sale of Sub-standard drug**

3. The Show-Cause Notice was issued to the accused person (s).

Reply of Show-Cause Notice:

With reference to your letter No. PQCB/SM-03-04/2021, R-686, 687/2021 dated 21-02- 2023, which we received on 27-02-2023. The Government Analyst, drug Testing Laboratory, Lahore had declared the Tab Doxycycline 100mg vide test report TRA No. 01-166000598/DTL dated: 05-05-2021 SUB-STANDARD on the basis of Assay, Dissolution and Uniformity of Dosage Units and Tab film coated Trezine 10mg sample vide test report TRA No. 01-166000599/DTL dated: 05-05-2021 "SUB-STANDARD" on the basis of dissolution, We did not receive DTL testing repot of both products above mentioned.

So, you are requested to provide us the testing report (Test/Analysis by Government Analyst, Lahore) as soon as possible. So we may proceed it according to the procedure and able to give complete and comprehensive answer according the reports.

5. Personal hearing notice(s) issued to accused person(s) dated 30.07.2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **283rd meeting** held on **08.08.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice-Chairperson PQCB. Dr. Asma, Secretary DQCB District Sheikhupura attended the meeting online via zoom link along with original case record. No one appeared before the Board on the behalf of M/s BJ Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.
7. The Board decided to adjourn the case on written request of firm and also decided to provide another opportunity of personal hearing in best interest of justice.
8. Personal hearing notice(s) issued to accused person(s) dated 20.03.2025.

Summary:

Manufacturing Date: 03.2021

Expiry Date: 03.2023

Seizure Date (Form 5): 15.03.2021

Sampling Date (Form 4): 15.03.2021

Sent to DTL (Form 6): 16.03.2021

Date of receipt in DTL: 17.03.2021

DTL Report Date (Form 7): 05.05.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 18.05.2021

Date of Retesting Request of Firm: N/A

Fate of Retesting: N/A

Investigation Report Dated: 16.12.2022

Permission of SCN:

SCN issued: 21.02.2023

Reply of firm: 01.03.2023

History (Last 03 Years): Product: 04 case reported, Firm: 13 cases reported.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

(Tehsil Ferozewala District Sheikhupura)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Muhammad Bilal 2. Muhammad Bilal S/o Liaqat Ali Butt Chief Executive Officer 3. Shehzad Mamoon S/o Muhammad Ashraf Production Incharge 4. Saleem Shahid S/o Jan Muhammad Quality Control Incharge/ Warrantor of **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. His Predecessor, on 15-03-2021, along-with other team members inspected the manufacturing premises of M/S B J Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.
ii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis and send to Drug Testing Laboratory Lahore vide memo number 87213 dated 16-03-2021. These samples were declared of substandard quality from Drug Testing Laboratory, Lahore as detailed below:
iii. A copy of test reports were sent to M/s B J Pharmaceuticals 18-km, Mandiali Stop Lahore-Sheikhupura Road, Lahore with directions to provide requisite information in this regard.

Name of drug	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Film-coated Tablet, TREZINE [Cetirizine 2HCl…10 MG] **Mfg. Date 03-2021** **Expiry Date: 03-2023** **Reg No. 082782**	036	M/s B J Pharmaceuticals 18-km, Mandiali Stop Lahore-Sheikhupura Road, Lahore.	TRA No. 01-166000599/DTL Dated: 05-05-2021	**Analysis with specifications applied:** USP 2020 **Physical Characteristics:** Blue colored oval shaped tablet with line of bisection on one side in transparent blister p **Identification:** The retention time of the major peak in the sample chromatogram corresponds to the re major peak in standard chromatogram (CETIRIZINE DIHYDROCHLORIDE IDENTIF **Assay of Cetirizine Dihydrochloride:** Stated: 10 mg/tab Determined: 9.34 mg/tab Percentage: 93.39% Limit: 90-110% of Label Claim.

Dissolution Test: Does not comply with the USP Specifications as detailed below:

Tolerance Limit: NLT 80% (Q) of the labelled amount is dissolved in 30 minutes.

For S2: Average of 12 units (S1 + S2) is equal or greater than Q, and no unit is less tha

FOR S3: Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 Q-15%, and no unit is less than Q-25%.

Level	**Number tested**	**Acceptance Criteria**					
S1	6	Each individual unit should NLT 80% Q					
		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Un
Determined		**45.69%**	**46.21%**	**51.16%**	**45.16%**	**53.55%**	61.

The sample fails to comply at S1 stage, as 5 out of 6 units release is below the limit of Q

RESULT:

The above sample is Substandard, on the basis of DISSOLUTION TEST performed as p

2. In this way You have contravened the provisions of Section 23/27 of the Drugs Act, 1976 (as amended)/DRAP Act, 2012 and Rules framed there under by the way of :-

a. **Manufacturing for sale/ sale of Sub-standard drug**

3. The Show-Cause Notice was issued to the accused person (s).

Reply of Show-Cause Notice:

With reference to your letter No. PQCB/SM-03-04/2021, R-686, 687/2021 dated 21-02- 2023, which we received on 27-02-2023. The Government Analyst, drug Testing Laboratory, Lahore had declared the Tab Doxycycline 100mg vide test report TRA No. 01-166000598/DTL dated: 05-05-2021 SUB-STANDARD on the basis of Assay, Dissolution and Uniformity of Dosage Units and Tab film coated Trezine 10mg sample vide test report TRA No. 01-166000599/DTL dated: 05-05-2021 "SUB-STANDARD" on the basis of dissolution, We did not receive DTL testing repot of both products above mentioned.

So, you are requested to provide us the testing report (Test/Analysis by Government Analyst, Lahore) as soon as possible. So we may proceed it according to the procedure and able to give complete and comprehensive answer according the reports.

5. Personal hearing notice(s) issued to accused person(s) dated 30.07.2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **283**

rd **meeting** held on **08.08.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice-Chairperson PQCB. Dr. Asma, Secretary DQCB District Sheikhupura attended the meeting online via zoom link along with original case record. No one appeared before the Board on the behalf of M/s BJ Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.

7. The Board decided to adjourn the case on written request of firm and also decided to provide another opportunity of personal hearing in best interest of justice.
8. Personal hearing notice(s) issued to accused person(s) dated 20.03.2025.

Summary:

Manufacturing Date: 03.2021

Expiry Date: 03.2023

Seizure Date (Form 5): 15.03.2021

Sampling Date (Form 4): 15.03.2021

Sent to DTL (Form 6): 16.03.2021

Date of receipt in DTL: 17.03.2021

DTL Report Date (Form 7): 05.05.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 18.05.2021

Date of Retesting Request of Firm: N/A

Fate of Retesting: N/A

Investigation Report Dated: 16.12.2022

Permission of SCN:

SCN issued: 21.02.2023

Reply of firm: 01.03.2023

History (Last 03 Years): Product: 04 case reported, Firm: 13 cases reported.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 16

PQCB/R-686/2021

(Tehsil Ferozewala District Sheikhupura)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Muhammad Bilal 2. Muhammad Bilal S/o Liaqat Ali Butt Chief Executive Officer 3. Shehzad Mamoon S/o Muhammad Ashraf Production Incharge 4. Saleem Shahid S/o Jan Muhammad Quality Control Incharge/ Warrantor of **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. His Predecessor, on 15-03-2021, along-with other team members inspected the manufacturing premises of M/S B J Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.
ii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis and send to Drug Testing Laboratory Lahore vide memo number 87212 dated 16-03-2021. These samples were declared of substandard quality from Drug Testing Laboratory, Lahore as detailed below:
iii. A copy of test reports were sent to M/s B J Pharmaceuticals 18-km, Mandiali Stop Lahore-Sheikhupura Road, Lahore with directions to provide requisite information in this regard.

Name of drug	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Tablet Doxycycline [Doxycycline (as hyclate)…100mg] **Mfg. Date 03-2021** **Expiry Date: 03-2023** **Reg No. 082782**	013	M/s B J Pharmaceuticals 18-km, Mandiali Stop Lahore-Sheikhupura Road, Lahore.	TRA No. 01-166000598/DTL Dated: 05-05-2021	**Analysis with specifications applied:** USP 2020 **Physical Characteristics:** Green colored round shaped tablet, plain from both sides in opaque plastic bottle **Uniformity of Dosage Units:** Fails to comply the USP criteria for weight variation as detailed below: **Tolerance Limit:** the requirements for dosage uniformity are met if the acce first 10 dosage units is less than or equal to L 1%, test the next 20 units acceptance value. The requirements are met if the final acceptance value of the less than or equal to L1% and no individual content of any dosage uni (0.01)(L2)]M nor more than [1+(0.01)(L2)] M as specified in the calculation

under content uniformity or under weight variation. L1 is 15.0 and L2 is 25.0.

Determined:

L1 (10 units) =**22.7**

L1 (30 units) =**22.0 (Does not comply)**

Dissolution Test: Does not comply with the USP Specifications as detailed belo

Tolerance Limit: NLT 85% (Q) of the labelled amounts is dissolved in 90 m

For S2: Average of 12 units (S1 + S2) is equal or greater than Q, and no unit is

FOR S-3: Average of 24 units (S1+S2+S3) is equal to or greater than Q, not mo
less than Q-15%, and no unit is less than Q-25%.

Level	**Number tested**	**Acceptance Criteria**					
S1	6	Each individual unit should NLT 85% Q					
		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	U
Determined		**15.8%**	**16.8%**	**16.8%**	**17.7%**	**18.7%**	**1**

The sample fails to comply at S1 stage, as 6 out of 6 units release is below the li

Identification:

HPLC-PDA (Doxycycline identified)

Assay of Doxycycline:

Stated: 10 mg/tab

Determined: 79.81mg/ Tab

Percentage: 79.81% (Does not comply)

Limit: 90.0-120.0% of the label claim.

RESULT:

The above sample is Substandard, on the basis of ASSAY, DISSOLUTION a
OF DOSAGE UNITS, performed as per USP.

2. In this way You have contravened the provisions of Section 23/27 of the Drugs Act, 1976 (as amended)/DRAP Act, 2012 and Rules framed there under by the way of :-

a. **Manufacturing for sale/ sale of Sub-standard drug**

3. The Show-Cause Notice was issued to the accused person (s).

Reply of Show-Cause Notice:

With reference to your letter No. PQCB/SM-03-04/2021, R-686, 687/2021 dated 21-02- 2023, which we received on 27-02-2023. The Government Analyst, drug Testing Laboratory, Lahore had declared the Tab Doxycycline 100mg vide test report TRA No. 01-166000598/DTL dated: 05-05-2021 SUB-STANDARD on the basis of Assay, Dissolution and Uniformity of Dosage Units and Tab film coated Trezine 10mg sample vide test report TRA No. 01-166000599/DTL dated: 05-05-2021 "SUB-STANDARD" on the basis of dissolution, We did not receive DTL testing repot of both products above mentioned.

So, you are requested to provide us the testing report (Test/Analysis by Government Analyst, Lahore) as soon as possible. So we may proceed it according to the procedure and able to give complete and comprehensive answer according the reports.

5. Personal hearing notice(s) issued to accused person(s) dated 30.07.2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **283rd meeting** held on **08.08.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice-Chairperson PQCB. Dr. Asma, Secretary DQCB District Sheikhupura attended the meeting online via zoom link along with original case record. No one appeared before the Board on the behalf of M/s BJ Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.
7. The Board decided to adjourn the case on written request of firm and also decided to provide another opportunity of personal hearing in best interest of justice.
8. Personal hearing notice(s) issued to accused person(s) dated 20.03.2025.

Summary:

Manufacturing Date: 03.2021

Expiry Date: 03.2023

Sampling Date (Form 4): 15.03.2021

Sent to DTL (Form 6): 16.03.2021

Date of receipt in DTL: 17.03.2021

DTL Report Date (Form 7): 05.05.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 18.05.2021

Date of Retesting Request of Firm: N/A

Fate of Retesting: N/A

Investigation Report Dated: 16.12.2022

Permission of SCN:

SCN issued: 21.02.2023

Reply of firm: 01.03.2023

History (Last 03 Years): Product: 01 case reported, Firm: 13 cases reported.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-686/2021

(Tehsil Ferozewala District Sheikhupura)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Muhammad Bilal 2. Muhammad Bilal S/o Liaqat Ali Butt Chief Executive Officer 3. Shehzad Mamoon S/o Muhammad Ashraf Production Incharge 4. Saleem Shahid S/o Jan Muhammad Quality Control Incharge/ Warrantor of **M/S BJ Pharma, 18-km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. His Predecessor, on 15-03-2021, along-with other team members inspected the manufacturing premises of M/S B J Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.
ii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis and send to Drug Testing Laboratory Lahore vide memo number 87212 dated 16-03-2021. These samples were declared of substandard quality from Drug Testing Laboratory, Lahore as detailed below:
iii. A copy of test reports were sent to M/s B J Pharmaceuticals 18-km, Mandiali Stop Lahore-Sheikhupura Road, Lahore with directions to provide requisite information in this regard.

Name of drug	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Tablet Doxycycline [Doxycycline (as	013	M/s B J Pharmaceuticals 18-km,	TRA No. 01-166000598/DTL	**Analysis with specifications applied:** USP 2020

hyclate)…100mg]

Mfg. Date 03-2021

Expiry Date: 03-2023

Reg No. 082782

Mandiali Stop Lahore-Sheikhupura Road, Lahore.

Dated: 05-05-2021

Physical Characteristics:

Green colored round shaped tablet, plain from both sides in opaque plastic bottle

Uniformity of Dosage Units:

Fails to comply the USP criteria for weight variation as detailed below:

Tolerance Limit: the requirements for dosage uniformity are met if the acce first 10 dosage units is less than or equal to L 1%, test the next 20 units acceptance value. The requirements are met if the final acceptance value of the less than or equal to L1% and no individual content of any dosage uni (0.01)(L2)]M nor more than [1+(0.01)(L2)] M as specified in the calculation under content uniformity or under weight variation. L1 is 15.0 and L2 is 25.0.

Determined:

L1 (10 units) =**22.7**

L1 (30 units) =**22.0 (Does not comply)**

Dissolution Test: Does not comply with the USP Specifications as detailed belo

Tolerance Limit: NLT 85% (Q) of the labelled amounts is dissolved in 90 m

For S2: Average of 12 units (S1 + S2) is equal or greater than Q, and no unit is

FOR S-3: Average of 24 units (S1+S2+S3) is equal to or greater than Q, not mo less than Q-15%, and no unit is less than Q-25%.

Level	**Number tested**	**Acceptance Criteria**					
S1	6	Each individual unit should NLT 85% Q					
		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	U
Determined		**15.8%**	**16.8%**	**16.8%**	**17.7%**	**18.7%**	**1**

The sample fails to comply at S1 stage, as 6 out of 6 units release is below the li

Identification:

HPLC-PDA (Doxycycline identified)

Assay of Doxycycline:

Stated: 10 mg/tab

Determined: 79.81mg/ Tab

Percentage: 79.81% (Does not comply)

				Limit: 90.0-120.0% of the label claim. **RESULT:** The above sample is Substandard, on the basis of ASSAY, DISSOLUTION a OF DOSAGE UNITS, performed as per USP.

2. In this way You have contravened the provisions of Section 23/27 of the Drugs Act, 1976 (as amended)/DRAP Act, 2012 and Rules framed there under by the way of :-

a. **Manufacturing for sale/ sale of Sub-standard drug**

3. The Show-Cause Notice was issued to the accused person (s).

Reply of Show-Cause Notice:

With reference to your letter No. PQCB/SM-03-04/2021, R-686, 687/2021 dated 21-02- 2023, which we received on 27-02-2023. The Government Analyst, drug Testing Laboratory, Lahore had declared the Tab Doxycycline 100mg vide test report TRA No. 01-166000598/DTL dated: 05-05-2021 SUB-STANDARD on the basis of Assay, Dissolution and Uniformity of Dosage Units and Tab film coated Trezine 10mg sample vide test report TRA No. 01-166000599/DTL dated: 05-05-2021 "SUB-STANDARD" on the basis of dissolution, We did not receive DTL testing repot of both products above mentioned.

So, you are requested to provide us the testing report (Test/Analysis by Government Analyst, Lahore) as soon as possible. So we may proceed it according to the procedure and able to give complete and comprehensive answer according the reports.

5. Personal hearing notice(s) issued to accused person(s) dated 30.07.2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **283rd meeting** held on **08.08.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice-Chairperson PQCB. Dr. Asma, Secretary DQCB District Sheikhupura attended the meeting online via zoom link along with original case record. No one appeared before the Board on the behalf of M/s BJ Pharma, 18-km Sheikhupura Road, Ferozewala, District Sheikhupura.
7. The Board decided to adjourn the case on written request of firm and also decided to provide another opportunity of personal hearing in best interest of justice.
8. Personal hearing notice(s) issued to accused person(s) dated 20.03.2025.

Summary:

Manufacturing Date: 03.2021

Expiry Date: 03.2023

Sampling Date (Form 4): 15.03.2021

Sent to DTL (Form 6): 16.03.2021

Date of receipt in DTL: 17.03.2021

DTL Report Date (Form 7): 05.05.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 18.05.2021

Date of Retesting Request of Firm: N/A

Fate of Retesting: N/A

Investigation Report Dated: 16.12.2022

Permission of SCN:

SCN issued: 21.02.2023

Reply of firm: 01.03.2023

History (Last 03 Years): Product: 01 case reported, Firm: 13 cases reported.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 17

PQCB/R-490/2023
Tehsil Depalpur, District Okara

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. . **Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan** through its CEO, Tahir Hayat 2. Tahir Hayat CEO 3. Sarmat Tamjeed Production Incharge 4. Ayesha Iftikhar Quality Control Incharge/warrantor of M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Depalpur, Okara reported that: -

i. He, on 26-11-2022, inspected the business premises of M/s Tahir Medical Store Adda Sukhpur Pakpattan Road, Tehsil Depalpur, took two different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Bahawalpur vide memorandum no. 149935 dated 30-11-2022.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**TRA No. & Date**	**DTL Test Report Result**
Suspension. Bril [Ibuprofen: 100mg/5ml, 90ml] **Mfg Date:** 09-2022 **Exp Date:** 09-2024	39044	M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore-Pakistan.	01-10097001315/DTL Dated: 26-01-2023	**Specs Applied: USP 2022** **COMPOSITION** Each 5ml contains: Ibuprofen …….... 100mg. **DESCRIPTION** Orange color suspension filed in amber color plastic bottle (Labelled and sealed). Packed in outer hard carton. (Stated Volume: 90ml) **pH (USP)** ***Limit*** 3.6 – 4.6 ***Determined*** 4.095 **IDENTIFICATION (USP)** Ibuprofen is identified. **ASSAY (USP):** Ibuprofen **Stated**

				100mg/5ml **<u>Determined</u>** **63.94mg/5ml** **<u>Percentage</u>** **63.94%** **Limit: 90-110%** **Does not comply with specification** **<u>RESULT</u>**: The Sample is declared "**Sub-Standard**" on the basis of "**Assay Test**".

iii. Proprietor of M/s Tahir Medical Store Adda Sukhpur Pakpattan Road, Tehsil Depalpur provided invoice/ warranty bearing No. 14001 dated 26-11-2022 issued by M/s Tahir Traders Haveli Road Hujra Shah Muqeem Tehsil Depalpur Okara as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Tahir Traders Haveli Road Hujra Shah Muqeem Tehsil Depalpur who in-turn provided invoice/warranty bearing No. 31772 dated 15-10-2022 issued by M/s Sajid Trading Company Main Street Sindhi Mohalla District Okara who in turn provided invoice/warranty no. 2211000002 WI-0013 dated 01-11-2022 issued by M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan with directions to explain their position and provide requisite information in this regard.

v. A copy of test/analysis report was sent to M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan with request to provide requisite information in this regard. In response firm requested for retesting of the sample. Pursuant to request of retesting was allowed in 27th meeting dated 26-10-2023 and sample sent to NIH. From where subject sample declared of **substandard** quality. The detail is as follows:

Nomenclature	**Batch No.**	**Name of Manufacturer**	**Test report No. & Date**	**NIH test Report Result**
Bril Oral suspension 90ml **Mfg Date:** 09-2022 **Expiry Date:** 09-2024	39044	M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore-Pakistan.	0278-P/2023 dated: 7th February, 2024	**<u>Reference:</u>** USP-2022 **<u>ASSAY:</u> Ibuprofen** **Stated** 100 mg/ 5ml **Found** 44.45 mg/5ml **Percentage** **44.45%** **Limit** 90-110% **Does not Comply with USP-2022** **<u>CONCLUSION:</u>** The sample is of Sub-standard quality on

				the basis of test performed

vi. A copy of NIH test/analysis report was sent to M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan with request to provide requisite information

3. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/stock/ Sale of Substandard drug**
b. **Issuance of false warranty**

4. Show-cause notice (s) issued to the accused persons(s) dated 10-10-2024

5. Personal Hearing notice (s) issued to the accused persons(s) dated 20-03-2025

6. Case is placed before Board for Descion

Summary	
Sampling Date (Form 4):	26-11-2022
Sent to DTL (Form 6):	30-11-2022
Date of receipt in DTL	02-12-2022
DTL Report Date (Form 7):	26-01-2023
Time Extension granted	N/A
1st DI Communication with firm dated	13-04-2023
Date of Retesting Request of Firm:	19-04-2023
Fate of Retesting request	**Allowed in 27thCommittee Meeting dated 26-10-2023**
NIH Report	**Substandard from NIH vide Test Report No. 0278-P/2023 Dated 07-02-2024**
Investigation Report Dated	02-07-2024
Firm History 3 years	**Firm: 10**

	Product:4

PROCEEDING & DECISION BY THE BOARD:

PQCB/R-490/2023
Tehsil Depalpur, District Okara

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. . **Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan** through its CEO, Tahir Hayat 2. Tahir Hayat CEO 3. Sarmat Tamjeed Production Incharge 4. Ayesha Iftikhar Quality Control Incharge/warrantor of M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Depalpur, Okara reported that: -

i. He, on 26-11-2022, inspected the business premises of M/s Tahir Medical Store Adda Sukhpur Pakpattan Road, Tehsil Depalpur, took two different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Bahawalpur vide memorandum no. 149935 dated 30-11-2022.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Suspension. Bril [Ibuprofen: 100mg/5ml, 90ml] **Mfg Date:**	39044	M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore-Pakistan.	01-10097001315/DTL Dated: 26-01-2023	**Specs Applied: USP 2022** **COMPOSITION** Each 5ml contains: Ibuprofen …….... 100mg. **DESCRIPTION** Orange color suspension filed in amber color plastic bottle (Labelled and sealed). Packed in outer hard carton. (Stated Volume: 90ml)

09-2022 **Exp Date:** 09-2024				**pH (USP)** ***Limit*** 3.6 – 4.6 ***Determined*** 4.095 **IDENTIFICATION (USP)** Ibuprofen is identified. **ASSAY (USP):** Ibuprofen **Stated** 100mg/5ml **Determined** **63.94mg/5ml** **Percentage** **63.94%** **Limit:** **90-110%** **Does not comply with specification** **RESULT**: The Sample is declared "**Sub-Standard**" on the basis of "**Assay Test**".

iii. Proprietor of M/s Tahir Medical Store Adda Sukhpur Pakpattan Road, Tehsil Depalpur provided invoice/ warranty bearing No. 14001 dated 26-11-2022 issued by M/s Tahir Traders Haveli Road Hujra Shah Muqeem Tehsil Depalpur Okara as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Tahir Traders Haveli Road Hujra Shah Muqeem Tehsil Depalpur who in-turn provided invoice/warranty bearing No. 31772 dated 15-10-2022 issued by M/s Sajid Trading Company Main Street Sindhi Mohalla District Okara who in turn provided invoice/warranty no. 2211000002 WI-0013 dated 01-11-2022 issued by M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan with directions to explain their position and provide requisite information in this regard.

v. A copy of test/analysis report was sent to M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan with request to provide requisite information in this regard. In response firm requested for retesting of the sample. Pursuant to request of retesting was allowed in 27th meeting dated 26-10-2023 and sample sent to NIH. From where subject sample declared of **substandard** quality. The detail is as follows:

Nomenclature	**Batch No.**	**Name of Manufacturer**	**Test report No. & Date**	**NIH test Report Result**
Bril Oral suspension 90ml **Mfg Date:** 09-2022 **Expiry Date:** 09-2024	39044	M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore-Pakistan.	0278-P/2023 dated: 7th February, 2024	**Reference:** USP-2022 **ASSAY: Ibuprofen** **Stated** 100 mg/ 5ml **Found** 44.45 mg/5ml **Percentage** **44.45%** **Limit** 90-110%

				Does not Comply with USP-2022 **CONCLUSION:** The sample is of Sub-standard quality on the basis of test performed

vi. A copy of NIH test/analysis report was sent to M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan with request to provide requisite information

3. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/stock/ Sale of Substandard drug**
b. **Issuance of false warranty**

4. Show-cause notice (s) issued to the accused persons(s) dated 10-10-2024

5. Personal Hearing notice (s) issued to the accused persons(s) dated 20-03-2025

6. Case is placed before Board for Descion

Summary	
Sampling Date (Form 4):	26-11-2022
Sent to DTL (Form 6):	30-11-2022
Date of receipt in DTL	02-12-2022
DTL Report Date (Form 7):	26-01-2023
Time Extension granted	N/A
1st DI Communication with firm dated	13-04-2023
Date of Retesting Request of Firm:	19-04-2023
Fate of Retesting request	**Allowed in 27thCommittee Meeting dated 26-10-2023**
NIH Report	**Substandard from NIH vide Test Report No. 0278-P/2023 Dated 07-02-2024**

Investigation Report Dated	02-07-2024
Firm History 3 years	**Firm: 10** **Product:4**

PROCEEDING & DECISION BY THE BOARD:

Case No. 18

PQCB/MSS-191440/2024
Tehsil Renala Kurd,District Okara

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case**. 1. **M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan** through its CEO, Aamir Bashir 2. Aamir Bashir CEO 3. Shahzad Ahmad Khan Production Incharge 4. Irfan Ashiq Quality Control Incharge/warrantor of M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan.

BRIEF FACTS OF THE CASE
Provincial Inspector of Drugs, Tehsil Renala Khurd, Okara reported that: -

i. She, on 03-02-2024, inspected the business premises of M/s Bhatti medical store shop no. 4 Near Naveed & Brothers Super store Adda bama Bala Tehsil Renala Khurd, took subject drug sample on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide memorandum no. 191440 dated 05-02-2024.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**TRA No. & Date**	**DTL Test Report Result**
Suspension. Bril [Ibuprofen 100mg/5ml] **Mfg Date:** 12-2023 **Expiry Date:** 12-2025	39127	M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore-Pakistan.	01-10200000381/DTL Dated: 12-03-2024	**Specs Applied: USP 2023** **PHYSICAL APPEARANCE:** Orange color suspension in amber plastic bottle having label pasted on it with a sealed aluminim screw cap. Claimed volume: 90ml Determined Volume: 90ml **pH** ***Limit*** 3.6 – 4.6 ***Determined*** 4.2 at 23.1ºC

				IDENTIFICATION of ibuprofen USP test A, and USP Test B (Ibuprofen identified) **ASSAY of** Ibuprofen **Stated** 100mg/5mL **Determined** **84.28mg/5mL** **Percentage** **84.28%** **Limit:** **90-110% of labelled amount** **Does not comply** **IDENTIFICATUON OF ETHYLENE GLYCOL & DIETHYLNE GLYCOL** Ethylene glycol and Diethylene Glycol are not identified **RESULT**: The Sample is declared "**Sub-Standard**" on the basis of "**Assay Test**" performed as per USP.

iii. Proprietor of M/s Bhatti medical store shop no. 4 Near Naveed & Brothers Super store Adda Bama Bala Tehsil Renala Khurd provided invoice/ bill warranty No. 36256 dated 01-02-2024 issued by M/s Care well Medicine Distributors H# 1, St # 14Jinnah Park Sultan pura, Lahore as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Care well Medicine Distributors H# 1, St # 14Jinnah Park Sultan pura and provided invoice/ bill warranty No. LUP/1784 dated 10-01-2024 issued by M/s Lupin pharma Lahore 787 canal road Johar Avenue new Capus Lahore who in turn provided invoice/warranty no.231200107 dated 31-12-2023 issued by M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan.

v. A copy of test/analysis report was sent to M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan with request to provide requisite information in this regard.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing /stocking/ Selling of Substandard drug**
b. **Issuance of false warranty**

3. Show-cause notice(s) issued to the accused persons(s) dated 07-10-2024
4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025
5. Case is placed before the Board for decision.

Summary	
Sampling Date (Form 4):	03-02-2024

Sent to DTL (Form 6):	05-02-2024
Date of receipt in DTL	07-02-2024
DTL Report Date (Form 7):	12-03-2024
Time Extension granted	N/A
1st DI Communication with firm dated	20-06-2024
Date of Retesting Request of Firm:	N/A
Fate of Retesting request	N/A
Investigation Report Dated	18-07-2024
Firm History 3 years	**Firm: 10** **Product:4**

PROCEEDING & DECISION BY THE BOARD:

PQCB/MSS-191440/2024
Tehsil Renala Kurd,District Okara

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case**. 1. **M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan** through its CEO, Aamir Bashir 2. Aamir Bashir CEO 3. Shahzad Ahmad Khan Production Incharge 4. Irfan Ashiq Quality Control Incharge/warrantor of M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Renala Khurd, Okara reported that: -

i. She, on 03-02-2024, inspected the business premises of M/s Bhatti medical store shop no. 4 Near Naveed & Brothers Super store Adda bama Bala Tehsil Renala Khurd, took subject drug sample on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide memorandum no. 191440 dated 05-02-2024.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**TRA No. & Date**	**DTL Test Report Result**
Suspension. Bril [Ibuprofen 100mg/5ml] **Mfg Date:** 12-2023 **Expiry Date:** 12-2025	39127	M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore-Pakistan.	01-10200000381/DTL Dated: 12-03-2024	**Specs Applied: USP 2023** **PHYSICAL APPEARANCE:** Orange color suspension in amber plastic bottle having label pasted on it with a sealed aluminim screw cap. Claimed volume: 90ml Determined Volume: 90ml **pH** ***Limit*** 3.6 – 4.6 ***Determined*** 4.2 at 23.1ºC **IDENTIFICATION of ibuprofen** USP test A, and USP Test B (Ibuprofen identified) **ASSAY of** Ibuprofen **Stated** 100mg/5mL **Determined** **84.28mg/5mL** **Percentage** **84.28%** **Limit:** **90-110% of labelled amount** **Does not comply** **IDENTIFICATUON OF ETHYLENE GLYCOL & DIETHYLNE GLYCOL** Ethylene glycol and Diethylene Glycol are not identified **RESULT**:

				The Sample is declared "**Sub-Standard**" on the basis of "**Assay Test**" performed as per USP.

iii. Proprietor of M/s Bhatti medical store shop no. 4 Near Naveed & Brothers Super store Adda Bama Bala Tehsil Renala Khurd provided invoice/ bill warranty No. 36256 dated 01-02-2024 issued by M/s Care well Medicine Distributors H# 1, St # 14Jinnah Park Sultan pura, Lahore as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Care well Medicine Distributors H# 1, St # 14Jinnah Park Sultan pura and provided invoice/ bill warranty No. LUP/1784 dated 10-01-2024 issued by M/s Lupin pharma Lahore 787 canal road Johar Avenue new Capus Lahore who in turn provided invoice/warranty no.231200107 dated 31-12-2023 issued by M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan.

v. A copy of test/analysis report was sent to M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C Sundar Industrial Estate Lahore- Pakistan with request to provide requisite information in this regard.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing /stocking/ Selling of Substandard drug**
b. **Issuance of false warranty**

3. Show-cause notice(s) issued to the accused persons(s) dated 07-10-2024
4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025
5. Case is placed before the Board for decision.

Summary	
Sampling Date (Form 4):	03-02-2024
Sent to DTL (Form 6):	05-02-2024
Date of receipt in DTL	07-02-2024
DTL Report Date (Form 7):	12-03-2024
Time Extension granted	N/A
1st DI Communication with firm dated	20-06-2024
Date of Retesting Request of Firm:	N/A
Fate of Retesting request	N/A
Investigation Report Dated	18-07-2024

Firm History 3 years	**Firm: 10** **Product:4**

PROCEEDING & DECISION BY THE BOARD:

Case No. 19

PQCB/ MSS-167981/2023

Tehsil & District Toba Tek Singh

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone Rawat Islamabad** through its Managing Director Wassi Shan 2. Wassi Shan — Managing Director 3. Ghulam Muhammad — Production Incharge 4. Qurrat ul Ain — Quality Control Incharge/warrantor **Of M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone Rawat Islamabad**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Toba Tek Singh reported that: -

i. He, on 26.05.2023, inspected the business premises of M/s Ahad Medical Store situated at Zia Colony Toba Tek Singh and took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo. No. 167981, dated 26.05.2023.
ii. Following Drug samples after test/analysis were declared as **Misbranded** by Government Analyst Drug Testing Laboratory **Faisalabad,** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Capsule Hi-Mep (Each capsule contains: Omeprazole pellets (enteric coated) eq. to Omeprazole: 20mg) **Mfg Date:** 01.2023 **Exp Date:** 12.2024	C1022	M/S Gulf Pharmaceuticals, Plot No.49, Street No. S-5, National Industrial Zone Rawat Islamabad, Pakistan	01-68024704/DTL Dated. 19.07.2023	**Analysis with specifications applied: MS.** **Description:** Off white pellets encapsulated in transparent body and pink color transparent cap of hard gelatin, contained in Alu-Alu packing of 07 units, packed in outer hard carton. Note: Manufacturer in its method of analysis specify "**white to off white spherical, enteric coated pellets filled in capsules having Blue body and Blue cap"** but given sample is "**off white pellets filled in capsules having transparent body and pink color transparent cap"** that does not comply with manufacturer's description of capsule. **(Does not comply)** **IDENTIFICATION:** Omeprazole is identified. **ASSAY:** Complies **Result:** Given sample is Substandard with regards to description (Physical

Registration No. 073151				Appearance) of capsule.

iii. M/s Ahad Medical Store situated at Zia Colony Toba Tek Singh provided Invoice/warranty No. 6961 dated 25.05.2023 issued by M/S Target Medicose, Main Street Fiaz Colony Toba Tek Singh as a proof of its purchase.
iv. Warrantor portions of drug samples were sent to M/S Target Medicose, Main Street Fiaz Colony Toba Tek Singh.
v. M/s Target Medicose, Main Street Fiaz Colony Toba Tek Singh provided Invoice/warranty No. 3029 dated 28.04.2023 issued by M/S Gulf Pharmaceuticals, Plot No.49, Street No. S-5, National Industrial Zone Rawat Islamabad, Pakistan as a proof of its purchase.
vi. Copies of test/analysis reports were sent to M/S Gulf Pharmaceuticals, Plot No.49, Street No. S-5, National Industrial Zone Rawat Islamabad, Pakistan and they were directed to explain their position and to provide the requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard drug**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 09-01-2024

Firm replied to the show cause notice vide letter no. Gf / QC /PQCB /01-025 dated 19-01-2024

This is with reference to your letter No. PQCB /MSS-167981/2023 dated 09-01-2024 received in Gulf Pharmaceuticals today on 18-01-2024.
Our submissions are as follows;
Following are our submissions for your consideration please.
1. Hi Mep Capsules Batch No C1022 Mfg. Date 01/2023 Exp. Date. 12/2024, declared Misbranded by DTL via report No TRA No. 01-68024704/DTL dated 19-07-2023.
2. The batch in question was misbranded on the basis of color of capsule shells which were changed from blue/blue to transparent/ transparent Pink.
3. Color of the capsule shells changed from blue/blue to transparent white/ pink was due to the requirement from the marketing team.
4. Proper change control procedure was followed for the change in specification (color of capsule shells. Change control along with old and new specifications are attached for reference.
5. Request for the change in specifications (Color of Capsule shells) was applied in DRAP (Registration) with prescribed fee. Receipts and bank vouchers are attached for the reference.
6. Our new approved specifications clearly indicates color of capsule shells that is Transparent/pink transparent.
Following are the names and addresses of the required personnel's.
CEO/Managing Director
Mr. Wassi Shan s/o Mr. Inayat Ullah
CNIC No. 37405-2288811-1
Address: Plot No. 49 Street No. S-5 Rawat Industrial Zone Islamabad
Production In-charge
Mr. Ghulam Muhammad s/o Mr. ilamdin
CNIC No. 38201-7980134-5
Address: Plot No.49 Street No. S-5 Rawat Industrial Zone Islamabad

Quality Control In-Charge

Qurrat-ul-Ain D/O M Aslam

CNIC 41101-8143523-8

Permanent Address: House no 170 Street no 1 near malik restaurant Burji stop Model Town Islamabad

Warrantor

Masood Younas S/O Muhammad Younas

CNIC 31303-0901286-1

Address: Plot No. S-5 Rawat Industrial Zone Islamabad Keeping in view the above facts and the batch in question we request you to please take a lenient view and drop the case in our favour.

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	26-05-2023
2	**Sample Sent to DTL (Form-6)**	26-05-2023
3	**Receipt Date in DTL**	01-06-2023
4	**Issuance of DTL Report**	19-07-2023
5	**Time Extension**	Not Time Barred
6	**DI First Communication with Firm**	31-07-2023
7	**Retesting Request**	No
9	**Investigation Report by DI**	03-01-2024
10	**SCN Permission**	271-M (01-11-2023)
11	**Show Cause Notice Issued**	09-01-2024
12	**Reply of Firm to Show Cause Notice**	Yes (19-01-2024)

13	**History (3 years)**	Firm's Reported: 8
		Product's Reported: 3 (Subject Case)

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/ MSS-167981/2023

Tehsil & District Toba Tek Singh

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone Rawat Islamabad** through its Managing Director Wassi Shan 2. Wassi Shan — Managing Director 3. Ghulam Muhammad — Production Incharge 4. Qurrat ul Ain — Quality Control Incharge/warrantor **Of M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone Rawat Islamabad**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Toba Tek Singh reported that: -

i. He, on 26.05.2023, inspected the business premises of M/s Ahad Medical Store situated at Zia Colony Toba Tek Singh and took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo. No. 167981, dated 26.05.2023.
ii. Following Drug samples after test/analysis were declared as **Misbranded** by Government Analyst Drug Testing Laboratory **Faisalabad,** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Capsule Hi-Mep (Each capsule contains: Omeprazole pellets (enteric coated) eq. to	C1022	M/S Gulf Pharmaceuticals, Plot No.49, Street No. S-5, National Industrial Zone Rawat Islamabad,	01-68024704/DTL Dated. 19.07.2023	**Analysis with specifications applied: MS.** **Description:** Off white pellets encapsulated in transparent body and pink color transparent cap of hard gelatin, contained in Alu-Alu packing of 07 units, packed in outer hard carton.

Omeprazole: 20mg) **Mfg Date:** 01.2023 **Exp Date:** 12.2024 **Registration No.** 073151		Pakistan		Note: Manufacturer in its method of analysis specify "**white to off white spherical, enteric coated pellets filled in capsules having Blue body and Blue cap"** but given sample is "**off white pellets filled in capsules having transparent body and pink color transparent cap"** that does not comply with manufacturer's description of capsule. **(Does not comply)** **IDENTIFICATION:** Omeprazole is identified. **ASSAY:** Complies **Result:** Given sample is Substandard with regards to description (Physical Appearance) of capsule.

iii. M/s Ahad Medical Store situated at Zia Colony Toba Tek Singh provided Invoice/warranty No. 6961 dated 25.05.2023 issued by M/S Target Medicose, Main Street Fiaz Colony Toba Tek Singh as a proof of its purchase.
iv. Warrantor portions of drug samples were sent to M/S Target Medicose, Main Street Fiaz Colony Toba Tek Singh.
v. M/s Target Medicose, Main Street Fiaz Colony Toba Tek Singh provided Invoice/warranty No. 3029 dated 28.04.2023 issued by M/S Gulf Pharmaceuticals, Plot No.49, Street No. S-5, National Industrial Zone Rawat Islamabad, Pakistan as a proof of its purchase.
vi. Copies of test/analysis reports were sent to M/S Gulf Pharmaceuticals, Plot No.49, Street No. S-5, National Industrial Zone Rawat Islamabad, Pakistan and they were directed to explain their position and to provide the requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard drug**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 09-01-2024

Firm replied to the show cause notice vide letter no. Gf / QC /PQCB /01-025 dated 19-01-2024

This is with reference to your letter No. PQCB /MSS-167981/2023 dated 09-01-2024 received in Gulf Pharmaceuticals today on 18-01-2024. Our submissions are as follows;

Following are our submissions for your consideration please.

1. Hi Mep Capsules Batch No C1022 Mfg. Date 01/2023 Exp. Date. 12/2024, declared Misbranded by DTL via report No TRA No. 01-68024704/DTL dated 19-07-2023.

2. The batch in question was misbranded on the basis of color of capsule shells which were changed from blue/blue to transparent/ transparent Pink.

3. Color of the capsule shells changed from blue/blue to transparent white/ pink was due to the requirement from the marketing team.

4. Proper change control procedure was followed for the change in specification (color of capsule shells. Change control along with old and new specifications are attached for reference.

5. Request for the change in specifications (Color of Capsule shells) was applied in DRAP (Registration) with prescribed fee. Receipts and bank vouchers are attached for the reference.

6. Our new approved specifications clearly indicates color of capsule shells that is Transparent/pink transparent.

Following are the names and addresses of the required personnel's.

CEO/Managing Director

Mr. Wassi Shan s/o Mr. Inayat Ullah

CNIC No. 37405-2288811-1

Address: Plot No. 49 Street No. S-5 Rawat Industrial Zone Islamabad

Production In-charge

Mr. Ghulam Muhammad s/o Mr. ilamdin

CNIC No. 38201-7980134-5

Address: Plot No.49 Street No. S-5 Rawat Industrial Zone Islamabad

Quality Control In-Charge

Qurrat-ul-Ain D/O M Aslam

CNIC 41101-8143523-8

Permanent Address: House no 170 Street no 1 near malik restaurant Burji stop Model Town Islamabad

Warrantor

Masood Younas S/O Muhammad Younas

CNIC 31303-0901286-1

Address: Plot No. S-5 Rawat Industrial Zone Islamabad Keeping in view the above facts and the batch in question we request you to please take a lenient view and drop the case in our favour.

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	26-05-2023
2	**Sample Sent to DTL (Form-6)**	26-05-2023
3	**Receipt Date in DTL**	01-06-2023
4	**Issuance of DTL Report**	19-07-2023
5	**Time Extension**	Not Time Barred
6	**DI First Communication with Firm**	31-07-2023
7	**Retesting Request**	No

9	**Investigation Report by DI**	03-01-2024
10	**SCN Permission**	271-M (01-11-2023)
11	**Show Cause Notice Issued**	09-01-2024
12	**Reply of Firm to Show Cause Notice**	Yes (19-01-2024)
13	**History (3 years)**	Firm's Reported: 8
		Product's Reported: 3 (Subject Case)

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 20

PQCB/ R-511/2023

Tehsil Lalian and District Chiniot

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone Rawat Islamabad** through its Managing Director Wassi Shan 2. Wassi Shan — Managing Director 3. Ghulam Muhammad — Production Incharge 4. Qurrat ul Ain — Quality Control Incharge/warrantor **Of M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone Rawat Islamabad**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Lalian and District Chiniot reported that:-

i. He , on 20-03-2023 inspected the premises of M/s Pakistan Medical Store, adda Sheikhen Tehsil Lalian Distt Chiniot and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Faisalabad vide memo no. 161280 Dated 21-03-2023.
ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Faisalabad as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**
Capsule Hi-Mep 20 **Mfg. Date**: 02-2023 **Exp. Date**: 01-2025 **Reg** # 073151	C1028	M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone rawat Islamabad	01-68023297/ DTL dated: 23-05-2023
DTL Test Report Result: **Result of test/ analysis with specifications applied: USP 2023** **DESCRIPTION:** Off-white pellets encapsulated in transparent body and pink colour transparent cap of hard gelatine, contained in Alu-Alu packing of 07 units, packed in outer hard carton.			

Note: Manufacturer in its method of analysis specify " white to off white spherical, enteric coated pellets filled in capsules having blue body and blue cap" but given sample is "off white pellets filled in capsules having transparent body and pink colour transparent cap" that does not comply with manufacturer's description of capsule. **(Does not Comply)**

IDENTIFICATION:

Omeprazole is identified.

ASSAY:

Stated: 20mg/Capsule

Determined: 21.2774mg/capsule

Percentage: 106.387% (complies)

Limit: 90-110% (USP 2023)

DISSOLUTION TEST: complies with the dissolution test as per USP 2023 as detailed below:

Acid stage:

Tolerance Limit: Not more 15% of the labelled amount of omeprazole.

<table>
<tr><th>LEVEL</th><th>Unit tested</th><th colspan="6">ACCEPTANCE CRITERIA</th><th>REMARKS</th></tr>
<tr><td rowspan="3">L1</td><td>6</td><td colspan="6">No individual value exceeds 15% of the omeprazole dissolved.</td><td rowspan="3">Complies</td></tr>
<tr><td rowspan="2">After 2 hours</td><td>UNIT 1</td><td>UNIT 2</td><td>UNIT 3</td><td>UNIT 4</td><td>UNIT 5</td><td>UNIT 6</td></tr>
<tr><td>0.0%</td><td>0.0%</td><td>0.0%</td><td>0.0 %</td><td>0.0%</td><td>0.0 %</td></tr>
</table>

Buffer stage:

Tolerance Limit: Not less than 75% (Q) of the labelled amount of Omeprazole in 30 minutes.

<table>
<tr><th>LEVEL</th><th>Unit tested</th><th colspan="6">ACCEPTANCE CRITERIA</th><th>REMARKS</th></tr>
<tr><td rowspan="3">S1</td><td>6</td><td colspan="6">Each unit is Not less than Q + 5%</td><td rowspan="3">Complies</td></tr>
<tr><td rowspan="2">After 30 minutes</td><td>UNIT 1</td><td>UNIT 2</td><td>UNIT 3</td><td>UNIT 4</td><td>UNIT 5</td><td>UNIT 6</td></tr>
<tr><td>104.8%</td><td>106.6%</td><td>96.2%</td><td>94.5 %</td><td>107.8%</td><td>106.6 %</td></tr>
</table>

RESULT: Given sample is substandard with regards to description (physical appearance) of capsule.

iii. The Proprietor of M/s Pakistan Medical Store, adda Sheikhen Tehsil Lalian Distt Chiniot provided warranty/invoice No.13889 Dated 23-02-2023 issued by M/S Noor Ul Huda Medicine Marketing, street no. 2, Mohallah Mohammadi Gojra road, Jhang. In response they provided invoice/warranty no. 2685 dated 16-02-2023 issued by M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone rawat Islamabad

iv. Warrantor Portion was sent to M**/s** Noor Ul Huda Medicine Marketing, street no. 2, Mohallah Mohammadi Gojra road, Jhang.

A copy of Test/ Analysis reports was sent to M**/s** Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone rawat Islamabad

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard drug**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 28-02-2025

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	20-03-2023
2	**Sample Sent to DTL (Form-6)**	21-03-2023
3	**Receipt Date in DTL**	27-03-2023
4	**Issuance of DTL Report**	23-05-2025
5	**Time Extension**	Not Time Barred
6	**DI First Communication with Firm**	19-01-2024
7	**Retesting Request**	No
9	**Investigation Report by DI**	19-03-2024
10	**SCN Permission**	278-M (28-03-2024)
11	**Show Cause Notice Issued**	28-02-2025

12	**Reply of Firm to Show Cause Notice**	No
13	**History (3 years)**	Firm's Reported: 8
		Product's Reported: 3 (Subject Case)

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/ R-511/2023

Tehsil Lalian and District Chiniot

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone Rawat Islamabad** through its Managing Director Wassi Shan 2. Wassi Shan — Managing Director 3. Ghulam Muhammad — Production Incharge 4. Qurrat ul Ain — Quality Control Incharge/warrantor **Of M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone Rawat Islamabad**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Lalian and District Chiniot reported that:-

i. He , on 20-03-2023 inspected the premises of M/s Pakistan Medical Store, adda Sheikhen Tehsil Lalian Distt Chiniot and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Faisalabad vide memo no. 161280 Dated 21-03-2023.
ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Faisalabad as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**
Capsule Hi-Mep 20 **Mfg. Date**: 02-2023	C1028	M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone rawat Islamabad	01-68023297/ DTL dated: 23-05-2023

Exp. Date: 01-2025 **Reg #** 073151			

DTL Test Report Result:

Result of test/ analysis with specifications applied: USP 2023

DESCRIPTION:

Off-white pellets encapsulated in transparent body and pink colour transparent cap of hard gelatine, contained in Alu-Alu packing of 07 units, packed in outer hard carton.

Note: Manufacturer in its method of analysis specify " white to off white spherical, enteric coated pellets filled in capsules having blue body and blue cap" but given sample is "off white pellets filled in capsules having transparent body and pink colour transparent cap" that does not comply with manufacturer's description of capsule. **(Does not Comply)**

IDENTIFICATION:

Omeprazole is identified.

ASSAY:

Stated: 20mg/Capsule

Determined: 21.2774mg/capsule

Percentage: 106.387% (complies)

Limit: 90-110% (USP 2023)

DISSOLUTION TEST: complies with the dissolution test as per USP 2023 as detailed below:

Acid stage:

Tolerance Limit: Not more 15% of the labelled amount of omeprazole.

<table>
<tr><th>LEVEL</th><th>Unit tested</th><th colspan="6">ACCEPTANCE CRITERIA</th><th>REMARKS</th></tr>
<tr><td rowspan="3">L1</td><td>6</td><td colspan="6">No individual value exceeds 15% of the omeprazole dissolved.</td><td rowspan="3">Complies</td></tr>
<tr><td rowspan="2">After 2 hours</td><td>UNIT 1</td><td>UNIT 2</td><td>UNIT 3</td><td>UNIT 4</td><td>UNIT 5</td><td>UNIT 6</td></tr>
<tr><td>0.0%</td><td>0.0%</td><td>0.0%</td><td>0.0 %</td><td>0.0%</td><td>0.0 %</td></tr>
</table>

Buffer stage:

Tolerance Limit: Not less than 75% (Q) of the labelled amount of Omeprazole in 30 minutes.

LEVEL	Unit tested	ACCEPTANCE CRITERIA						REMARKS
S1	6	Each unit is Not less than Q + 5%						Complies
	After 30 minutes	UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6	
		104.8%	106.6%	96.2%	94.5 %	107.8%	106.6 %	

RESULT: Given sample is substandard with regards to description (physical appearance) of capsule.

iii. The Proprietor of M/s Pakistan Medical Store, adda Sheikhen Tehsil Lalian Distt Chiniot provided warranty/invoice No.13889 Dated 23-02-2023 issued by M/S Noor Ul Huda Medicine Marketing, street no. 2, Mohallah Mohammadi Gojra road, Jhang. In response they provided invoice/warranty no. 2685 dated 16-02-2023 issued by M/s Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone rawat Islamabad

iv. Warrantor Portion was sent to M**/s** Noor Ul Huda Medicine Marketing, street no. 2, Mohallah Mohammadi Gojra road, Jhang.

A copy of Test/ Analysis reports was sent to M**/s** Gulf Pharmaceuticals Pvt Ltd., plot no. 49, street no. S-5 National Industrial zone rawat Islamabad

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard drug**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 28-02-2025

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	20-03-2023
2	**Sample Sent to DTL (Form-6)**	21-03-2023
3	**Receipt Date in DTL**	27-03-2023
4	**Issuance of DTL Report**	23-05-2025

5	**Time Extension**	Not Time Barred
6	**DI First Communication with Firm**	19-01-2024
7	**Retesting Request**	No
9	**Investigation Report by DI**	19-03-2024
10	**SCN Permission**	278-M (28-03-2024)
11	**Show Cause Notice Issued**	28-02-2025
12	**Reply of Firm to Show Cause Notice**	No
13	**History (3 years)**	Firm’s Reported: 8
		Product’s Reported: 3 (Subject Case)

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 21

PQCB/R-477/2021

(Ravi Town, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore** through its Chief Executive Officer, Dr. Shehla Javed Akram. 2. Dr. Shehla Javed Akram — Chief Executive Officer 3. Muhammad Yamin — Production In-charge/ Warrantor 4. Tariq Mehmood — Quality Control Incharge Of **M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Ravi Town Lahore reported that-

i. He, on 19-11-2020 inspected the premises of Main Medicine Store, Government Said Mitha Hospital, Said Mitha Bazar, Lahore and took sample of the subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Lahore vide memo No. 78190 Dated 19-11-2020.
ii. The drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, Lahore as detailed below.

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**
Film Coated Tablet Ulsin (Famotidine USP: 40mg) **Mfg Date: Expiry Date: Regn No.** 09.2020 09.2022 021518	EM-20-001	M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore	01-149002436/DTL dated 30.01.2021

DTL Test Report Result

Analysis with specifications applied: BP 2020

PHYSICAL DESCRIPTION: Green coloured eliptical tablets with "D.V" engraved on one side in green blister packing of ten units.

UNIFORMITY OF DOSAGE UNITS: Sample comply the USP criteria for weight variation as detailed below:

DOSAGE UNITS: limit L1≤ 15, Determined: L1=10.56

IDENTIFICATION: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the

major peak in standard chromatogram. (Famotidine Identified)

ASSAY OF Famotidine: Stated: 40mg/Tab, Determined: 37.864mg/Tab, Percentage: 94.66%, Limit: 90-110% of the labeled amount.

Dissolution Test: Does not comply with the USP specifications as detailed below:

Tolerance Limit: NLT 80% (Q) of the labeled amount of famotidine is dissolved

S1: Each unit is NLT Q+5%

S2: Average of 12 units (S1+S2) is ≥Q, and no unit is <Q-15%

S3: Average of 24 units (S1+S2+S3) is ≥Q, NMT 2 units are <Q-15%, and no unit is <Q-25%

Level	Number tested	Acceptance Criteria						Average	Remarks
S1	6	Each individual unit should NLT 85% (Q+5%)						-	**Does not Comply**
		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
Determined (%)		69.81	69.35	73.70	75.09	69.97	67.72		
S2	6	Average of 12 units (S1+S2) should NLT Q (80%)						S1+S2 68.75	**Does not Comply**
		Unit 7	Unit 8	Unit 9	Unit 10	Unit 11	Unit 12		
Determined (%)		64.94	62.47	74.41	75.94	62.18	59.48		

The sample fails to comply the release limits at S2, as 4 out of 12 units showed release less than Q-15% (i.e. 65%) and average of 12 units is less than Q (i.e. 80%). Hence, not proceeded to S3.

RESULT: The above sample is **SUBSTANDARD** on the basis of Dissolution Test performed as per USP.

iii. The Store keeper, Main Medicine Store, Government Said Mitha Hospital, Said Mitha Bazar, Lahore provided invoice/ warranty bearing No. 73 dated 21-10-2020 issued by M/s Hi-Q medicos, office no. 312, 3rd Floor, PMA centre opposite Camp Jalil, Ferozepur Road, Lahore.

iv. Warrantor Portion was sent to Mis Hi-Q medicos, office no. 312, 3rd Floor, PMA centre opposite Camp Jail, Ferozepur Road, Lahore who in tum provided invoice/warranty No 2010-16899 dated 20-10-2020 issued by M/s Don Valley Pharmaceuticals Lahore.

v. A copy of Test/ Analysis report was sent to M/s Don Valley Pharmaceuticals Lahore and they were directed to provide requisite information in this regard.

vi. Pursuant to the retesting request of the firm, sample was sent to Appellate Laboratory. National Institute of Health (NIH), Islamabad from where the sample was declared substandard. Detail of the tests are as follows:

Name of Drug	Batch No.	Name of Manufacturer	Test Report No.	Details of Result of Test or Analysis (with protocols of test applies)
Ulsin Tablet 40mg	EM-20-001	M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore	0248-P/2021 Dated 16th August, 2021	**Description:** Light green colourd, oval shaped, film coated tablets having inscription "DV" on one side whereas plain from other side packed in blister packing further contained in an outer carton. **Identification:** Famotidine identified. **Dissolution Test:** Determined: 54.20 Limit: Not less than 75% (Q) of the labeled amount of Famotidine is dissolved.**(Does not comply with USP-39)** **Conclusion:** The sample is of **Sub-Standard** quality on the basis of the tests performed.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard Drug**
b. **Issuance of false warranty**

3. Show Cause Notice issued to the accused dated 09.09.2022.

Reply of Show Cause Notice:

1. This is in reference to the Show Cause Notice No. PQCB/R-477/2021 dated 09-09-2022 wherein your good-self has instructed M/s Don Valley Pharmaceuticals (the "Company") to show cause as to why any legal action including the initiation of prosecution before the Honorable Drug Court as-well as suspension/cancellation of Drug Manufacturing License, may not be taken against the Company for allegedly contravening the provisions of the Drugs Act, 1976 as-well as the DRAP Act, 2012.

2. At the very out-set it is submitted that the Company is one of the leading national pharmaceutical companies and is engaged in the manufacturing of the high-quality, safe and efficacious pharmaceutical products. Admittedly, the products manufactured by the Company are increasingly being prescribed by the doctors across the country on account of their excellent quality and efficacy. It is against this backdrop, that the Company intends to refute the inaccurate findings rendered by the Government Analyst Drug Testing Laboratory Lahore vide TRA No. 01-149002436 dated 30-01-2021 as-well (the "DTL Report") as the National Institute of Health Islamabad vide TRA No. 0248-P/2021 dated 16-08-2021 (the "NIH Report") vis-à-vis Tablet Ulsin Batch No. EM-20-001 (the "Product").

(Copies of the Drug Manufacturing License along with the Drug Registration Certificate are enclosed herewith as "Enclosures I-II")

3. That it is essential to note that the sample of the Product was received by the Government Analyst on 20-11-2020, however, the DTL Report was issued on 30-01-2021 after the prescribed time period of sixty

(60) days as provided under Section 22(2) of the Drugs Act. The Superior Courts in various pronouncements have held that it is incumbent upon a Government Analyst to furnish the test report within sixty days and the failure to do so shall render the same as unlawful. In view thereof, it is submitted that the DTL Report has been issued in violation of the mandatory provisions of law hence the same is illegal and all subsequent proceedings initiated on the basis of the same are unlawful.

4. Without prejudice to the submission made hereinabove, it is submitted that the alleged variation in the NIH Report is likely to have occurred as a result of the non-calibrated dissolution apparatus as the same is one of the most common causes for fluctuations in the temperature and RPM of the apparatus. A non-calibrated apparatus is highly likely to produce an accurate result and the same has been observed in the present case. Even otherwise, it is probable that the Government Analyst has not been able to prepare the buffer of pH 4.5 of pH of phosphate buffer whilst testing the Product which has caused the Dissolution of the Product to fail. In view thereof it is mandatory for the matter to be thoroughly investigated to determine the actual cause for the alleged variation observed in the Product and to prevent the unlawful conviction of the Company and its officials.

5. We have tested our retained sample and the results of all the tests conducted on the retention sample of the Product have been found as satisfactory and within the limits set in the specifications. The results of the tests conducted on the retention samples are of paramount importance in determining the quality of the Product since the same are kept in a controlled environment best suited for the Product. The aforementioned submission further substantiates that the Product is of standard quality and the findings of the Government Analyst Drug Testing Laboratory Bahawalpur and the NIH are baseless and unreliable.

. That it is reiterated that the Company has always maintained the highest standards whilst manufacturing its products and has acted as a responsible pharmaceutical concern. In this regard, it is submitted that the Company has recalled the entire stock of the Product vide advertisement dated 14th December 2021. Accordingly, it shall be against the dictates of justice to take any adverse action against the Company and its officials.

(Copy of the recall advertisement is enclosed herewith as "Enclosure V")

7. Notwithstanding the absolute innocence of the Company and its officials, please find the following information as per your requirement:

Name of Director: Dr.Shelah Javed Akram

Name of Production In-charge ; Shabana Kashif

Insert Name of Quality Control In-charge. Mr. Tariq Mahmood

8. In view of the foregoing, it is reiterated that the Company and its officials have not contravened the provisions of the Drugs Act, 1976 along with the DRAP Act, 2012. The reports issued by the Government Analyst as-well as the National Institute of Health Islamabad are defective and flawed hence the same cannot be made the basis for taking any action against the Company and its officials. Accordingly, it is kindly requested that the Show Cause Notice under reply and any subsequent proceedings to be initiated on the basis of the same may kindly be withdrawn in the interest of justice and equity.

5. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 01.2021

Expiry Date: 12.2022

Sampling Date (Form 4): 31.03.2021

Sent to DTL (Form 6): 02.04.2021

Date of receipt in DTL: 02.04.2021

DTL Report Date (Form 7): 28.05.2021

Time Extension:

1ST DI Communication with firm on dated: 06.02.2021

Retesting Request of Firm: 23.02.2021

Fate of Firm's Retest Request: Allowed in 16-CM dated 16.06.2021 (Substandard by NIH)

Investigation Report Dated: 28.05.2022

SCN Permission: 247-M

SCN: 09.09.2022

Reply of SCN: 20.09.2022

History (Last 03 Years): Product: 00 cases reported, Firm: 27 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-477/2021

(Ravi Town, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore** through its Chief Executive Officer, Dr. Shehla Javed Akram. 2. Dr. Shehla Javed Akram — Chief Executive Officer 3. Muhammad Yamin — Production In-charge/ Warrantor 4. Tariq Mehmood — Quality Control Incharge Of **M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Ravi Town Lahore reported that-

i. He, on 19-11-2020 inspected the premises of Main Medicine Store, Government Said Mitha Hospital, Said Mitha Bazar, Lahore and took sample of the subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Lahore vide memo No. 78190 Dated 19-11-2020.
ii. The drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, Lahore as detailed below.

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**
Film Coated Tablet Ulsin (Famotidine USP: 40mg) **Mfg Date: Expiry Date: Regn No.** 09.2020 09.2022 021518	EM-20-001	M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore	01-149002436/DTL dated 30.01.2021

DTL Test Report Result

Analysis with specifications applied: BP 2020

PHYSICAL DESCRIPTION: Green coloured eliptical tablets with "D.V" engraved on one side in green blister packing of ten units.

UNIFORMITY OF DOSAGE UNITS: Sample comply the USP criteria for weight variation as detailed below:

DOSAGE UNITS: limit L1≤ 15, Determined: L1=10.56

IDENTIFICATION: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (Famotidine Identified)

ASSAY OF Famotidine: Stated: 40mg/Tab, Determined: 37.864mg/Tab, Percentage: 94.66%, Limit: 90-110% of the labeled amount.

Dissolution Test: Does not comply with the USP specifications as detailed below:

Tolerance Limit: NLT 80% (Q) of the labeled amount of famotidine is dissolved

S1: Each unit is NLT Q+5%

S2: Average of 12 units (S1+S2) is ≥Q, and no unit is <Q-15%

S3: Average of 24 units (S1+S2+S3) is ≥Q, NMT 2 units are <Q-15%, and no unit is <Q-25%

Level	Number tested	Acceptance Criteria	Average	Remarks
S1	6	Each individual unit should NLT 85% (Q+5%)	-	**Does not**

Determined (%)		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		**Comply**
		69.81	69.35	73.70	75.09	69.97	67.72		
S2	6	Average of 12 units (S1+S2) should NLT Q (80%)						S1+S2 68.75	**Does not Comply**
		Unit 7	Unit 8	Unit 9	Unit 10	Unit 11	Unit 12		
Determined (%)		64.94	62.47	74.41	75.94	62.18	59.48		

The sample fails to comply the release limits at S2, as 4 out of 12 units showed release less than Q-15% (i.e. 65%) and average of 12 units is less than Q (i.e. 80%). Hence, not proceeded to S3.

RESULT: The above sample is **SUBSTANDARD** on the basis of Dissolution Test performed as per USP.

iii. The Store keeper, Main Medicine Store, Government Said Mitha Hospital, Said Mitha Bazar, Lahore provided invoice/ warranty bearing No. 73 dated 21-10-2020 issued by M/s Hi-Q medicos, office no. 312, 3rd Floor, PMA centre opposite Camp Jalil, Ferozepur Road, Lahore.

iv. Warrantor Portion was sent to Mis Hi-Q medicos, office no. 312, 3rd Floor, PMA centre opposite Camp Jail, Ferozepur Road, Lahore who in tum provided invoice/warranty No 2010-16899 dated 20-10-2020 issued by M/s Don Valley Pharmaceuticals Lahore.

v. A copy of Test/ Analysis report was sent to M/s Don Valley Pharmaceuticals Lahore and they were directed to provide requisite information in this regard.

vi. Pursuant to the retesting request of the firm, sample was sent to Appellate Laboratory. National Institute of Health (NIH), Islamabad from where the sample was declared substandard. Detail of the tests are as follows:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**Test Report No.**	**Details of Result of Test or Analysis (with protocols of test applies)**
Ulsin Tablet 40mg	EM-20-001	M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore	0248-P/2021 Dated 16th August, 2021	**Description:** Light green colourd, oval shaped, film coated tablets having inscription "DV" on one side whereas plain from other side packed in blister packing further contained in an outer carton. **Identification:** Famotidine identified. **Dissolution Test:** Determined: 54.20 Limit: Not less than 75% (Q) of the labeled amount of Famotidine is dissolved.**(Does not comply with USP-39)** **Conclusion:** The sample is of **Sub-Standard** quality on the basis of the tests performed.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard Drug**
b. **Issuance of false warranty**

3. Show Cause Notice issued to the accused dated 09.09.2022.

Reply of Show Cause Notice:

1. This is in reference to the Show Cause Notice No. PQCB/R-477/2021 dated 09-09-2022 wherein your good-self has instructed M/s Don Valley Pharmaceuticals (the "Company") to show cause as to why any legal action including the initiation of prosecution before the Honorable Drug Court as-well as suspension/cancellation of Drug Manufacturing License, may not be taken against the Company for allegedly contravening the provisions of the Drugs Act, 1976 as-well as the DRAP Act, 2012.

2. At the very out-set it is submitted that the Company is one of the leading national pharmaceutical companies and is engaged in the manufacturing of the high-quality, safe and efficacious pharmaceutical products. Admittedly, the products manufactured by the Company are increasingly being prescribed by the doctors across the country on account of their excellent quality and efficacy. It is against this backdrop, that the Company intends to refute the inaccurate findings rendered by the Government Analyst Drug Testing Laboratory Lahore vide TRA No. 01-149002436 dated 30-01-2021 as-well (the "DTL Report") as the National Institute of Health Islamabad vide TRA No. 0248-P/2021 dated 16-08-2021 (the "NIH Report") vis-à-vis Tablet Ulsin Batch No. EM-20-001 (the "Product").

(Copies of the Drug Manufacturing License along with the Drug Registration Certificate are enclosed herewith as "Enclosures I-II")

3. That it is essential to note that the sample of the Product was received by the Government Analyst on 20-11-2020, however, the DTL Report was issued on 30-01-2021 after the prescribed time period of sixty (60) days as provided under Section 22(2) of the Drugs Act. The Superior Courts in various pronouncements have held that it is incumbent upon a Government Analyst to furnish the test report within sixty days and the failure to do so shall render the same as unlawful. In view thereof, it is submitted that the DTL Report has been issued in violation of the mandatory provisions of law hence the same is illegal and all subsequent proceedings initiated on the basis of the same are unlawful.

4. Without prejudice to the submission made hereinabove, it is submitted that the alleged variation in the NIH Report is likely to have occurred as a result of the non-calibrated dissolution apparatus as the same is one of the most common causes for fluctuations in the temperature and RPM of the apparatus. A non-calibrated apparatus is highly likely to produce an accurate result and the same has been observed in the present case. Even otherwise, it is probable that the Government Analyst has not been able to prepare the buffer of pH 4.5 of pH of phosphate buffer whilst testing the Product which has caused the Dissolution of the Product to fail. In view thereof it is mandatory for the matter to be thoroughly investigated to determine the actual cause for the alleged variation observed in the Product and to prevent the unlawful conviction of the Company and its officials.

5. We have tested our retained sample and the results of all the tests conducted on the retention sample of the Product have been found as satisfactory and within the limits set in the specifications. The results of the tests conducted on the retention samples are of paramount importance in determining the quality of the Product since the same are kept in a controlled environment best suited for the Product. The aforementioned submission further substantiates that the Product is of standard quality and the findings of the Government Analyst Drug Testing Laboratory Bahawalpur and the NIH are baseless and unreliable.

. That it is reiterated that the Company has always maintained the highest standards whilst manufacturing its products and has acted as a responsible pharmaceutical concern. In this regard, it is submitted that the Company has recalled the entire stock of the Product vide advertisement dated 14th December 2021. Accordingly, it shall be against the dictates of justice to take any adverse action against the Company and its officials.

(Copy of the recall advertisement is enclosed herewith as "Enclosure V")

7. Notwithstanding the absolute innocence of the Company and its officials, please find the following information as per your requirement:

Name of Director: Dr.Shelah Javed Akram

Name of Production In-charge ; Shabana Kashif

Insert Name of Quality Control In-charge. Mr. Tariq Mahmood

8. In view of the foregoing, it is reiterated that the Company and its officials have not contravened the provisions of the Drugs Act, 1976 along with the DRAP Act, 2012. The reports issued by the Government Analyst as-well as the National Institute of Health Islamabad are defective and flawed hence the same cannot be made the basis for taking any action against the Company and its officials. Accordingly, it is kindly requested that the Show Cause Notice under reply and any subsequent proceedings to be initiated on the basis of the same may kindly be withdrawn in the interest of justice and equity.

5. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 01.2021

Expiry Date: 12.2022

Sampling Date (Form 4): 31.03.2021

Sent to DTL (Form 6): 02.04.2021

Date of receipt in DTL: 02.04.2021

DTL Report Date (Form 7): 28.05.2021

Time Extension:

1ST DI Communication with firm on dated: 06.02.2021

Retesting Request of Firm: 23.02.2021

Fate of Firm's Retest Request: Allowed in 16-CM dated 16.06.2021 (Substandard by NIH)

Investigation Report Dated: 28.05.2022

SCN Permission: 247-M

SCN: 09.09.2022

Reply of SCN: 20.09.2022

History (Last 03 Years): Product: 00 cases reported, Firm: 27 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 22

PQCB/MSS-207336/2024

(Punjab Institute of Cardiology, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore** through its CEO/ Proprietor, Ali Jan Shaukat. 2. Ali Jan Shaukat CEO/ Proprietor/ Warrantor 3. Hafiz Hammad Ur Rehman Qualified Person **of M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Punjab Institute of Cardiology, Lahore reported that: -

i. The then Provincial Inspector of Drugs, on 10.10.2024, inspected the Main Disposable Store, PIC, Lahore. He confiscated following drug/ article from the premises in the presence of Amna Hafeez (Pharmacist), M. Azeem (Store Keeper) & M. Aslam (DI Assistant) and seized on Form 5 as follows:

Sr.	Drug/ Article	Batch No.	Name of Manufacturer	Quantity	Reason for Seizure
1	Reinforced Surgical Gown (XL), Towel (40 x 40)	41240209	MHK Medikal Tekstil San. Ve TIC. Ltd. STI, Turkiye	01	1. Suspected to be **adulterated** as tiny parts of insect was seen with naked eye inside the sealed pack.

ii. He also took sample on Form 4 for the purpose of test/ analysis and send to Drug Testing Laboratory Lahore vide memo number 207336 dated 10.10.2024.

iii. Following sample after test/analysis was declared as **Misbranded** as detailed below and other by Government Analyst Drug Testing Laboratory Lahore:

Name of Drug/ Medical Device	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Sterile Disposable MHKMEDIKAL Reinforced Surgical Gown (XL) (16-042-04) **Mfg. Date: Exp. Date: Registration No.** 02.2024 02.2029 MDIE-0000417	41240209	M/S MHK Medikal Tekstil San. VE TIC, Ltd., STI, Korkun Mah Hidayat Cad. No. 23/1 Oguzeli/ Gaziantep/ Turkiye	01-141000664/DTL Dated. 25.11.2024

DTL Test Report Result

Specification applied: USP 2024

Description: A surgical gown claimed to be sterilized provided with one towel 40x40 and gown of claimed size "XL" packed in paper dispense polythene packing.

Labelling: Label of the gown does not mention units of measurement of towel, only 40 x 40 size is mentioned. **(Misbranded)**

Length: Determined: 40cm

Width: Determined: 30cm

Sterility Test: The sample is sterile.

Result: The above sample is **Misbranded**.

iv. Store Keeper, Main Disposable Store, PIC, Lahore provided Invoice/ Delivery Challan/ warranty No. TRF 1406665, dated 15.04.2024 issued by M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore as a proof of its purchase.
v. Warrantor portion of drug sample was sent to M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore.
vi. A copy of test/analysis report was sent to M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore and they were directed to explain their position and to provide the requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Import and selling of Adulterated and Misbranded Medical Device**
b. **Issuance of False Warranty**

3. Show Cause/ Personal Hearing Notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 02.2024

Expiry Date: 02.2029

Sampling Date (Form 4): 10.10.2024

Sent to DTL (Form 6): 10.10.2024

Date of receipt in DTL: 10.10.2024

DTL Report Date (Form 7): 25.11.2024

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 08.01.2025

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 11.02.2025

SC-PHN: 20.03.2025

History (Last 03 Years): Firm: 00 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-207336/2024

(Punjab Institute of Cardiology, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore** through its CEO/ Proprietor, Ali Jan Shaukat. 2. Ali Jan Shaukat CEO/ Proprietor/ Warrantor 3. Hafiz Hammad Ur Rehman Qualified Person **of M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Punjab Institute of Cardiology, Lahore reported that: -

i. The then Provincial Inspector of Drugs, on 10.10.2024, inspected the Main Disposable Store, PIC, Lahore. He confiscated following drug/ article from the premises in the presence of Amna Hafeez (Pharmacist), M. Azeem (Store Keeper) & M. Aslam (DI Assistant) and seized on Form 5 as follows:

Sr.	Drug/ Article	Batch No.	Name of Manufacturer	Quantity	Reason for Seizure
1	Reinforced Surgical Gown (XL), Towel (40 x 40)	41240209	MHK Medikal Tekstil San. Ve TIC. Ltd. STI, Turkiye	01	1. Suspected to be **adulterated** as tiny parts of insect was seen with naked eye inside the sealed pack.

ii. He also took sample on Form 4 for the purpose of test/ analysis and send to Drug Testing Laboratory Lahore vide memo number 207336 dated 10.10.2024.

iii. Following sample after test/analysis was declared as **Misbranded** as detailed below and other by Government Analyst Drug Testing Laboratory Lahore:

Name of Drug/ Medical Device	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**
Sterile Disposable MHKMEDIKAL Reinforced Surgical Gown (XL) (16-042-04) **Mfg. Date: Exp. Date: Registration No.** 02.2024 02.2029 MDIE-0000417	41240209	M/S MHK Medikal Tekstil San. VE TIC, Ltd., STI, Korkun Mah Hidayat Cad. No. 23/1 Oguzeli/ Gaziantep/ Turkiye	01-141000664/DTL Dated. 25.11.2024

DTL Test Report Result

Specification applied: USP 2024

Description: A surgical gown claimed to be sterilized provided with one towel 40x40 and gown of claimed size "XL" packed in paper dispense polythene packing.

Labelling: Label of the gown does not mention units of measurement of towel, only 40 x 40 size is mentioned. **(Misbranded)**

Length: Determined: 40cm

Width: Determined: 30cm

Sterility Test: The sample is sterile.

Result: The above sample is **Misbranded**.

iv. Store Keeper, Main Disposable Store, PIC, Lahore provided Invoice/ Delivery Challan/ warranty No. TRF 1406665, dated 15.04.2024 issued by M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore as a proof of its purchase.

v. Warrantor portion of drug sample was sent to M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore.

vi. A copy of test/analysis report was sent to M/S PAK Punjab Cardex Medical System, Ground Floor, 210 J2-Blcok M.A Johar Town, Lahore and they were directed to explain their position and to provide the requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Import and selling of Adulterated and Misbranded Medical Device**
b. **Issuance of False Warranty**

3. Show Cause/ Personal Hearing Notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 02.2024

Expiry Date: 02.2029

Sampling Date (Form 4): 10.10.2024

Sent to DTL (Form 6): 10.10.2024

Date of receipt in DTL: 10.10.2024

DTL Report Date (Form 7): 25.11.2024

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 08.01.2025

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 11.02.2025

SC-PHN: 20.03.2025

History (Last 03 Years): Firm: 00 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 23

PQCB/ SM-18-08/2023

Iqbal Town, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan** through its Director, Ghulam Murtaza 2. Ghulam Murtaza Director 3. Muhammad Aslam Production Incharge/ Warrantor 4. Muhammad Naeem Shah Quality Control Incharge of M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Iqbal Town, District Faisalabad reported that: -

i. He, on 21-12-2021, inspected the licensee business premises of M/s Shoukat Care Pharmacy, situated at Shop No. 01, Near Jutt Karyana Store, Chak No. 272/R. B Kahna Pull, District Faisalabad. Following drug sample was recovered & seized on Form-5 as detailed below:

Name of drug	Batch No.	Manufactured by	Quantity	Reason of seizure
Rudazole (Metronidazole) 500mg/ 100ml vial Injection	RD-024	M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan	5 Vials	Exhibiting/ Stocking for Sale/ Selling the Adulterated Drug (Solid Milky coloured particles visible with naked eye are present in all recovered vials Adulterated Drugs) W/o Invoice/ Warranty

ii. Proprietor M/s Shoukat Care Pharmacy, situated at Shop No. 01, Near Jutt Karyana Store, Chak No. 272/R. B Kahna Pull, District Faisalabad provided invoice/ warranty bearing No. 064 dated 06-08-2021 issued by M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan as a proof of its purchase.

iii. A copy of invoice/ warranty was sent to M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan with directions to explain their position and provide requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard/ Adulterated drugs**

(Particulate Contamination/ Visible Particles)

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 22-04-2024

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Form-5 (Seizure date)**	21-12-2021
2	**DI First Communication with Firm**	22-12-2021
3	**Investigation Report by DI**	24-07-2023
4	**SCN Permission**	267-M (07-09-2023)
5	**Show Cause Notice Issued**	22-04-2024
6	**Reply of Firm to Show Cause Notice**	No Reply Yet
7	**History (3 years)**	Firm's Reported: 11
		Product's Reported: 9 (Including Subject Case)

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/ SM-18-08/2023

Iqbal Town, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug**	**Accused Persons involved in subject case** 1. **M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan** through its Director, Ghulam Murtaza 2. Ghulam Murtaza Director 3. Muhammad Aslam Production Incharge/ Warrantor

Inspector	4. Muhammad Naeem Shah Quality Control Incharge of M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Iqbal Town, District Faisalabad reported that: -

i. He, on 21-12-2021, inspected the licensee business premises of M/s Shoukat Care Pharmacy, situated at Shop No. 01, Near Jutt Karyana Store, Chak No. 272/R. B Kahna Pull, District Faisalabad. Following drug sample was recovered & seized on Form-5 as detailed below:

Name of drug	Batch No.	Manufactured by	Quantity	Reason of seizure
Rudazole (Metronidazole) 500mg/ 100ml vial Injection	RD-024	M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan	5 Vials	Exhibiting/ Stocking for Sale/ Selling the Adulterated Drug (Solid Milky coloured particles visible with naked eye are present in all recovered vials Adulterated Drugs) W/o Invoice/ Warranty

ii. Proprietor M/s Shoukat Care Pharmacy, situated at Shop No. 01, Near Jutt Karyana Store, Chak No. 272/R. B Kahna Pull, District Faisalabad provided invoice/ warranty bearing No. 064 dated 06-08-2021 issued by M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan as a proof of its purchase.

iii. A copy of invoice/ warranty was sent to M/s Rukha Pharmaceutical & Laboratories (Pvt.) Ltd., 537 D/E Sundar Industrial Estate Lahore-Pakistan with directions to explain their position and provide requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard/ Adulterated drugs**

(Particulate Contamination/ Visible Particles)

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 22-04-2024

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case

1	**Form-5 (Seizure date)**	21-12-2021
2	**DI First Communication with Firm**	22-12-2021
3	**Investigation Report by DI**	24-07-2023
4	**SCN Permission**	267-M (07-09-2023)
5	**Show Cause Notice Issued**	22-04-2024
6	**Reply of Firm to Show Cause Notice**	No Reply Yet
7	**History (3 years)**	Firm's Reported: 11
		Product's Reported: 9 (Including Subject Case)

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 24

PQCB/ MSS-200223/2024

Faisalabad Institute of Cardiology, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Citi Pharma Pvt. Ltd. 3-km Head Balloki Road, Phool Nagar, District Kasur** though its Chief Executive Officer Rizwan Ahmed 2. Rizwan Ahmed — Chief Executive Officer 3. Nadeem Amjad — Managing Partner 4. Zameer-ul-Hassan — Managing Director 5. Mushoraf Shahzad — Production Manager 6. Khansa Rustam — Head of Quality Operations/ Warrantor Of **M/S Citi Pharma Pvt. Ltd. 3-km Head Balloki Road, Phool Nagar, District Kasur.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Faisalabad Institute of Cardiology, Faisalabad reported that:-

i. He, on 03-06-2024, inspected the premises of Main Medicine Store, FIC Faisalabad and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memo number 200223 dated 03-06-2024.

ii. The drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, Faisalabad as detailed below:

Drug Sample	**Batch**	**Manufacturer**
Askprol (Paracetamol) 500 mg Tablets Mfg. Date: March-2024 Exp. Date: Feb-2027 Reg. No. 030726	24AT061	M/S Citi Pharma Pvt. Ltd. Forn 3-km Head Balloki Road, Phoo

Specification applied: BP 2024

DESCRIPTION:

White color round shaped biconvex tablet, without beveled edges, plain on both sides, contained in ALU-PVC blis

NOTE: Manufacturer specifies the appearance of tablet as, "White to almost white color round beveled edges cor White color round shaped biconvex tablet, without beveled edges, plain on both sides" which does not comply with manufacture

UNIFORMITY OF WEIGHT (MASS):

Complies the BP's acceptance criteria of Uniformity of weight (Mass)

(Average weight of Tablet: 595.86 mg)

Tolerance Limit: ± 5 % of Average weight.

Reference Limit: 566.067 – 625.653 mg

Determined Limit: 581.90 – 634.20 mg

NOTE: As per BP 2024, not more than two of the individual masses deviate from the average mass by more than the pe
case of given sample, one unit deviates by more than ± 5% and none deviates by more than twice of that percentage i.e. ± 10%. (Comp

IDENTIFICATION Paracetamol is identified.

ASSAY

(By UV-VIS spectrophotometry)

Stated: 500 mg / Tablet

Determined: 516.65 mg / Tablet

Percentage: 103.330 % (Complies)

Limit: 95.0 – 105.0% of the stated amount

DISSOLUTION TEST: Complies with the dissolution test as per BP as detailed below:

Tolerance Limit: NLT 70 % of the stated amount.

Dissolution test was performed using apparatus 2 at 50 rpm using 900 ml of phosphate buffer pH 5.8.

LLEVEL	**NNUMBER TESTED**	**ACCEPTANCE CRITERIA**			
SS_1	6	Each unit is not less 70 %.			
	TTime	UNIT 1	UUNIT 2	UUNIT 3	4
	46 minutes	1101.4 %	1102.0 %	1102.5 %	%

RESULT: **Given sample is Sub-Standard with regards to physical appearance of Tablet.**

iii. Storekeeper Faisalabad Institute of Cardiology provided invoice/ warranty no. GP/771/2024 dated 30-04-2024

issued by M/S Citi Pharma Pvt. Ltd., 3-km Head Balloki Road, Phool Nagar, District Kasur. as a proof of its purchase of the said drug.

iv. Warrantor portion was sent M/S Citi Pharma Pvt. Ltd., 3-km Head Balloki Road, Phool Nagar, District Kasur..

v. A Copy of test report of the drug sample was sent to M/S Citi Pharma Pvt. Ltd., 3-km Head Balloki Road, Phool Nagar, District Kasur with directions to provide the requisite information and to explain their position in this regard. In response, the firm requested for re-test/ analysis of the drug sample. The with-drawl of retesting request of the firm was accepted by the committee of the Board in its 44th committee meeting dated 19-09-2024.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard drug**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 28-01-2025

Firm replied to the show cause notice vide letter no. CP /PQCB /2025/002 dated 24-02-2025

With reference to your letter no. PQCB/MSS-200223/2024, dated 28/01/2025, we respectfully request that no legal action be taken concerning this matter. Furthermore, we kindly ask that you refrain from recommending the licensing authority for the cancellation of our DML or initiating prosecution in the drug court for the contraventions mentioned.
We would like to clarify that the change made to the Askprol 500mg Tablet (removal of beveled edges in the 12mm round tablet shape) was communicated to DRAP on 01 February 2024 and shared with all DTLs, including DTL Faisalabad. Despite the test report from DTL Faisalabad declaring Batch No. 24AT061 as 'substandard' based on its appearance, all other parameters were complying.
In line with the above, we are submitting the necessary documents for the Askprol 500mg Tablet, Batch No. 24AT061, Registration No. 030726 for your review:

Requisite documents were attached along.

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	03-06-2024
2	**Sample Sent to DTL (Form-6)**	03-06-2024
3	**Receipt Date in DTL**	05-06-2024
4	**Issuance of DTL Report**	24-07-2024

5	**Time Extension**	Not Time Barred
6	**DI First Communication with Firm**	31-07-2024
7	**Retesting Request**	24-08-2024
9	**Investigation Report by DI**	18-11-2024
10	**SCN Permission**	287-M (08-01-2025)
11	**Show Cause Notice Issued**	28-01-2025
12	**Reply of Firm to Show Cause Notice**	Yes (24-02-2025) received in PQCB on 24-03-2025
13	**History (3 years)**	Firm's Reported: 21
		Product's Reported: 2 (Subject Case)

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/ MSS-200223/2024

Faisalabad Institute of Cardiology, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Citi Pharma Pvt. Ltd. 3-km Head Balloki Road, Phool Nagar, District Kasur** though its Chief Executive Officer Rizwan Ahmed 2. Rizwan Ahmed — Chief Executive Officer 3. Nadeem Amjad — Managing Partner 4. Zameer-ul-Hassan — Managing Director 5. Mushoraf Shahzad — Production Manager 6. Khansa Rustam — Head of Quality Operations/ Warrantor Of **M/S Citi Pharma Pvt. Ltd. 3-km Head Balloki Road, Phool Nagar, District Kasur.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Faisalabad Institute of Cardiology, Faisalabad reported that:-

i. He, on 03-06-2024, inspected the premises of Main Medicine Store, FIC Faisalabad and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memo number 200223 dated 03-06-2024.

ii. The drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, Faisalabad as detailed below:

Drug Sample	**Batch**	**Manufacturer**
Askprol (Paracetamol) 500 mg Tablets Mfg. Date: March-2024 Exp. Date: Feb-2027 Reg. No. 030726	24AT061	M/S Citi Pharma Pvt. Ltd. Form 3-km Head Balloki Road, Phoo

Specification applied: BP 2024

DESCRIPTION:

White color round shaped biconvex tablet, without beveled edges, plain on both sides, contained in ALU-PVC blis

NOTE: Manufacturer specifies the appearance of tablet as, "White to almost white color round beveled edges cor White color round shaped biconvex tablet, without beveled edges, plain on both sides" which does not comply with manufacture

UNIFORMITY OF WEIGHT (MASS):

Complies the BP's acceptance criteria of Uniformity of weight (Mass)

(Average weight of Tablet: 595.86 mg)

Tolerance Limit: ± 5 % of Average weight.

Reference Limit: 566.067 – 625.653 mg

Determined Limit: 581.90 – 634.20 mg

NOTE: As per BP 2024, not more than two of the individual masses deviate from the average mass by more than the pe case of given sample, one unit deviates by more than ± 5% and none deviates by more than twice of that percentage i.e. ± 10%. (Comp

IDENTIFICATION Paracetamol is identified.

ASSAY

(By UV-VIS spectrophotometry)

Stated: 500 mg / Tablet

Determined: 516.65 mg / Tablet

Percentage: 103.330 % (Complies)

Limit: 95.0 – 105.0% of the stated amount

DISSOLUTION TEST: Complies with the dissolution test as per BP as detailed below:

Tolerance Limit: NLT 70 % of the stated amount.

Dissolution test was performed using apparatus 2 at 50 rpm using 900 ml of phosphate buffer pH 5.8.

LLEVEL	NNUMBER TESTED	ACCEPTANCE CRITERIA			
SS_1	6	Each unit is not less 70 %.			
	TTime	UNIT 1	UUNIT 2	UUNIT 3	4
	46 minutes	1101.4 %	1102.0 %	1102.5 %	%

RESULT: **Given sample is Sub-Standard with regards to physical appearance of Tablet.**

iii. Storekeeper Faisalabad Institute of Cardiology provided invoice/ warranty no. GP/771/2024 dated 30-04-2024 issued by M/S Citi Pharma Pvt. Ltd., 3-km Head Balloki Road, Phool Nagar, District Kasur. as a proof of its purchase of the said drug.

iv. Warrantor portion was sent M/S Citi Pharma Pvt. Ltd., 3-km Head Balloki Road, Phool Nagar, District Kasur..

v. A Copy of test report of the drug sample was sent to M/S Citi Pharma Pvt. Ltd., 3-km Head Balloki Road, Phool Nagar, District Kasur with directions to provide the requisite information and to explain their position in this regard. In response, the firm requested for re-test/ analysis of the drug sample. The with-drawl of retesting request of the firm was accepted by the committee of the Board in its 44th committee meeting dated 19-09-2024.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture for sale/ Sale of Substandard drug**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 28-01-2025

Firm replied to the show cause notice vide letter no. CP /PQCB /2025/002 dated 24-02-2025

With reference to your letter no. PQCB/MSS-200223/2024, dated 28/01/2025, we respectfully request that no legal action be taken concerning this matter. Furthermore, we kindly ask that you refrain from recommending the licensing authority for the cancellation of our DML or initiating prosecution in the drug court for the contraventions mentioned.

We would like to clarify that the change made to the Askprol 500mg Tablet (removal of beveled edges in the 12mm round tablet shape) was communicated to DRAP on 01 February 2024 and shared with all DTLs, including DTL Faisalabad. Despite the test report from DTL Faisalabad declaring Batch No. 24AT061 as 'substandard' based on its appearance, all other parameters were complying.
In line with the above, we are submitting the necessary documents for the Askprol 500mg Tablet, Batch No. 24AT061, Registration No. 030726 for your review:

Requisite documents were attached along.

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	03-06-2024
2	**Sample Sent to DTL (Form-6)**	03-06-2024
3	**Receipt Date in DTL**	05-06-2024
4	**Issuance of DTL Report**	24-07-2024
5	**Time Extension**	Not Time Barred
6	**DI First Communication with Firm**	31-07-2024
7	**Retesting Request**	24-08-2024
9	**Investigation Report by DI**	18-11-2024
10	**SCN Permission**	287-M (08-01-2025)
11	**Show Cause Notice Issued**	28-01-2025
12	**Reply of Firm to Show Cause Notice**	Yes (24-02-2025) received in PQCB on 24-03-2025
13	**History (3 years)**	Firm’s Reported: 21

		Product’s Reported: 2 (Subject Case)

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 25

PQCB/MSS-183004/2024
Tehsil Hafizabad

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan** through its Chief Executive Officer Rizwan Ahmad 2. Rizwan Ahmad Chief Executive Officer 3. Nadeem Amjad Managing Partner 4. Zameer Ul Hassan Managing Director 5. Mushoraf Shahzad Production Manager 6. Khansa Rustam Head of Quality Operations/ Warrantor of **M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan**.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil & District Hafizabad reported that:

i. He, on 20-11-2023, inspected the premises of Main Medicine Store CEO DHA Hafizabad, took samples of four different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Faisalabad vide memorandum no. 0000183004 dated 20-11-2023.
ii. The following drug sample after test/analyses was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Faisalabad**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report TRA No. & Date**
Film Coated Tablet Flurip (Each film coated tablet contains: Flurbiprofen BP.....100mg) **Mfg. date**: 09-2023 **Exp. date**: 08-2025 **Reg.No.** 030719	23FL002	M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan.	01-94000282/DTL Dated:19-01-2024 (DTL Faisalabad)
Specification applied: BP 2024 **DESCRIPTION:** Blue color oval shape biconvex tablet, with central break line on one side contained in ALU-PVC packing of 05's , packed in outer hard carton.			

UNIFORMITY OF WEIGHT (MASS):

Does not Comply the BP's acceptance criteria of Uniformity of weight (Mass)

(Average weight of Tablet: 324.2 mg)

Tolerance Limit: ± 5 % of Average weight.

Reference Limit: 308.0 – 340.4 mg

Determined Limit: 292.5 – 344.2 mg (Does Not Comply)

Tablet No.	1	2	3	4	5	6	7	8	9	10	Average (mg)
Individual weight (mg)	326.3	340.1	**305.2**	339.6	**299**	321.5	321.4	**340.8**	**305.8**	**292.5**	
% Deviation	0.6	4.9	**-5.9**	4.8	**-7.8**	-0.8	-0.9	**5.1**	**-5.7**	**-9.8**	
Tablet No.	11	12	13	14	15	16	17	18	19	20	324.2
Individual weight (mg)	334.7	320.3	337.5	336.5	323.9	309.1	324	323.3	338.3	**344.2**	
% Deviation	3.2	-1.2	4.1	3.8	-0.1	-4.7	-0.1	-0.3	4.3	**6.2**	

NOTE: As per BP 2024, not more than two of the individual masses deviate from the average mass by more than the percentage deviation (± 5%) and none deviates by more than twice that percentage. In case of given sample, Six units deviate by more than ± 5%.

IDENTIFICATION Flurbiprofen is identified.

ASSAY

Stated: 100 mg /Tablet

Determined: 101.787 mg /Tablet

Percentage: 101.787 % (Complies)

Limit: 92.5 – 107.5 % of the stated amount

DISSOLUTION TEST: Complies with the dissolution test as per MS as detailed below: -

Tolerance Limit: NLT 75% (*Q*) in 45 minutes of label claim.

LEVEL	NUMBER TESTED	ACCEPTANCE CRITERIA	REMARKS

S_1	6	Each unit is NLT *Q* + 5%.						Complies
	Time	UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6	
	45 minutes	102.0 %	100.0 %	91.6 %	93.7 %	91.6 %	101.0 %	

RESULT: **Given sample is sub-standard with regards to uniformity of weight (mass).**

iii. Store Keeper, Main Medicine Store CEO DHA Hafizabad provided invoice/warranty bearing No. GP/503/23 dated 07-11-2023 issued by M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan as a proof of its purchase of subject drug samples.

iv. Warrantor portion of subject drug sample was sent M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan with directions to explain their position and provide requisite information in this regard.

v. Copy of test/analysis report was sent to M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis reports and requested to re-test the above-mentioned drug samples from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to the request of firm, the Committee of PQCB in its 39th Committee Meeting of the Board held on 30-05-2024 decided to accept the firm's request for withdrawal of the retesting request of the subject drug sample

Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing /stocking/ Selling of Substandard drug**
b. **Issuance of false warranty**

3. Show-cause notice(s) issued to the accused persons(s) dated 06-11-2024

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-202

5. Case is placed before the Board for decision

Summary	
Sampling Date (Form 4):	20-11-2023
Sent to DTL (Form 6):	20-11-2023
Date of receipt in DTL	20-11-2023
DTL Report Date (Form 7):	19-01-2024
Time Extension granted	N/A

1st DI Communication with firm dated	29-01-2024
Date of Retesting Request of Firm:	03-02-2024
Fate of Retesting request	Withdrawn by firm in **39th** **Committee Meeting dated 30-05-2024**
Investigation Report Dated	14-10-2024
Firm History 3 years	**Firm: 21** **Product:4**

PROCEEDING & DECISION BY THE BOARD:

PQCB/MSS-183004/2024
Tehsil Hafizabad

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan** through its Chief Executive Officer Rizwan Ahmad 2. Rizwan Ahmad Chief Executive Officer 3. Nadeem Amjad Managing Partner 4. Zameer Ul Hassan Managing Director 5. Mushoraf Shahzad Production Manager 6. Khansa Rustam Head of Quality Operations/ Warrantor of **M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan**.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil & District Hafizabad reported that:

i. He, on 20-11-2023, inspected the premises of Main Medicine Store CEO DHA Hafizabad, took samples of four different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Faisalabad vide memorandum no. 0000183004 dated 20-11-2023.

ii. The following drug sample after test/analyses was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Faisalabad**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report TRA No. & Date**
Film Coated Tablet Flurip (Each film coated tablet contains: Flurbiprofen BP.....100mg) **Mfg. date**: 09-2023 **Exp. date**: 08-2025 **Reg.No.** 030719	23FL002	M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan.	01-94000282/DTL Dated:19-01-2024 (DTL Faisalabad)

Specification applied: BP 2024

DESCRIPTION:

Blue color oval shape biconvex tablet, with central break line on one side contained in ALU-PVC packing of 05's , packed in outer hard carton.

UNIFORMITY OF WEIGHT (MASS):

Does not Comply the BP's acceptance criteria of Uniformity of weight (Mass)

(Average weight of Tablet: 324.2 mg)

Tolerance Limit: ± 5 % of Average weight.

Reference Limit: 308.0 – 340.4 mg

Determined Limit: 292.5 – 344.2 mg (Does Not Comply)

Tablet No.	1	2	3	4	5	6	7	8	9	10	Average (mg)
Individual weight (mg)	326.3	340.1	**305.2**	339.6	**299**	321.5	321.4	**340.8**	**305.8**	**292.5**	
% Deviation	0.6	4.9	**-5.9**	4.8	**-7.8**	-0.8	-0.9	**5.1**	**-5.7**	**-9.8**	
Tablet No.	11	12	13	14	15	16	17	18	19	20	324.2
Individual weight (mg)	334.7	320.3	337.5	336.5	323.9	309.1	324	323.3	338.3	**344.2**	
% Deviation	3.2	-1.2	4.1	3.8	-0.1	-4.7	-0.1	-0.3	4.3	**6.2**	

NOTE: As per BP 2024, not more than two of the individual masses deviate from the average mass by more than the percentage deviation (± 5%) and none deviates by more than twice that percentage. In case of given sample, Six units deviate by more than ± 5%.

IDENTIFICATION Flurbiprofen is identified.

ASSAY

Stated: 100 mg /Tablet

Determined: 101.787 mg /Tablet

Percentage: 101.787 % (Complies)

Limit: 92.5 – 107.5 % of the stated amount

DISSOLUTION TEST: Complies with the dissolution test as per MS as detailed below: -

Tolerance Limit: NLT 75% (*Q*) in 45 minutes of label claim.

LEVEL	NUMBER TESTED	ACCEPTANCE CRITERIA						REMARKS
S_1	6	Each unit is NLT *Q* + 5%.						Complies
	Time	UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6	
	45 minutes	102.0 %	100.0 %	91.6 %	93.7 %	91.6 %	101.0 %	

RESULT: Given sample is sub-standard with regards to uniformity of weight (mass).

iii. Store Keeper, Main Medicine Store CEO DHA Hafizabad provided invoice/warranty bearing No. GP/503/23 dated 07-11-2023 issued by M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan as a proof of its purchase of subject drug samples.

iv. Warrantor portion of subject drug sample was sent M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan with directions to explain their position and provide requisite information in this regard.

v. Copy of test/analysis report was sent to M/S Citi Pharma Ltd. 3-Km, Head Balloki Road, Phool Nagar, Kasur-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis reports and requested to re-test the above-mentioned drug samples from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to the request of firm, the Committee of PQCB in its 39th Committee Meeting of the Board held on 30-05-2024 decided to accept the firm's request for withdrawal of the retesting request of the subject drug sample

Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing /stocking/ Selling of Substandard drug**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to the accused persons(s) dated 06-11-2024

4. Personal hearing notice(s) issued to accused person(s) dated 20-03-202

5. Case is placed before the Board for decision

Summary	
Sampling Date (Form 4):	20-11-2023
Sent to DTL (Form 6):	20-11-2023
Date of receipt in DTL	20-11-2023
DTL Report Date (Form 7):	19-01-2024
Time Extension granted	N/A
1st DI Communication with firm dated	29-01-2024
Date of Retesting Request of Firm:	03-02-2024
Fate of Retesting request	Withdrawn by firm in **39th** **Committee Meeting dated 30-05-2024**
Investigation Report Dated	14-10-2024
Firm History 3 years	**Firm: 21** **Product:4**

PROCEEDING & DECISION BY THE BOARD:

Case No. 26

PQCB/ SM-15-07/2021

Drug Inspector Licensed Manufacturing Premises, District Sheikhupura

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Elite Pharma 9.5 km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura** through its Chief Executive Officer Tahir Mehmood S/o Muhammad Ayub 2. Tahir Mehmood S/o Muhammad Ayub — Chief Executive Officer 3. Khalid Mehmood S/o Bashir Ahmad — Quality Control Incharge 4. Muhammad Tahir S/o Abdul Aziz — Production Incharge of **M/S Elite Pharma 9.5 km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura**.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. He, on 23-06-2021, alongwith other team members, inspected the premises of M/s Elite Pharma, 9.5 Km Sheikhupura Road, Ferozewala and recovered and seized following different types of drugs on Form 5:

Sr. No.	Name of drugs	Batch No.	Name of Manufacturer	Quantity	Reason of Seizure
1.	Injection Rocelite 500mg	C21344	Elite Pharma	80 vials/ pack+ Lignocain 1% (B. No. 112)	Violation of GMP
2.	Injection Lignocaine 1 %	112	Elite Pharma	30 x 100 ampoules	Packed on outer carton of Adrenaline, Maridine (Metoclopramide), Lignocaine and Ashtec (Nalbuphin), Misbranded drugs / unwarranted drugs/ Violation of GMP
Above mentioned drugs have been seized by drug inspector from packing/ production area. Item mentioned at Sr. No. 2 were placed in different cartons out of negligence of workers as these injections (Lignocain 1%) were to be placed in Inj. Rocelite (Dry Powder Inj.)					

ii. He locked and sealed the packaging/ Production area of Cephalosporin Section for the contravention of the Drugs Act 1976/ The DRAP Act 2012.

iii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis. These samples were declared of standard Quality from Drug Testing Laboratory, Lahore.

Drug Inspector sought permission to keep the custody of seized drugs/ API and extension in sealing period. Drug Inspector was granted to keep the seized stock in custody in 239th meeting held on 24-02-2021.

Whereas, the premises has already been de-sealed upon the directions of Honorable Drug Court Lahore dated 28-06-2021.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Violation of GMP (Packing and Stocking of Inj. Lignocaine in outer cartons of Adrenaline, Maridine** (Metoclopramide), **Lignocaine and Ashtec** (Nalbuphin)

3. Show-cause notice(s) issued to accused person(s) dated 06-02-2023

Firm submitted reply to the show cause notice vide letter dated 23-02-2023

Refer your letter no. PQCB/SM-15-07/2021 dated 06-02-2023 which was received by us on 22-02-2023.

We would like to bring your kind attention to the fact that during the inspection of the esteemed team members along with the Provincial Inspector of Drugs lignocaine 1% (Batch No. 112) was being blistered with Injection Rocelite 500mg (Batch No. C21344) for IM purposes. The Lignocaine 1% injection was not kept for sale purposes but was solely present to be used with our Rocelite Injection in blister pack.

These injection of Lignocaine 1% however were packed in the outer cartons of other products which was due to the negligence of our working staff.

Furthermore, all observations made by the team were rectified and all SOPs are being strictly followed on our part. All injections being used with our Dry Injections are being properly packed and labelled.

Therefore, in this regard you are requested not to take any legal actions on our part and not recommend DRAP for the cancellation/suspension of our license.

In addition, as required by your goodself the following documents and information have been attached with this letter.

Name of CEO Mr. Tahir Mahmood

Name of Production Incharge Muhammad Tahir

Name of Quality Control Incharge Mr. Khalid Mahmood

4. Show cause notice was revised on 31-12-2024 keeping in view the name of Quality Control Incharge as provided by the firm in its reply to show cause notice.

5. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

6. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Form-5 (Seizure date)**	21-12-2021
2	**Investigation Report by DI**	08-03-2023
3	**SCN Permission**	258-M (05-04-2023)
4	**Show Cause Notice Issued**	06-02-2023, 31-12-2024 (Revised)
5	**Reply of Firm to Show Cause Notice**	23-02-2023
6	**History (3 years)**	Firm's Reported: Nil
		Product's Reported: Nil

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/ SM-15-07/2021

Drug Inspector Licensed Manufacturing Premises, District Sheikhupura

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Elite Pharma 9.5 km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura** through its Chief Executive Officer Tahir Mehmood S/o Muhammad Ayub 2. Tahir Mehmood S/o Muhammad Ayub — Chief Executive Officer 3. Khalid Mehmood S/o Bashir Ahmad — Quality Control Incharge 4. Muhammad Tahir S/o Abdul Aziz — Production Incharge of **M/S Elite Pharma 9.5 km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura**.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. He, on 23-06-2021, alongwith other team members, inspected the premises of M/s Elite Pharma,

9.5 Km Sheikhupura Road, Ferozewala and recovered and seized following different types of drugs on Form 5:

Sr. No.	Name of drugs	Batch No.	Name of Manufacturer	Quantity	Reason of Seizure
1.	Injection Rocelite 500mg	C21344	Elite Pharma	80 vials/ pack+ Lignocain 1% (B. No. 112)	Violation of GMP
2.	Injection Lignocaine 1 %	112	Elite Pharma	30 x 100 ampoules	Packed on outer carton of Adrenaline, Maridine (Metoclopramide), Lignocaine and Ashtec (Nalbuphin), Misbranded drugs / unwarranted drugs/ Violation of GMP
Above mentioned drugs have been seized by drug inspector from packing/ production area. Item mentioned at Sr. No. 2 were placed in different cartons out of negligence of workers as these injections (Lignocain 1%) were to be placed in Inj. Rocelite (Dry Powder Inj.)					

ii. He locked and sealed the packaging/ Production area of Cephalosporin Section for the contravention of the Drugs Act 1976/ The DRAP Act 2012.
iii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis. These samples were declared of standard Quality from Drug Testing Laboratory, Lahore.

Drug Inspector sought permission to keep the custody of seized drugs/ API and extension in sealing period. Drug Inspector was granted to keep the seized stock in custody in 239th meeting held on 24-02-2021.

Whereas, the premises has already been de-sealed upon the directions of Honorable Drug Court Lahore dated 28-06-2021.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Violation of GMP (Packing and Stocking of Inj. Lignocaine in outer cartons of Adrenaline, Maridine** (Metoclopramide), **Lignocaine and Ashtec** (Nalbuphin)

3. Show-cause notice(s) issued to accused person(s) dated 06-02-2023

Firm submitted reply to the show cause notice vide letter dated 23-02-2023

Refer your letter no. PQCB/SM-15-07/2021 dated 06-02-2023 which was received by us on 22-02-2023.

We would like to bring your kind attention to the fact that during the inspection of the esteemed team members along with the Provincial Inspector of Drugs lignocaine 1% (Batch No. 112) was

being blistered with Injection Rocelite 500mg (Batch No. C21344) for IM purposes. The Lignocaine 1% injection was not kept for sale purposes but was solely present to be used with our Rocelite Injection in blister pack.

These injection of Lignocaine 1% however were packed in the outer cartons of other products which was due to the negligence of our working staff.

Furthermore, all observations made by the team were rectified and all SOPs are being strictly followed on our part. All injections being used with our Dry Injections are being properly packed and labelled.

Therefore, in this regard you are requested not to take any legal actions on our part and not recommend DRAP for the cancellation/suspension of our license.

In addition, as required by your goodself the following documents and information have been attached with this letter.

Name of CEO *Mr. Tahir Mahmood*

Name of Production Incharge *Muhammad Tahir*

Name of Quality Control Incharge Mr. Khalid Mahmood

4. Show cause notice was revised on 31-12-2024 keeping in view the name of Quality Control Incharge as provided by the firm in its reply to show cause notice.

5. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

6. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Form-5 (Seizure date)**	21-12-2021
2	**Investigation Report by DI**	08-03-2023
3	**SCN Permission**	258-M (05-04-2023)
4	**Show Cause Notice Issued**	06-02-2023, 31-12-2024 (Revised)
5	**Reply of Firm to Show Cause Notice**	23-02-2023
6	**History (3 years)**	Firm's Reported: Nil
		Product's Reported: Nil

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/ SM-15-07/2021

Drug Inspector Licensed Manufacturing Premises, District Sheikhupura

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Elite Pharma 9.5 km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura** through its Chief Executive Officer Tahir Mehmood S/o Muhammad Ayub 2. Tahir Mehmood S/o Muhammad Ayub — Chief Executive Officer 3. Khalid Mehmood S/o Bashir Ahmad — Quality Control Incharge 4. Muhammad Tahir S/o Abdul Aziz — Production Incharge of **M/S Elite Pharma 9.5 km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura**.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. He, on 23-06-2021, alongwith other team members, inspected the premises of M/s Elite Pharma, 9.5 Km Sheikhupura Road, Ferozewala and recovered and seized following different types of drugs on Form 5:

Sr. No.	Name of drugs	Batch No.	Name of Manufacturer	Quantity	Reason of Seizure
1.	Injection Rocelite 500mg	C21344	Elite Pharma	80 vials/ pack+ Lignocain 1% (B. No. 112)	Violation of GMP
2.	Injection Lignocaine 1 %	112	Elite Pharma	30 x 100 ampoules	Packed on outer carton of Adrenaline, Maridine (Metoclopramide), Lignocaine and Ashtec (Nalbuphin), Misbranded drugs / unwarranted drugs/ Violation of GMP
Above mentioned drugs have been seized by drug inspector from packing/ production area. Item mentioned at Sr. No. 2 were placed in different cartons out of negligence of workers as these injections (Lignocain 1%) were to be placed in Inj. Rocelite (Dry Powder Inj.)					

ii. He locked and sealed the packaging/ Production area of Cephalosporin Section for the contravention of the Drugs Act 1976/ The DRAP Act 2012.
iii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis. These samples were declared of standard Quality from Drug Testing Laboratory, Lahore.

Drug Inspector sought permission to keep the custody of seized drugs/ API and extension in sealing period. Drug Inspector was granted to keep the seized stock in custody in 239th meeting held on 24-02-2021.

Whereas, the premises has already been de-sealed upon the directions of Honorable Drug Court Lahore dated 28-06-2021.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Violation of GMP (Packing and Stocking of Inj. Lignocaine in outer cartons of Adrenaline, Maridine** (Metoclopramide), **Lignocaine and Ashtec** (Nalbuphin)

3. Show-cause notice(s) issued to accused person(s) dated 06-02-2023

Firm submitted reply to the show cause notice vide letter dated 23-02-2023

Refer your letter no. PQCB/SM-15-07/2021 dated 06-02-2023 which was received by us on 22-02-2023.

We would like to bring your kind attention to the fact that during the inspection of the esteemed team members along with the Provincial Inspector of Drugs lignocaine 1% (Batch No. 112) was being blistered with Injection Rocelite 500mg (Batch No. C21344) for IM purposes. The Lignocaine 1% injection was not kept for sale purposes but was solely present to be used with our Rocelite Injection in blister pack.

These injection of Lignocaine 1% however were packed in the outer cartons of other products which was due to the negligence of our working staff.

Furthermore, all observations made by the team were rectified and all SOPs are being strictly followed on our part. All injections being used with our Dry Injections are being properly packed and labelled.

Therefore, in this regard you are requested not to take any legal actions on our part and not recommend DRAP for the cancellation/suspension of our license.

In addition, as required by your goodself the following documents and information have been attached with this letter.

Name of CEO Mr. Tahir Mahmood

Name of Production Incharge Muhammad Tahir

Name of Quality Control Incharge Mr. Khalid Mahmood

4. Show cause notice was revised on 31-12-2024 keeping in view the name of Quality Control

Incharge as provided by the firm in its reply to show cause notice.

5. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

6. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Form-5 (Seizure date)**	21-12-2021
2	**Investigation Report by DI**	08-03-2023
3	**SCN Permission**	258-M (05-04-2023)
4	**Show Cause Notice Issued**	06-02-2023, 31-12-2024 (Revised)
5	**Reply of Firm to Show Cause Notice**	23-02-2023
6	**History (3 years)**	Firm’s Reported: Nil
		Product’s Reported: Nil

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 27

PQCB/R-383/2021

(Lady Atchison Hospital, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Bajwa Pharmaceuticals (Pvt.) Ltd., 36-Km, Off G.T. Road, Lahore** through its Managing Director, Farhat Munawar Bajwa. 2. Farhat Munawar Bajwa Managing Director 3. Abdul Khaliq Production In-charge 4. Sulman Aslam Quality Control Incharge/ Warrantor Of **M/s Bajwa Pharmaceuticals (Pvt.) Ltd., 36-Km, Off G.T. Road, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Government Lady Aitchison Hospital Lahore reported that: -

i. The then drug inspector, on 31-03-2021, inspected the Main Medicine Store of Government Lady Aitchison Hospital, Lahore, took sample of following drug on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore and sent to Drug Testing Laboratory Lahore vide memorandum no. 88419 dated 02-04-2021.
ii. The drug sample after test/analysis was declared as **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**	**DTL Test Report Result**
Injection. BALIGNO INJECTION [LIGNOCAIN HCl BP …. 20mg/ml] **Mfg Date:** Jan 2021 **Expiry Date:**	BL-0121	M/S BAJWA Pharmaceuticals Pvt. Ltd., 36-Km, Off G.T Road, Lahore Pakistan	01-156000924/DTL dated 28-05-2021	**Analysis with specifications applied: BP 2020** **PHYSICAL DESCRIPTION:** Colorless liquid in a transparent glass ampoule with label printed on it. Claimed Volume = 10mL **LABELING: THE LABEL OF THE DRUG DOES NOT BEAR "DOSAGE AND INSTRUCTIONS IN URDU" ON ITS IMMEDIATE CONTAINER.** **(Misbranded)** **IDENTIFICATION:** Lignocain HCl identified **ASSAY OF LIGNOCAIN HCl:**

Dec 2022 **Regn No.** 078954				Stated	20 mg/ mL
				Determined	9.22 mg/ mL
				Percentage	46.12%
				Limit	95.0% - 105.0% of the stated amount **(Substandard)**

STERILITY: MUST BE STERILE (Complies)

RESULT: The above sample is **SUBSTANDARD** on the basis of assay test performed as per BP and also **MISBRANDED**, as per THE DRUGS (LABELING AND PACKING) RULES, 1986, 3 [h(ii & iii)].

iii. Storekeeper of Main Medicine Store of Government Lady Aitchison Hospital, Lahore provided invoice/warranty bearing No. 4357 dated 16-03-2021 issued by M/S Bajwa Pharmaceuticals, Pvt. Ltd., 36-Km, Off G.T Road, Lahore -Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Bajwa Pharmaceuticals, Pvt. Ltd., 36-Km, Off G.T Road, Lahore -Pakistan.

v. A copy of test/analysis report was sent to M/s Bajwa Pharmaceuticals, Pvt. Ltd., 36-Km, Off G.T Road, Lahore -Pakistan with directions to explain their position and provide requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture/ Sale of Substandard & Misbranded drug**
b. **Issuance of false warranty**

3. Show Cause Notice issued to the accused dated 15.11.2024.

Reply of Show Cause Notice:

With reference to your letter No.PQCB/R-383/2021, dated: 15-11-2024 which received us on 29-11-2024 in the evening. It was about Baligno10ml (Reg: 078952 batch No. BL-0121) which was sub-standard and misbranded declared by Drug testing Laboratory report (TRA 01-156000924/DTL), dated May 28, 2021.

Dear Designee,

1. Sampling procedure was not properly followed by the DI. We received only 2 ampoules of the sampled batch which is insufficient for our testing.

2. We have rectified the label of our product (rectified label attached)

3. We have checked our retained samples and found that the assay of the product is as per specifications and complies.

4. Moreover we are sending your requisites

We want to challenge our case in APPELLET BOARD so kindly grant us retest

5. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 01.2021

Expiry Date: 12.2022

Sampling Date (Form 4): 31.03.2021

Sent to DTL (Form 6): 02.04.2021

Date of receipt in DTL: 02.04.2021

DTL Report Date (Form 7): 28.05.2021

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 02.08.2021

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 02.07.2024

SCN: 15.11.2024

Reply of SCN: 30.11.2024

History (Last 03 Years): Firm: 00 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-383/2021

(Lady Atchison Hospital, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**<u>Accused Persons involved in subject case</u>** 1. **M/s Bajwa Pharmaceuticals (Pvt.) Ltd., 36-Km, Off G.T. Road, Lahore** through its Managing Director, Farhat Munawar Bajwa. 2. Farhat Munawar Bajwa Managing Director 3. Abdul Khaliq Production In-charge 4. Sulman Aslam Quality Control Incharge/ Warrantor Of **M/s Bajwa Pharmaceuticals (Pvt.) Ltd., 36-Km, Off G.T. Road, Lahore.**

<u>BRIEF FACTS OF THE CASE:</u>

Provincial Inspector of Drugs, Government Lady Aitchison Hospital Lahore reported that: -

i. The then drug inspector, on 31-03-2021, inspected the Main Medicine Store of Government Lady Aitchison Hospital, Lahore, took sample of following drug on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore and sent to Drug Testing Laboratory Lahore vide memorandum no. 88419 dated 02-04-2021.
ii. The drug sample after test/analysis was declared as **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**	**DTL Test Report Result**
Injection. BALIGNO INJECTION [LIGNOCAIN HCl BP …. 20mg/ml] **Mfg Date:** Jan 2021 **Expiry Date:** Dec 2022 **Regn No.** 078954	BL-0121	M/S BAJWA Pharmaceuticals Pvt. Ltd., 36-Km, Off G.T Road, Lahore Pakistan	01-156000924/DTL dated 28-05-2021	**Analysis with specifications applied: BP 2020** **<u>PHYSICAL DESCRIPTION:</u>** Colorless liquid in a transparent glass ampoule with label printed on it. Claimed Volume = 10mL **<u>LABELING:</u> THE LABEL OF THE DRUG DOES NOT BEAR "DOSAGE AND INSTRUCTIONS IN URDU" ON ITS IMMEDIATE CONTAINER.** **(Misbranded)** **<u>IDENTIFICATION:</u>** Lignocain HCl identified **<u>ASSAY OF LIGNOCAIN HCl:</u>** Stated: 20 mg/ mL Determined: 9.22 mg/ mL Percentage: 46.12%

				Limit	95.0% - 105.0% of the stated amount **(Substandard)**

STERILITY: MUST BE STERILE (Complies)

RESULT: The above sample is **SUBSTANDARD** on the basis of assay test performed as per BP and also **MISBRANDED**, as per THE DRUGS (LABELING AND PACKING) RULES, 1986, 3 [h(ii & iii)].

iii. Storekeeper of Main Medicine Store of Government Lady Aitchison Hospital, Lahore provided invoice/warranty bearing No. 4357 dated 16-03-2021 issued by M/S Bajwa Pharmaceuticals, Pvt. Ltd., 36-Km, Off G.T Road, Lahore -Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Bajwa Pharmaceuticals, Pvt. Ltd., 36-Km, Off G.T Road, Lahore -Pakistan.

v. A copy of test/analysis report was sent to M/s Bajwa Pharmaceuticals, Pvt. Ltd., 36-Km, Off G.T Road, Lahore -Pakistan with directions to explain their position and provide requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a. **Manufacture/ Sale of Substandard & Misbranded drug**
b. **Issuance of false warranty**

3. Show Cause Notice issued to the accused dated 15.11.2024.

Reply of Show Cause Notice:

With reference to your letter No.PQCB/R-383/2021, dated: 15-11-2024 which received us on 29-11-2024 in the evening. It was about Baligno10ml (Reg: 078952 batch No. BL-0121) which was sub-standard and misbranded declared by Drug testing Laboratory report (TRA 01-156000924/DTL), dated May 28, 2021.

Dear Designee,

1. Sampling procedure was not properly followed by the DI. We received only 2 ampoules of the sampled batch which is insufficient for our testing.

2. We have rectified the label of our product (rectified label attached)

3. We have checked our retained samples and found that the assay of the product is as per specifications and complies.

4. Moreover we are sending your requisites

We want to challenge our case in APPELLET BOARD so kindly grant us retest

5. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 01.2021

Expiry Date: 12.2022

Sampling Date (Form 4): 31.03.2021

Sent to DTL (Form 6): 02.04.2021

Date of receipt in DTL: 02.04.2021

DTL Report Date (Form 7): 28.05.2021

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 02.08.2021

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 02.07.2024

SCN: 15.11.2024

Reply of SCN: 30.11.2024

History (Last 03 Years): Firm: 00 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 28

PQCB/MSS-171486/2023

Tehsil Jatoi, District Muzaffargarh

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in the subject case** 1. **M/S Chiesi Pharmaceuticals (Pvt.) Limited, Office # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Boulevard Gulberg-III, Lahore, Pakistan** through its MD/ CEO/ Proprietor, Umar Masood 2. Umar Masood — MD/CEO 3. Abdul Waheed — Qualified Person 4. Mansoor Akram — Warrantor 5. Mehreen Obaid — Current Warrantor **of M/S Chiesi Pharmaceuticals (Pvt.) Limited, Office # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Boulevard Gulberg-III, Lahore, Pakistan**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Jatoi, District Muzaffargarh reported that: -

i. He, on 07-07-2023 inspected the premises of Main Medicine Store, THQ Hospital Jatoi, District Muzaffargarh, and took 06 different types of drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.
ii. The subject drug sample, sent vide memo no. 171486 dated 13-07-2023, after test/analysis was declared **Substandard & Misbranded** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Atem 0.025% Nebuliser Soln. [(ipratropium bromide monohydrate 0.5218mg, equivalent to ipratropium bromide 0.50 mg)/ 2ml] **Mfg. Date:** 12-2022	1162184	M/S C.O.C. FARMACEUTICI SRL, VIA MODENA, 15-40019 SANTA GATA BOLOGNESE (BO).	01-105003878/DTL Dated. 03-11-2023	**Analysis with specifications applied:** **USP 2023** **DESCRIPTION:** Clear colorless solution filled in 2ml plastic vial **Note:** As per DRAP order No. F.3-5/2020-I & V-II (M-297)/ dated 7th February 2022 states, "a) all registration holders shall follow official pharmacopeial specifications for all such formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia. Product Specifications of given sample is **''Manufacturer's Specifications''** and it is manufactured after the expiration timeline to apply such specifications despite the availability of **"Ipratropium Bromide Inhalation Solution"** monograph in **USP 2023**, so the manufacturer's claim regarding product specifications is in contradiction to DRAP circular and in violation to Drugs Act 1976. **Mis-Branded (Does not comply)**

Exp Date: 12-2024 **Reg. #.** 033167				**EXTRACTABLE VOLUME**: Limit: NLT stated Determined: 2.0 mL **pH:** Limit: **3.0-4.0** Determined: **5.31** **(DOES NOT COMPLY)** **STERILITY TEST:** It conforms to sterility test. **(Complies)** **IDENTIFICATION:** IPRATROPIUM BROMIDE is identified. **ASSAY:** Ipratropium Bromide Stated: 0.5mg/2mL Determined: 0.5088 mg/2mL Percentage: 101.76 % . **(Complies)** Limit: 90-110% **RESULT:** The above-mentioned sample is **MISBRANDED** as defined under section **3 (s) (iv)** of the Drugs Act 1976**,** in compliance of DRAP Order No. F.3-5/2020-I & V-II (M-297)/ dated 7th February 2022 and **SUBSTANDARD** on the basis of **pH test.**

iii. Storekeeper, Main Medicine Store, THQ Hospital Jatoi, District Muzaffargarh provided invoice/warranty bearing No. 1903/05/23, dated 17-05-2023 issued by M/s Chiesi Pharmaceuticals (Pvt.) Limited, Office # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Boulevard Gulberg-III, Lahore, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Chiesi Pharmaceuticals (Pvt.) Limited, 60/1a-Xx, Phase III, Commercial Zone, Khayaban-e-Iqbal, DHA, Lahore, Pakistan.

v. A copy of test/analysis report was sent to M/s Chiesi Pharmaceuticals (Pvt.) Limited, Office # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Boulevard Gulberg-III, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard.

2. Drug Inspector requested for grant of permission for prosecution against the accused person nominated in the subject case, who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of: -

a. **Import for sale/ Sale of Substandard and Misbranded Drug**
b. **Issuance of false warranty**

3. Show-cause/ Personal Hearing Notice(s) issued to accused person(s) dated 17-03-2025

4. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	07-07-2023
2	**Sample Sent to DTL (Form-6)**	13-07-2023
3	**Receipt Date in DTL**	17-07-2023
4	**Issuance of DTL Report**	03-11-2023
5	**Time Extension**	26-CM dated 11-10-2023
6	**DI First Communication with Firm**	05-12-2023
7	**Retesting Request**	No
9	**Investigation Report by DI**	Received on 06-01-2025
10	**SCN Permission**	288-M (25-02-2025)
11	**Show Cause Notice Issued**	17-03-2025
12	**Reply of Firm to Show Cause Notice**	Not yet
13	**History (3 years)**	Firm's Reported: 12
		Product's Reported: 12

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/MSS-171486/2023

Tehsil Jatoi, District Muzaffargarh

ATTENDANCE:

Secretary	**Accused Persons involved in the subject case**

DQCB Drug Inspector	1. **M/S Chiesi Pharmaceuticals (Pvt.) Limited, Office # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Boulevard Gulberg-III, Lahore, Pakistan** through its MD/ CEO/ Proprietor, Umar Masood 2. Umar Masood MD/CEO 3. Abdul Waheed Qualified Person 4. Mansoor Akram Warrantor 5. Mehreen Obaid Current Warrantor **of M/S Chiesi Pharmaceuticals (Pvt.) Limited, Office # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Boulevard Gulberg-III, Lahore, Pakistan**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Jatoi, District Muzaffargarh reported that: -

i. He, on 07-07-2023 inspected the premises of Main Medicine Store, THQ Hospital Jatoi, District Muzaffargarh, and took 06 different types of drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.
ii. The subject drug sample, sent vide memo no. 171486 dated 13-07-2023, after test/analysis was declared **Substandard & Misbranded** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Atem 0.025% Nebuliser Soln. [(ipratropium bromide monohydrate 0.5218mg, equivalent to ipratropium bromide 0.50 mg)/ 2ml] **Mfg. Date:** 12-2022 **Exp Date:** 12-2024 **Reg. #.** 033167	1162184	M/S C.O.C. FARMACEUTICI SRL, VIA MODENA, 15-40019 SANTA GATA BOLOGNESE (BO).	01-105003878/DTL Dated. 03-11-2023	**Analysis with specifications applied:** **USP 2023** **DESCRIPTION:** Clear colorless solution filled in 2ml plastic vial **Note:** As per DRAP order No. F.3-5/2020-I & V-II (M-297)/ dated 7th February 2022 states, "a) all registration holders shall follow official pharmacopeial specifications for all such formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia. Product Specifications of given sample is **''Manufacturer's Specifications''** and it is manufactured after the expiration timeline to apply such specifications despite the availability of **"Ipratropium Bromide Inhalation Solution"** monograph in **USP 2023**, so the manufacturer's claim regarding product specifications is in contradiction to DRAP circular and in violation to Drugs Act 1976. **Mis-Branded (Does not comply)** **EXTRACTABLE VOLUME**: Limit: NLT stated Determined: 2.0 mL **pH:** Limit: **3.0-4.0**

				Determined: **5.31** **(DOES NOT COMPLY)** **STERILITY TEST:** It conforms to sterility test. **(Complies)** **IDENTIFICATION:** IPRATROPIUM BROMIDE is identified. **ASSAY:** Ipratropium Bromide Stated: 0.5mg/2mL Determined: 0.5088 mg/2mL Percentage: 101.76 % . **(Complies)** Limit: 90-110% **RESULT:** The above-mentioned sample is **MISBRANDED** as defined under section **3 (s) (iv)** of the Drugs Act 1976**,** in compliance of DRAP Order No. F.3-5/2020-I & V-II (M-297)/ dated 7th February 2022 and **SUBSTANDARD** on the basis of **pH test.**

iii. Storekeeper, Main Medicine Store, THQ Hospital Jatoi, District Muzaffargarh provided invoice/warranty bearing No. 1903/05/23, dated 17-05-2023 issued by M/s Chiesi Pharmaceuticals (Pvt.) Limited, Office # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Boulevard Gulberg-III, Lahore, Pakistan as a proof of its purchase.
iv. Warrantor portion of drug sample was sent to M/s Chiesi Pharmaceuticals (Pvt.) Limited, 60/1a-Xx, Phase III, Commercial Zone, Khayaban-e-Iqbal, DHA, Lahore, Pakistan.
v. A copy of test/analysis report was sent to M/s Chiesi Pharmaceuticals (Pvt.) Limited, Office # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Boulevard Gulberg-III, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard.

2. Drug Inspector requested for grant of permission for prosecution against the accused person nominated in the subject case, who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of: -

a. **Import for sale/ Sale of Substandard and Misbranded Drug**
b. **Issuance of false warranty**

3. Show-cause/ Personal Hearing Notice(s) issued to accused person(s) dated 17-03-2025

4. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	07-07-2023
2	**Sample Sent to DTL (Form-6)**	13-07-2023
3	**Receipt Date in DTL**	17-07-2023

4	**Issuance of DTL Report**	03-11-2023
5	**Time Extension**	26-CM dated 11-10-2023
6	**DI First Communication with Firm**	05-12-2023
7	**Retesting Request**	No
9	**Investigation Report by DI**	Received on 06-01-2025
10	**SCN Permission**	288-M (25-02-2025)
11	**Show Cause Notice Issued**	17-03-2025
12	**Reply of Firm to Show Cause Notice**	Not yet
13	**History (3 years)**	Firm’s Reported: 12
		Product’s Reported: 12

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 29

PQCB/R-800/2021

(Wahga Town, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. Muhammad Aslam Ghani Proprietor 2. Shahid Ali Khan Qualified Person 3. Farhan Warrantor of **M/s Ghani Brothers, 2nd Floor, Karimji Building opposite HBL, Napier Road, Karachi-Pakistan.** 4. M. Ishaq Warrantor of **M/s Al-Siraj Medicine Company, Shop No.4, Imam Din Medicine Market, Lohari Gate, Lahore- Pakistan.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Wagha Town, District Lahore reported that: -

i. The then drug inspector, on 14-01-2021, inspected the business premises of M/s Ghafoor Pharmacy, 329-GT Road, Daroghawala Lahore, took four different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide memorandum no. 83229 dated 18-01-2021.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report No. & Date	DTL Test Report Results
Capsule. INDOMETHACIN [INDOMETHACIN 25 mg] **Mfg Date** Aug 2019 **Expiry Date** Aug 2023	190806	M/S Taiyuan Pharmaceutical Factories, Foreign Trade, Taiyuan, China.	01-73007425/DTL dated 19-03-2021	Specs Applied: USP 2024/Others/In house COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg PHYSICAL CHARACTERISTICS: Stated: Pinkish red sweet suspension. Determined: Parapol is a pinkish red, bitter viscous liquid from any dispersed solid particles, filled in an amber plasti sealed with a white screw cap, further packed in a labeled carton.

Regn No. 019600				As per USP <1151> Pharmaceutical Dosage Forms “A sus biphasic preparation consisting of solid particles dispersed a liquid phase. (DOES NOT COMPLY) pH: Limit: 4.0-6.9 Determined: 5.4 @ 23.4ºC IDENTIFICATION: Paracetamol is identified. ASSAY OF PARACETAMOL: Stated 120 mg/5ml Determined 122.50 mg/5ml Limit 90.0- TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLY PROPYLENE GLYCOL BY GAS CHROMATOGRAPH Note: The given sample was analyzed for Test of Ethylene Diethylene Glycol & Propylene Glycol. WHO Working Document QAS/23.922/rev3 Dated 31 October 2023 Ethylene Glycol: Limit: NMT 0.1% Determined: Not Detected Diethylene Glycol: Limit: NMT 0.1% Determined: Not Detected Propylene Glycol Determined: 10.815% **ASSAY:** Stated: 25 mg/cap Determined: 25.02 mg /cap

				Percentage: 100.1% Limit: 90 – 110% **<u>WEIGHT VARIATION:</u> Fails to comply the BP criteria for weight varia below:** **Tolerance Limit:** Not more than 2 out of 20 capsules content deviate from deviates from ± 20% of average weight. Average Weight: 109mg **Determined:** 6 units are out of the limit of 109mg ± 10% and 2 units, out of out of the limit of 109mg ± 20% **(DOES NOT COMPLY)** **RESULT:** The above sample is **<u>SUB-STANDARD,</u>** on the basis of VARIATION test performed as per BP.

iii. Proprietor of M/s Ghafoor Pharmacy, 329-GT Road, Daroghawala Lahore provided invoice/warranty bearing No. 11288 dated 09-01-2021 issued by M/s Al-Siraj Medicine Company, Shop No.4, Imam Din Medicine Market, Lohari Gate, Lahore- Pakistan.

iv. Warrantor portion of drug sample was sent to M/s Al-Siraj Medicine Company, Shop No.4, Imam Din Medicine Market, Lohari Gate, Lahore- Pakistan who in-turn provided invoice/warranty bearing No. 273 dated 26-10-2020 issued by M/s Ghani Brothers, 2nd Floor, Karimji Building opposite HBL, Napier Road, Karachi-Pakistan.

v. A copy of test/analysis report was sent to M/s Ghani Brothers, 2nd Floor, Karimji Building opposite HBL, Napier Road, Karachi-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample, pursuant to firm's request, the Provincial Quality Control Board in its 240th meeting held on 15-03-2022, after due deliberation and discussion unanimously decide to turn down the firm's request for retesting of the subject sample.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

Names of Accused Persons	Offences
1. Muhammad Aslam Ghani, Proprietor 2. Shahid Ali Khan, Qualified Person 3. Farhan, Warrantor of **M/s Ghani Brothers, 2nd Floor, Karimji Building opposite HBL, Napier Road, Karachi-Pakistan.**	a. **Import for sale/ sale of Substandard drug** b. **Issuance of false warranty** c. **Violation of section 23 (1) (f) and 27 (3) of the Drugs Act 1976 & rules framed thereunder** (Dis-abeyance of lawful authority & provision of incomplete information when required under Drug Act 1976 & rules framed thereunder.
1. M. Ishaq Warrantor of **M/s Al-Siraj Medicine Company, Shop No.4, Imam Din Medicine Market, Lohari Gate, Lahore-**	a. **Selling/ stocking for sale of Substandard Drug** b. **Provision of false warranty**

Pakistan.	

3. Show Cause Notices issued to the accused dated 09.09.2022.

Reply of Show Cause Notice (Ghani Brothers):

Kindly refer to SCN No. PQCB/R-800/2021 dated 30.08.2023. Copy pasted below.

The Show Cause Notice has been issued based upon the report of an incompetent and inefficient Drug Inspector Wahga Town, Lahore. The company had submitted appropriate confrontation to the regulatory unlawful acts and omission. Defence ascertains & confrontations have been innocently + boorishly + maliciously concealed by DI in his report submitted to you.

The above mechanical and non speaking SCN is prepared & designed as coverup for the wrongdoings & illegalties of Kamal Sikandar DI-Aziz Bhati Town, Lahore because nothing has been mentioned related to the coresspondence between Ghani Brothers and Regulatory Authorties (DI, PQCB and the Director DTL). The facts have been misreprented, concealed and twisted in the SCN specially related to warrantor's portion and Challenge of the Report NO.TRA No.01 94000328/DTL Dated 24-01-2022 and Fictional Retesting Request. It is absolutely false that Ghani Brother, Karachi had ever asked for RETESTING. PQCB Order No. PQCB/P-251-3/2021 Dated 15.03.2022 dispatch date 02.06.2022.The PETITION was submitted to the Chairman Provincial Quality Control Board, Punjab,492, R-II, Johar Town, Lahore, for withdrawl of an Unlawful Non-Speaking PQCB Order No. PQCB/P-251-3/2021 Dated 15.03.2022 Dispatch Date 02.06.2022 to turn down Retesting Request of sample Cap. Indomethacin 25 Mg, Batch No. 190806, manufactured by Taiyuan Pharmaceutical Factory, Foreign Trade, Taiyuan, China Unlawfully Declared Substandard Vide Test / Anais Report NO.TRA No.01 94000328/DTL Dated 24-01-2022- Request which was never submitted by the Ghani Brothers Karachi. The petition is still lying pending before the PQCB. The issuance of present SCN No. PQCB/R-800/2021 Dated 30.08.2023 during pendency of this petition raises reasonable doubts.

The No. GN070423-1 Date. 07.04.2023 is reproduced below as a ready reference.

xxxxxxxxxxxxxxxxxxxx

No. GN070423-1 Date. 07.04.2023

To

The Chairman

Provincial Quality Control Board, Punjab

Office: 492, R-II, Johar Town,

Lahore. Pakistan Email-scrutiny.pqcb@gmail.com

PETITION

FOR WITHDRAWL OF UNLAWFUL NON-SPEAKING PQCB ORDER NO. PQCB/P-251-3/2021 DATED 15.03.2022 DISPATCH DATE 02.06.2022 TO TURN DOWN RETESTING REQUEST OF SAMPLE CAP. INDOMETHACIN 25 MG, BATCH NO. 190806, MANUFACTURED BY TAIYUAN PHARMACEUTICAL FACTORY, FOREIGN TRADE, TAIYUAN, CHINA UNLAWFULLY DECLARED SUBSTANDARD VIDE TEST / ANAIS REPORT NO.TRA NO.01

94000328/DTL DATED 24-01-2022-REQUEST WHICH WAS NEVER SUBMITTED BY THE COMPANY

Kindly refer to the above PQCB ORDER received from the Provincial Drugs Inspector Wagha Town, Dist. Lahore, 24-Cooper Road, Lahore vide his 04-04/SUBS/DI-WT/2023 Dated Lahore the 01-04-23.

The copy of impugned PQCB OREDER is pasted below as ready reference. PQCB OREDER DATED 15.03.2022 DISPATCH DATE 02.06.2022 Received from DI on 03.04.2023

THE FOLLOWING SUBMISSIONS ARE MADE

1. That all the correspondence made with Di and PQCB may please be taken as the part of this petition.

2. The Drug Inspector committed misconduct by issuing + Serving backdated letters.

A. The back dated letter No. letter No.04-03/SUBS/DI-WT/2021 Dated 01.07.2021 has been delivered on 24.08.2021. Back Dated Letter raises doubts.

B. The warrantor's portion of sample sent to Alsiraj Medicine Company, Imam Din Medicine market, Lohari Gate, Lahore vide letter No.0301/Com/DI-WT/2021 Dated 21.01.2021 was delivered on 06.04.2021. Back Dated Letter raises doubts as well as illegal. Copy of letter pasted below.

That there is no provision in any prevailing Drug law in Pakistan which could empower any regulatory authority (Neither Drug Inspector Nor PQCB) to condone delay by ignoring mandatory prescribed period of SEVEN DAYS for disposing Warrantor's portion of the sample. NON-COMPLIANCE to Section 19 (3) related to statutory requirement of sending warrantor's portion within seven days, is an illegality. The Warrantor's portion has not been disposed off within statutory period of seven days as prescribed under Section 19(3) (iv) of the Drugs Act 1976. The non-observance to said procedure is reasonably doubtful and is an illegality. The PQCB had unanimously dropped a Case No. PQCB R-577-09/2016 related to Infusion Dorcip Batch No. Dc-075 declared as Adulterated and Substandard by Government Analyst Drug Testing Laboratory Rawalpindi vide DTL Report. TRA. No. 1077/DTL Dated: 22-09-2016. The PQCB had observed that this case was FIT FOR PROSECUTION based on report. But this case was DROPPED as PQCB had observed that case would fail in court because warrantor portion was not sent to the manufacturer within statutory period as prescribed under Section 19 (3) of the Drug Act 1976.PQCB members may kindly compare the present case with the IGNORED CASE of Infusion Dorcip to ascertain level of potential and real clinical Risks/ADR. Both cases are similar with the ignored case may differentiated as of more seventy.

3. That Personal Hearing Notice was never delivered to us for presentation of GB-viewpoints on Section 22(4) & 222(5) of the Drug Act 1976. The Drug Law as well as principle o principle of natural justice have been violated by deciding the issue in the absence of the aggrieved person.

4. That PQCB order is unlawful as well as malicious as PQCB has turned down a Fictional Request ar92-21-32735518 Retest, which was never submitted by the GB-Karachi.

5. That report is non-conclusive + unlawful as full protocols of the test applied to reach the conclusion and Result of disputed drug as substandard have not been given in the above Test Report. There is always likelihood of errors in Tests / analysis report, which would be of adverse consequence and affects substantial rights of a person. The single bench of Lahore High Court has held that Reports of Analyst must be conclusive and must disclose the tests applied to formulate opinion of Government Analyst. There is always likelihood of errors in Tests / analysis report, which would be of adverse consequence and affects substantial rights of a person. Therefore, the description of the experiment including method evaluating standards / results must be Crystal clear whenever report would be disputed. Reliance on PLD 2003 Lah. 115. The honorable Single Judge relied on these judgments in the reported cases- Gyanendra Nath Mittal v. State AIR 1959 All, 634; S. Dutta and another. The DB Judgments of Peshawar High Court

and Quetta High Court had also held that report without protocol were fatally defective and unlawful. Reliance on 1996 P Cr.L. J 1183 (Peshawar). 115, PLJ 2012 Cr.C. (Quetta) 546 (DB). The honorable Supreme Court has held in case reported as 2019 SCM 930 "Report of the Government Analyst must contain Protocol. The term "protocol" has not been defined in the Rules. Its dictionary meaning is "A plan of scientific experiment or other procedure. It is also referred to as "the precise method for carrying out or reproducing a given experiment. (Chambers 21st Century Dictionary, 2007 Edition, page 1114. (https://wikidiff.com/protocol/method.) These definitions are in line with the elaboration of the term "protocol" given in case of Imam Bakhsh wherein the Court stated the expression "protocol" to mean an explicit plan of an experiment, procedure, or test. It is clarified that "protocol" is, therefore, a recognized standard method or plan for carrying out the test applied to ascertain the nature of the substance under examination. No test can take place without protocol. The Report of the Government Analyst must show that the test applied was in accordance with a recognized standard protocol. Any test conducted without protocol loses its reliability and evidentiary value. Therefore, to serve the purposes of the Act and the Rules, the Report of the Government Analyst must contain.

(i) The Tests Applied

(ii) The Protocols Applied to Carry Out These Tests

(iii) The Result of the Test(s).

6. That the mechanical scrutiny and subsequent disputed unlawful decision / order is without appropriate reasoning and annulated confrontation. The explanation on the viewpoints leading to creation of one sided unanimous PQCB Order to Tum Down the invented request for retesting of the sample are given below.

PQCB - Decision/Order without Personal Hearing	**Explanation By Aggrieved Person**
The Board thoroughly scrutinized the evidence submitted by the Firm to Weight Variation. Government Analyst submitted descriptive and justified proof about the test protocol of the drug. Weight Variation is one in a series of tests in a therapeutic product specification that assesses the quality of a batch. Testing for Weight Variation helps ensure that the strength of a therapeutic product remains within specified acceptance limits.	Determination of noncompliance to the BP criteria for weight variation is reasonably doubtful because of the following facts Tolerance Limit: Not more than 2 out of 20 capsules content deviate from ±10% and none deviates from ±20% of average weight Average weight: 109mg.
Role of Weight Variation and its impact on Tablet formulation was discussed at length. The Board was of the considered view that Weight Variation ensures uniform distribution of active ingredients in tablets. If the product does not fall in the prescribed limits of weight variation which result in uneven distribution of active ingredient that may result in overdosage and toxicity (in case of active ingredient more than the therapeutic level) or underdosage with no therapeutic activity (in case active ingredient less than the therapeutic level).	Determined: 6 units are out of the limit of 109mg ± 10% and 2 units, out of these 6 units are out of the limit of 109mg + 20%. Because weight of individual tablet and its deviation not given.
In view of the above-mentioned facts, the Board	The weight variation test must be evaluated by Co-relating with other tests. When Assay Result (Effectiveness and Safely) and Dissolution Tests (Bioavailability Compliance) are complying. It is fictional statement + opinion originating from the belligerent abuse of discretionary powers that "weight variation would adverse effect on the therapeutic response as result overdosage and toxicity (in case of active ingredient more than the therapeutic level) or underdosage with no

after due deliberation unanimously decided to Turn Down the subject request for retesting of the sample.

The Board further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

therapeutic activity (in case active ingredient less than the therapeutic level)."

Directing the Inspector for investigation of case constructed on unlawful test / analysis report is nothing but inventing malicious prosecution which is against fundamental rights guaranteed IRP-1973 Constitution of Pakistan. If basic document test / analysis report was without lawful authority, superstructure built on it would fall on ground automatically. Constitution of Pakistan (1973)-Art.4 is Crystal Clear that -Public functionaries were obliged to act justly, fairly, equitably, reasonably without any element of discrimination and squarely within parameters of law as envisaged by Art.4 of Constitution of Pakistan.

In the light of the above legal points and factual controversies, it is respectfully requested that the petition may please be accepted by withdrawing the unlawful order of turn down request of retesting which was never submitted. The statuary personal hearing may please be given whenever the case is presented before the PQCB for any interim or Final Order.

For Ghani Brother, Karachi

No. and Date Even. Copy forwarded for information and necessary action to the provincial Inspector of Drugs, Wagha Town, Dist. Lahore, 24-Cooper Road, Lahore wir to his letter No.04-04/SUBS/DI-WT/2023 Dated Lahore the 01-04-23.

In the light of the above assertions and contentions, it is respectfully requested that above mentioned PETITION No.GN070423-1 Date. 07.04.2023 may kindly be decided on merit prior to initiating any proceeding related to unlawful issuance of Show Cause Notice. We are ready to appear before the PQCB as and when required for a personal hearing on the above petition if so desired. Every citizen of Pakistan is entitled to be dealt in accordance with law and Due Process, without any discrimination as per requirement of 1973 Constitution of Islamic Republic of Pakistan.

Reply of Show Cause Notice (Al-Siraj Medicine Company):

1. It is very clear that I am "WHOLESALER" deals in the Sale /Distribution of various Drugs Manufactured and / or Imported by the Manufacturers and / or Importers etc. in Pakistan.

2. As related with the Drug mentioned in the Show Cause Notice No.PQCB/R-800/2021 i.e; Cap. INDOMETHACIN 25mg Batch No. 190806, Manufactured by: "TAIYUAN", Pharmaceutical Factories, China as mentioned in the Invoice No.273 dated 26.10.2020 / WARRANTY issued by MR. FARHAN, in the capacity of IMPORTER/ INDENTER OF M/S GHANI BROTHERS, 2nd Floor, Karmji Building opp. HBL, Napier Road, Karachi, (purchased 400 Boxes of 10 x 10 capsules).

3. The said drug was received in November, 2010 from M/s GHANI BROTHERS Karachi and on 09.012021, 10 Boxes were sold to M/s GAFOOR PHARMACY, 329, G.T. Road, Daroghawala, Lahore (from whom Sample was taken).

4. Respected Sir, according to the record the said Drug was sold to M/s Ghafoor Pharmacy by me within 60/70 days from the receiving / supply of said drug by the importer / warrantor i.e M/s Ghani Brothers, which was remained in the same State as when I acquired that drug.

5. Sir, Al Siraj Medicine Company situated IN THE IMAM DIN MEDICINE MARKET, LOHARI GATE LAHORE, which is Almost 24 HOURS under the Supervision and Control of Law enforcing agencies and the Drug Inspectors.

6. Drugs are stored 100% under the required storage conditions and in compliance with all the requirements.

7. Respected Sir, I soon as I received the warrantor portion of the Sample from the Drug Inspector, I immediately forward the same to M/s Ghani Brothers Karachi, "The Importer". (Copy of the letter enclosed).

8. Another letter No.04-02/SUBS/DI-WT/2021 dated 08.6.2021 was received by me from the Drug Inspector, M/s Al-Siraj Medicine Company, submitted the reply with facts to the Drug Inspector in details, and copy was also to M/s Ghani Brothers "The Warrantor" for M/s Al-Siraj Medicine Company. (Copy enclosed).

9. In the meanwhile, I received the response from M/s Ghani Brothers Karachi, wherein it was stated that;

"Kindly refer to your telephonic massage regarding receiving of Indomethacin Cap. 25mg Seal Portion. It is confirmed that we have received the above Sample.

For your kind information pls note that we have not received any official letter from the Drug Inspector.

We have also NOT yet received the original drug test report for the above mentioned Medicine either."

(Copy enclosed).

10. In the above facts and applicable law, it is respectfully prayed, please drop the proceedings to the extent of M/s Al-Siraj Medicine Company, for the facts that,

In the Show Cause Notice No specific allegation is leveled against M/s Al-Siraj Medicine Company.

That, M/s Al-Siraj Medicine Company rightly & correctly taken the defence under Section 32(3)(b) of the Drugs Act 1976.

That M/s Al-Siraj Medicine Company is WHOLESALLER / DISTRIBUTOR, lawfully sold the Drug to M/s Ghafoor Pharmacy, Daroghawala, Lahore.

M/s Al-Siraj Medicine Company is not responsible for the Manufacturing, Importing of that drug, lawfully relied on the lawful warranty issued by M/s Ghani Brothers the Importer. It is proved that the drug stored by M/s Al-Siraj Medicine Company was remained in the same State as acquired from M/s Al-Ghani Brothers Karachi.

Respected Sir,

Keeping in view the above facts and realities please consider that:-

M/s Al-Siraj Medicine Company does not contravened or committed any violation of Section 23/27 of the Drug Act 1976 (as amended) / DRAP Act 2012 and Rules framed thereunder. Valid defence under Section 32(3)(b) of the Drugs Act 1976 was taken, please provide the benefit of Section 32(3)(b).

Please No action may please be taken against M/s Al-Siraj Medicine Company and oblige.

5. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 08.2019

Expiry Date: 08.2023

Sampling Date (Form 4): 14.01.2021

Sent to DTL (Form 6): 18.01.2021

Date of receipt in DTL: 20.01.2021

DTL Report Date (Form 7): 19.03.2021

Time Extension: Not time barred

1ST DI Communication with firm on dated: 01.07.2021

Retesting Request of Firm: 27.08.2021

Fate of Firm's Retest Request: Turn Down (240-M)

Investigation Report Dated: 24.07.2023

SCN Permission: 265-M

SCN: 30.08.2023

Reply of SCN: 09.09.2023 and 14.09.2023

History (Last 03 Years): Product: 00 cases reported, Firm: 00 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-800/2021

(Wahga Town, Lahore)

ATTENDANCE

Secretary DQCB	**Accused Persons involved in subject case** 1. Muhammad Aslam Ghani — Proprietor 2. Shahid Ali Khan — Qualified Person 3. Farhan — Warrantor

Drug Inspector	of **M/s Ghani Brothers, 2nd Floor, Karimji Building opposite HBL, Napier Road, Karachi-Pakistan.** 4. M. Ishaq Warrantor of **M/s Al-Siraj Medicine Company, Shop No.4, Imam Din Medicine Market, Lohari Gate, Lahore- Pakistan.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Wagha Town, District Lahore reported that: -

i. The then drug inspector, on 14-01-2021, inspected the business premises of M/s Ghafoor Pharmacy, 329-GT Road, Daroghawala Lahore, took four different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide memorandum no. 83229 dated 18-01-2021.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of drug	**Batch no.**	**Name of manufacturer**	**DTL Report No. & Date**	**DTL Test Report Results**
Capsule. INDOMETHACIN [INDOMETHACIN 25 mg] **Mfg Date** Aug 2019 **Expiry Date** Aug 2023 **Regn No.** 019600	190806	M/S Taiyuan Pharmaceutical Factories, Foreign Trade, Taiyuan, China.	01-73007425/DTL dated 19-03-2021	Specs Applied: USP 2024/Others/In house COMPOSITION: Each 5ml contains: Paracetamol USP…. 120mg PHYSICAL CHARACTERISTICS: Stated: Pinkish red sweet suspension. Determined: Parapol is a pinkish red, bitter viscous liquid from any dispersed solid particles, filled in an amber plasti sealed with a white screw cap, further packed in a labeled carton. As per USP <1151> Pharmaceutical Dosage Forms “A sus biphasic preparation consisting of solid particles dispersed a liquid phase. (DOES NOT COMPLY) pH: Limit: 4.0-6.9 Determined: 5.4 @ 23.4ºC IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 120 mg/5ml

Determined 122.50 mg/5ml

Limit 90.0-

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLY
PROPYLENE GLYCOL BY GAS CHROMATOGRAPH

Note: The given sample was analyzed for Test of Ethylene
Diethylene Glycol & Propylene Glycol.

WHO Working Document

QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected

Diethylene Glycol:

Limit: NMT 0.1%

Determined: Not Detected

Propylene Glycol

Determined: 10.815%

ASSAY:

Stated: 25 mg/cap

Determined: 25.02 mg /cap

Percentage: 100.1%

Limit: 90 – 110%

**WEIGHT VARIATION: Fails to comply the BP criteria for weight varia
below:**

Tolerance Limit: Not more than 2 out of 20 capsules content deviate from
deviates from ± 20% of average weight.

Average Weight: 109mg

Determined: 6 units are out of the limit of 109mg ± 10% and 2 units, out of
out of the limit of 109mg ± 20%

				(DOES NOT COMPLY) **RESULT:** The above sample is **<u>SUB-STANDARD,</u>** on the basis of VARIATION test performed as per BP.

iii. Proprietor of M/s Ghafoor Pharmacy, 329-GT Road, Daroghawala Lahore provided invoice/warranty bearing No. 11288 dated 09-01-2021 issued by M/s Al-Siraj Medicine Company, Shop No.4, Imam Din Medicine Market, Lohari Gate, Lahore- Pakistan.

iv. Warrantor portion of drug sample was sent to M/s Al-Siraj Medicine Company, Shop No.4, Imam Din Medicine Market, Lohari Gate, Lahore- Pakistan who in-turn provided invoice/warranty bearing No. 273 dated 26-10-2020 issued by M/s Ghani Brothers, 2nd Floor, Karimji Building opposite HBL, Napier Road, Karachi-Pakistan.

v. A copy of test/analysis report was sent to M/s Ghani Brothers, 2nd Floor, Karimji Building opposite HBL, Napier Road, Karachi-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample, pursuant to firm's request, the Provincial Quality Control Board in its 240th meeting held on 15-03-2022, after due deliberation and discussion unanimously decide to turn down the firm's request for retesting of the subject sample.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

Names of Accused Persons	**Offences**
1. Muhammad Aslam Ghani, Proprietor 2. Shahid Ali Khan, Qualified Person 3. Farhan, Warrantor of **M/s Ghani Brothers, 2nd Floor, Karimji Building opposite HBL, Napier Road, Karachi-Pakistan.**	a. **Import for sale/ sale of Substandard drug** b. **Issuance of false warranty** c. **Violation of section 23 (1) (f) and 27 (3) of the Drugs Act 1976 & rules framed thereunder** (Dis-abeyance of lawful authority & provision of incomplete information when required under Drug Act 1976 & rules framed thereunder.
1. M. Ishaq Warrantor of **M/s Al-Siraj Medicine Company, Shop No.4, Imam Din Medicine Market, Lohari Gate, Lahore-Pakistan.**	a. **Selling/ stocking for sale of Substandard Drug** b. **Provision of false warranty**

3. Show Cause Notices issued to the accused dated 09.09.2022.

<u>Reply of Show Cause Notice (Ghani Brothers):</u>

Kindly refer to SCN No. PQCB/R-800/2021 dated 30.08.2023. Copy pasted below.

The Show Cause Notice has been issued based upon the report of an incompetent and inefficient Drug Inspector Wahga Town, Lahore. The company had submitted appropriate confrontation to the regulatory unlawful acts and omission. Defence ascertains & confrontations have been innocently + boorishly + maliciously concealed by DI in his report submitted to you.

The above mechanical and non speaking SCN is prepared & designed as coverup for the wrongdoings & illegalties of Kamal Sikandar DI-Aziz Bhati Town, Lahore because nothing has been mentioned related to the coresspondence between Ghani Brothers and Regulatory Authorties (DI, PQCB and the Director DTL). The facts have been misreprented, concealed and twisted in the SCN specially related to warrantor's portion and Challenge of the Report NO.TRA No.01 94000328/DTL Dated 24-01-2022 and Fictional Retesting Request. It is absolutely false that Ghani Brother, Karachi had ever asked for RETESTING. PQCB Order No. PQCB/P-251-3/2021 Dated 15.03.2022 dispatch date 02.06.2022.The PETITION was submitted to the Chairman Provincial Quality Control Board, Punjab,492, R-II, Johar Town, Lahore, for withdrawl of an Unlawful Non-Speaking PQCB Order No. PQCB/P-251-3/2021 Dated 15.03.2022 Dispatch Date 02.06.2022 to turn down Retesting Request of sample Cap. Indomethacin 25 Mg, Batch No. 190806, manufactured by Taiyuan Pharmaceutical Factory, Foreign Trade, Taiyuan, China Unlawfully Declared Substandard Vide Test / Anais Report NO.TRA No.01 94000328/DTL Dated 24-01-2022- Request which was never submitted by the Ghani Brothers Karachi. The petition is still lying pending before the PQCB. The issuance of present SCN No. PQCB/R-800/2021 Dated 30.08.2023 during pendency of this petition raises reasonable doubts.

The No. GN070423-1 Date. 07.04.2023 is reproduced below as a ready reference.

xxxxxxxxxxxxxxxxxxxx

No. GN070423-1 Date. 07.04.2023

To

The Chairman

Provincial Quality Control Board, Punjab

Office: 492, R-II, Johar Town,

Lahore. Pakistan Email-scrutiny.pqcb@gmail.com

PETITION

FOR WITHDRAWL OF UNLAWFUL NON-SPEAKING PQCB ORDER NO. PQCB/P-251-3/2021 DATED 15.03.2022 DISPATCH DATE 02.06.2022 TO TURN DOWN RETESTING REQUEST OF SAMPLE CAP. INDOMETHACIN 25 MG, BATCH NO. 190806, MANUFACTURED BY TAIYUAN PHARMACEUTICAL FACTORY, FOREIGN TRADE, TAIYUAN, CHINA UNLAWFULLY DECLARED SUBSTANDARD VIDE TEST / ANAIS REPORT NO.TRA NO.01 94000328/DTL DATED 24-01-2022-REQUEST WHICH WAS NEVER SUBMITTED BY THE COMPANY

Kindly refer to the above PQCB ORDER received from the Provincial Drugs Inspector Wagha Town, Dist. Lahore, 24-Cooper Road, Lahore vide his 04-04/SUBS/DI-WT/2023 Dated Lahore the 01-04-23.

The copy of impugned PQCB OREDER is pasted below as ready reference. PQCB OREDER DATED 15.03.2022 DISPATCH DATE 02.06.2022 Received from DI on 03.04.2023

THE FOLLOWING SUBMISSIONS ARE MADE

1. That all the correspondence made with Di and PQCB may please be taken as the part of this petition.

2. The Drug Inspector committed misconduct by issuing + Serving backdated letters.

A. The back dated letter No. letter No.04-03/SUBS/DI-WT/2021 Dated 01.07.2021 has been delivered on 24.08.2021. Back Dated Letter raises doubts.

B. The warrantor's portion of sample sent to Alsiraj Medicine Company, Imam Din Medicine market, Lohari Gate, Lahore vide letter No.0301/Com/DI-WT/2021 Dated 21.01.2021 was delivered on 06.04.2021. Back Dated Letter raises doubts as well as illegal. Copy of letter pasted below.

That there is no provision in any prevailing Drug law in Pakistan which could empower any regulatory authority (Neither Drug Inspector Nor PQCB) to condone delay by ignoring mandatory prescribed period of SEVEN DAYS for disposing Warrantor's portion of the sample. NON-COMPLIANCE to Section 19 (3) related to statutory requirement of sending warrantor's portion within seven days, is an illegality. The Warrantor's portion has not been disposed off within statutory period of seven days as prescribed under Section 19(3) (iv) of the Drugs Act 1976. The non-observance to said procedure is reasonably doubtful and is an illegality. The PQCB had unanimously dropped a Case No. PQCB R-577-09/2016 related to Infusion Dorcip Batch No. Dc-075 declared as Adulterated and Substandard by Government Analyst Drug Testing Laboratory Rawalpindi vide DTL Report. TRA. No. 1077/DTL Dated: 22-09-2016. The PQCB had observed that this case was FIT FOR PROSECUTION based on report. But this case was DROPPED as PQCB had observed that case would fail in court because warrantor portion was not sent to the manufacturer within statutory period as prescribed under Section 19 (3) of the Drug Act 1976.PQCB members may kindly compare the present case with the IGNORED CASE of Infusion Dorcip to ascertain level of potential and real clinical Risks/ADR. Both cases are similar with the ignored case may differentiated as of more seventy.

3. That Personal Hearing Notice was never delivered to us for presentation of GB-viewpoints on Section 22(4) & 222(5) of the Drug Act 1976. The Drug Law as well as principle o principle of natural justice have been violated by deciding the issue in the absence of the aggrieved person.

4. That PQCB order is unlawful as well as malicious as PQCB has turned down a Fictional Request ar92-21-32735518 Retest, which was never submitted by the GB-Karachi.

5. That report is non-conclusive + unlawful as full protocols of the test applied to reach the conclusion and Result of disputed drug as substandard have not been given in the above Test Report. There is always likelihood of errors in Tests / analysis report, which would be of adverse consequence and affects substantial rights of a person. The single bench of Lahore High Court has held that Reports of Analyst must be conclusive and must disclose the tests applied to formulate opinion of Government Analyst. There is always likelihood of errors in Tests / analysis report, which would be of adverse consequence and affects substantial rights of a person. Therefore, the description of the experiment including method evaluating standards / results must be Crystal clear whenever report would be disputed. Reliance on PLD 2003 Lah. 115. The honorable Single Judge relied on these judgments in the reported cases- Gyanendra Nath Mittal v. State AIR 1959 All, 634; S. Dutta and another. The DB Judgments of Peshawar High Court and Quetta High Court had also held that report without protocol were fatally defective and unlawful. Reliance on 1996 P Cr.L. J 1183 (Peshawar). 115, PLJ 2012 Cr.C. (Quetta) 546 (DB). The honorable Supreme Court has held in case reported as 2019 SCM 930 "Report of the Government Analyst must contain Protocol. The term "protocol" has not been defined in the Rules. Its dictionary meaning is "A plan of scientific experiment or other procedure. It is also referred to as "the precise method for carrying out or reproducing a given experiment. (Chambers 21st Century Dictionary, 2007 Edition, page 1114. (https://wikidiff.com/protocol/method.) These definitions are in line with the elaboration of the term "protocol" given in case of Imam Bakhsh wherein the Court stated the expression "protocol" to mean an explicit plan of an experiment, procedure, or test. It is clarified that "protocol" is, therefore, a recognized standard method or plan for carrying out the test applied to ascertain the nature of the substance under examination. No test can take place without protocol. The Report of the Government Analyst must show that the test applied was in accordance with a recognized standard protocol. Any test conducted without protocol loses its reliability and evidentiary value. Therefore, to serve the purposes of the Act and the Rules, the Report of the Government Analyst must contain.

(i) The Tests Applied

(ii) The Protocols Applied to Carry Out These Tests

(iii) The Result of the Test(s).

6. That the mechanical scrutiny and subsequent disputed unlawful decision / order is without appropriate reasoning and annulated confrontation. The explanation on the viewpoints leading to creation of one sided unanimous PQCB Order to Tum Down the invented request for retesting of the sample are given below.

PQCB - Decision/Order without Personal Hearing

The Board thoroughly scrutinized the evidence submitted by the Firm to Weight Variation. Government Analyst submitted descriptive and justified proof about the test protocol of the drug. Weight Variation is one in a series of tests in a therapeutic product specification that assesses the quality of a batch. Testing for Weight Variation helps ensure that the strength of a therapeutic product remains within specified acceptance limits.

Role of Weight Variation and its impact on Tablet formulation was discussed at length. The Board was of the considered view that Weight Variation ensures uniform distribution of active ingredients in tablets. If the product does not fall in the prescribed limits of weight variation which result in uneven distribution of active ingredient that may result in overdosage and toxicity (in case of active ingredient more than the therapeutic level) or underdosage with no therapeutic activity (in case active ingredient less than the therapeutic level).

In view of the above-mentioned facts, the Board after due deliberation unanimously decided to Turn Down the subject request for retesting of the sample.

The Board further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

Explanation By Aggrieved Person

Determination of noncompliance to the BP

criteria for weight variation is reasonably doubtful because of the following facts Tolerance Limit: Not more than 2 out of 20 capsules content deviate from ±10% and none deviates from ±20% of average weight Average weight: 109mg.

Determined: 6 units are out of the limit of

109mg ± 10% and 2 units, out of these 6 units are out of the limit of 109mg + 20%.

Because weight of individual tablet and its deviation not given.

The weight variation test must be evaluated by Co-relating with other tests. When Assay Result (Effectiveness and Safely) and Dissolution Tests (Bioavailability Compliance) are complying. It is fictional statement + opinion originating from the belligerent abuse of discretionary powers that "weight variation would adverse effect on the therapeutic response as result overdosage and toxicity (in case of active ingredient more than the therapeutic level) or underdosage with no therapeutic activity (in case active ingredient less than the therapeutic level)."

Directing the Inspector for investigation of case constructed on unlawful test / analysis report is nothing but inventing malicious prosecution which is against fundamental rights guaranteed IRP-1973 Constitution of Pakistan. If basic document test / analysis report was without lawful authority, superstructure built on it would fall on ground automatically. Constitution of Pakistan (1973)-Art.4 is Crystal Clear that -Public functionaries were obliged to act justly, fairly, equitably, reasonably without any element of discrimination and squarely within parameters of law as

envisaged by Art.4 of Constitution of Pakistan.

In the light of the above legal points and factual controversies, it is respectfully requested that the petition may please be accepted by withdrawing the unlawful order of turn down request of retesting which was never submitted. The statuary personal hearing may please be given whenever the case is presented before the PQCB for any interim or Final Order.

For Ghani Brother, Karachi

No. and Date Even. Copy forwarded for information and necessary action to the provincial Inspector of Drugs, Wagha Town, Dist. Lahore, 24-Cooper Road, Lahore wir to his letter No.04-04/SUBS/DI-WT/2023 Dated Lahore the 01-04-23.

In the light of the above assertions and contentions, it is respectfully requested that above mentioned PETITION No.GN070423-1 Date. 07.04.2023 may kindly be decided on merit prior to initiating any proceeding related to unlawful issuance of Show Cause Notice. We are ready to appear before the PQCB as and when required for a personal hearing on the above petition if so desired. Every citizen of Pakistan is entitled to be dealt in accordance with law and Due Process, without any discrimination as per requirement of 1973 Constitution of Islamic Republic of Pakistan.

Reply of Show Cause Notice (Al-Siraj Medicine Company):

1. It is very clear that I am "WHOLESALER" deals in the Sale /Distribution of various Drugs Manufactured and / or Imported by the Manufacturers and / or Importers etc. in Pakistan.

2. As related with the Drug mentioned in the Show Cause Notice No.PQCB/R-800/2021 i.e; Cap. INDOMETHACIN 25mg Batch No. 190806, Manufactured by: "TAIYUAN", Pharmaceutical Factories, China as mentioned in the Invoice No.273 dated 26.10.2020 / WARRANTY issued by MR. FARHAN, in the capacity of IMPORTER/ INDENTER OF M/S GHANI BROTHERS, 2nd Floor, Karmji Building opp. HBL, Napier Road, Karachi, (purchased 400 Boxes of 10 x 10 capsules).

3. The said drug was received in November, 2010 from M/s GHANI BROTHERS Karachi and on 09.012021, 10 Boxes were sold to M/s GAFOOR PHARMACY, 329, G.T. Road, Daroghawala, Lahore (from whom Sample was taken).

4. Respected Sir, according to the record the said Drug was sold to M/s Ghafoor Pharmacy by me within 60/70 days from the receiving / supply of said drug by the importer / warrantor i.e M/s Ghani Brothers, which was remained in the same State as when I acquired that drug.

5. Sir, Al Siraj Medicine Company situated IN THE IMAM DIN MEDICINE MARKET, LOHARI GATE LAHORE, which is Almost 24 HOURS under the Supervision and Control of Law enforcing agencies and the Drug Inspectors.

6. Drugs are stored 100% under the required storage conditions and in compliance with all the requirements.

7. Respected Sir, I soon as I received the warrantor portion of the Sample from the Drug Inspector, I immediately forward the same to M/s Ghani Brothers Karachi, "The Importer". (Copy of the letter enclosed).

8. Another letter No.04-02/SUBS/DI-WT/2021 dated 08.6.2021 was received by me from the Drug Inspector, M/s Al-Siraj Medicine Company, submitted the reply with facts to the Drug Inspector in details, and copy was also to M/s Ghani Brothers "The Warrantor" for M/s Al-Siraj Medicine Company. (Copy enclosed).

9. In the meanwhile, I received the response from M/s Ghani Brothers Karachi, wherein it was stated that;

"Kindly refer to your telephonic massage regarding receiving of Indomethacin Cap. 25mg Seal Portion. It is confirmed that we have received the above Sample.

For your kind information pls note that we have not received any official letter from the Drug Inspector.

We have also NOT yet received the original drug test report for the above mentioned Medicine either."

(Copy enclosed).

10. In the above facts and applicable law, it is respectfully prayed, please drop the proceedings to the extent of M/s Al-Siraj Medicine Company, for the facts that,

In the Show Cause Notice No specific allegation is leveled against M/s Al-Siraj Medicine Company.

That, M/s Al-Siraj Medicine Company rightly & correctly taken the defence under Section 32(3)(b) of the Drugs Act 1976.

That M/s Al-Siraj Medicine Company is WHOLESALLER / DISTRIBUTOR, lawfully sold the Drug to M/s Ghafoor Pharmacy, Daroghawala, Lahore.

M/s Al-Siraj Medicine Company is not responsible for the Manufacturing, Importing of that drug, lawfully relied on the lawful warranty issued by M/s Ghani Brothers the Importer. It is proved that the drug stored by M/s Al-Siraj Medicine Company was remained in the same State as acquired from M/s Al-Ghani Brothers Karachi.

Respected Sir,

Keeping in view the above facts and realities please consider that:-

M/s Al-Siraj Medicine Company does not contravened or committed any violation of Section 23/27 of the Drug Act 1976 (as amended) / DRAP Act 2012 and Rules framed thereunder. Valid defence under Section 32(3)(b) of the Drugs Act 1976 was taken, please provide the benefit of Section 32(3)(b).

Please No action may please be taken against M/s Al-Siraj Medicine Company and oblige.

5. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 08.2019

Expiry Date: 08.2023

Sampling Date (Form 4): 14.01.2021

Sent to DTL (Form 6): 18.01.2021

Date of receipt in DTL: 20.01.2021

DTL Report Date (Form 7): 19.03.2021

Time Extension: Not time barred

1ST DI Communication with firm on dated: 01.07.2021

Retesting Request of Firm: 27.08.2021

Fate of Firm's Retest Request: Turn Down (240-M)

Investigation Report Dated: 24.07.2023

SCN Permission: 265-M

SCN: 30.08.2023

Reply of SCN: 09.09.2023 and 14.09.2023

History (Last 03 Years): Product: 00 cases reported, Firm: 00 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 30

PQCB/MSS-171054/2023

(Jinnah Burn & Reconstructive Surgery Center AIMC, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan** through its CEO/Managing Director, Muhammad Sher 2. Muhammad Sher — CEO/Managing Director/ Warrantor 3. Nishat Anjum Chaudhry — Production Incharge 4. Muhammad Saeed — Quality Control Incharge of M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan.

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Jinnah Burn & Reconstructive Surgery Center AIMC, Lahore reported that:-

i. She, on 05-07-2023, inspected the premises of Medicine Store of Jinnah Burn & Reconstructive Surgery Center, Lahore, took following sample on Form No.04 for the purpose of test/analysis and sent the subject sample to Drug Testing Laboratory, Lahore vide memorandum no. 171054 dated 05-07-2023.
ii. Following sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below:
iii. Store Keeper, Main Medicine Store Jinnah Burn & Reconstructive Surgery Center AIMC, Lahore submitted invoice/warranty no. G/P-0467 dated 05-07-2023 issued by M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan as a proof of its purchase of the said sample.
iv. Warrantor portion of the drug sample was sent to M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan.
v. A copy of test/analysis report was sent to M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan with direction to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above mentioned sample from Appellate Laboratory, National Institute of Health, Islamabad. Later on, firm submitted request to withdraw its retesting request vide letter dated 05-11-2023.
vi. Pursuant to the request of M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan the Committee of PQCB in its 28th Committee Meeting of the Board held on 08-11-2023 decided to accept the firm's request for withdrawal of the retesting request of the subject sample.

Name of drug	Batch No.	Name of manufacturer	DTL TRA No. & Date	DTL Test Report Results
Gauze. Hospitex	0059	M/s General	01-129006082/	**Analysis with specifications applied:** BPC

Gauze [Absorbent Gauze 1Mx30M] **Mfg Date:** Apr 2023 **Expiry Date:** Mar 2026 **Regn No.** 066204		Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan.	DTL dated 08-08-2023	**DESCRIPTION:** B.P.C monograph of Absorbant Cotton Gauze describes Standard description as "Cotton cloth of plain weave, bleached to a good white, clean, and reasonably free from weaving defects, cotton leaf and shell." **Observed:** Cotton cloth of plain weave bleached to a good white, odourless and clean, one out of three units has **torns along the length.** Claimed Size=30m x 1m. **(DOES NOT COMPLY)** **WARPS:** Limit: Average 73/10cm Determined: 75/10cm **WEFTS:** Limit: Average 57/10cm Determined: 57/10cm **WEIGHT PER UNIT AREA:** Limit: Average 15g/m^2 Determined: 23.8g/m^2 **LENGTH:** Determined: **UNIT 1= 24 m** **UNIT 2= 23.3 m** **UNIT 3= 23.6 m** Labelled: 30 m ± 5% **(DOES NOT COMPLY)** **WIDTH:** Determined: 1 m Claimed: 1m ± 5% **Result:** The above sample is **SUBSTANDARD** on the basis of PHYSICAL DESCRIPTION as per BPC and Length as per Label.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a) Manufacturing/ Stocking of the Substandard Therapeutic goods

(Drug/Medical device)

b) Issuance of false warranty

3. Show Cause Notices issued to the accused dated 06.02.2025.

5. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 04.2023

Expiry Date: 03.2026

Sampling Date (Form 4): 05.07.2023

Sent to DTL (Form 6): 05.07.2023

Date of receipt in DTL: 06.07.2023

DTL Report Date (Form 7): 08.08.2023

Time Extension: Not time barred

1ST DI Communication with firm on dated: 28.08.2023

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 06.12.2024

SCN Permission: 265-M

SCN: 06.02.2025

Reply of SCN:

History (Last 03 Years): Product: 02 cases reported including subject case, Firm: 05 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

(Jinnah Burn & Reconstructive Surgery Center AIMC, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan** through its CEO/Managing Director, Muhammad Sher 2. Muhammad Sher — CEO/Managing Director/ Warrantor 3. Nishat Anjum Chaudhry — Production Incharge 4. Muhammad Saeed — Quality Control Incharge of M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan.

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Jinnah Burn & Reconstructive Surgery Center AIMC, Lahore reported that:-

i. She, on 05-07-2023, inspected the premises of Medicine Store of Jinnah Burn & Reconstructive Surgery Center, Lahore, took following sample on Form No.04 for the purpose of test/analysis and sent the subject sample to Drug Testing Laboratory, Lahore vide memorandum no. 171054 dated 05-07-2023.
ii. Following sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below:
iii. Store Keeper, Main Medicine Store Jinnah Burn & Reconstructive Surgery Center AIMC, Lahore submitted invoice/warranty no. G/P-0467 dated 05-07-2023 issued by M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan as a proof of its purchase of the said sample.
iv. Warrantor portion of the drug sample was sent to M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan.
v. A copy of test/analysis report was sent to M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan with direction to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above mentioned sample from Appellate Laboratory, National Institute of Health, Islamabad. Later on, firm submitted request to withdraw its retesting request vide letter dated 05-11-2023.
vi. Pursuant to the request of M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan the Committee of PQCB in its 28th Committee Meeting of the Board held on 08-11-2023 decided to accept the firm's request for withdrawal of the retesting request of the subject sample.

Name of drug	Batch No.	Name of manufacturer	DTL TRA No. & Date	DTL Test Report Results
Gauze. Hospitex Gauze [Absorbent Gauze 1Mx30M]	0059	M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha)	01-129006082/ DTL dated 08-08-2023	**Analysis with specifications applied:** BPC **DESCRIPTION:** B.P.C monograph of Absorbant Cotton Gauze describes Standard description as "Cotton cloth of plain weave, bleached to a good white, clean, and

Mfg Date: Apr 2023 **Expiry Date:** Mar 2026 **Regn No.** 066204		Kamoke District Gujranwala Pakistan.		reasonably free from weaving defects, cotton leaf and shell." **<u>Observed:</u>** Cotton cloth of plain weave bleached to a good white, odourless and clean, one out of three units has **torns along the length.** Claimed Size=30m x 1m. **(DOES NOT COMPLY)** **<u>WARPS:</u>** Limit: Average 73/10cm Determined: 75/10cm **<u>WEFTS:</u>** Limit: Average 57/10cm Determined: 57/10cm **<u>WEIGHT PER UNIT AREA:</u>** Limit: Average 15g/m^2 Determined: 23.8g/m^2 **<u>LENGTH:</u>** Determined: **UNIT 1= 24 m** **UNIT 2= 23.3 m** **UNIT 3= 23.6 m** Labelled: 30 m <u>+</u> 5% **(DOES NOT COMPLY)** **<u>WIDTH:</u>** Determined: 1 m Claimed: 1m <u>+</u> 5% **<u>Result:</u>** The above sample is **<u>SUBSTANDARD</u>** on the basis of PHYSICAL DESCRIPTION as per BPC and Length as per Label.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

a) Manufacturing/ Stocking of the Substandard Therapeutic goods

(Drug/Medical device)

b) Issuance of false warranty

3. Show Cause Notices issued to the accused dated 06.02.2025.

5. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 04.2023

Expiry Date: 03.2026

Sampling Date (Form 4): 05.07.2023

Sent to DTL (Form 6): 05.07.2023

Date of receipt in DTL: 06.07.2023

DTL Report Date (Form 7): 08.08.2023

Time Extension: Not time barred

1ST DI Communication with firm on dated: 28.08.2023

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 06.12.2024

SCN Permission: 265-M

SCN: 06.02.2025

Reply of SCN:

History (Last 03 Years): Product: 02 cases reported including subject case, Firm: 05 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 31

PQCB/MSS-174268/2023

(Jinnah Burn & Reconstructive Surgery Center AIMC, Lahore)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan** through its CEO/Managing Director, Muhammad Sher 2. Muhammad Sher — CEO/Managing Director/ Warrantor 3. Nishat Anjum Chaudhry — Production Incharge 4. Muhammad Saeed — Quality Control Incharge of M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan.

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Jinnah Burn & Reconstructive Surgery Center AIMC, Lahore reported that:-

i. She, on 28-08-2023, inspected the premises of Medicine Store of Jinnah Burn & Reconstructive Surgery Center, Lahore, took following sample on Form No.04 for the purpose of test/analysis and sent the subject sample to Drug Testing Laboratory, Lahore vide memorandum no. 174268 dated 29-08-2023.
ii. Following sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below:
iii. Store Keeper, Main Medicine Store Jinnah Burn & Reconstructive Surgery Center AIMC, Lahore submitted invoice/warranty no. G/P-0467 dated 05-07-2023 issued by M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan as a proof of its purchase of the said sample.
iv. Warrantor portion of the sample was sent to M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan.
v. A copy of test/analysis report was sent to M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan with direction to explain their position and provide requisite information in this regard.

Name of drug	Batch No.	Name of manufacturer	DTL TRA No. & Date	DTL Test Report Results
Gauze. Hospitex Gauze [Absorbent Gauze 1Mx30M]	0059	M/s General Pharma, Farm Road, 3-Km G.T. Road Manhes (Kotli Wagha) Kamoke District Gujranwala Pakistan.	01-10194003201/ DTL dated 07-10-2023	**Analysis with specifications applied:** BPC **DESCRIPTION:** B.P.C monograph of Absorbant Cotton Gauze describes Standard description as "Cotton cloth of plain weave, bleached to a good white, clean, and reasonably free from weaving defects, cotton leaf and shell."

Mfg Date: Apr 2023 **Expiry Date:** Mar 2026 **Regn No.** 066204				**Observed:** Cotton cloth of plain weave bleached to white and odourless. Claimed Size=1m x 30m (+/- 5%), 4 ply folded gauze. **Two out of three units are not free from weaving defects and have torns along the length.** **(DOES NOT COMPLY)** **WARPS:** Limit: Average 73/10cm Determined: 86/10cm **WEFTS:** Limit: Average 57/10cm Determined: 71/10cm **WEIGHT PER UNIT AREA:** Limit: Average 15g/m^2 Determined: 21g/m^2 **NOTE:** Below are the results of length and width of 01 unit that is complying the physical description and is in one continuous length. **LENGTH:** Determined: 30m Labelled: 30 m $\pm$ 5% **WIDTH:** Determined: 1 m Claimed: 1m $\pm$ 5% **Result:** The above sample is **SUBSTANDARD** on the basis of PHYSICAL DESCRIPTION as per BPC.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

    a) Manufacturing/ Stocking of the Substandard Therapeutic goods

    (Drug/Medical device)

    b) Issuance of false warranty

3. Show Cause Notices issued to the accused dated 06.02.2025.

Reply of Show Cause Notice:

With the reference of your letter no. PQCB/MSS-174268/2023 dated:-06-02-2025 of Show Cause notice. We would like to informed you that our firm had been replaced that particular stock into the hospital against order #6046-49/ED/JB&RSC dated 24-06-223 of surgical gauze with the new batch (0065) which had been declared Standard on 26-09-2023 by the DTL.

Therefor we would like to request you to kindly give them instruction to release our stock which has been seized by the department.

It's an humble request you to do an favor to us for better relation!

5. Personal hearing notice issued to the accused dated 20.03.2025.

Summary:

Manufacturing Date: 04.2023

Expiry Date: 03.2026

Sampling Date (Form 4): 28.08.2023

Sent to DTL (Form 6): 29.08.2023

Date of receipt in DTL: 29.08.2023

DTL Report Date (Form 7): 07.10.2023

Time Extension: Not time barred

1ST DI Communication with firm on dated:

Retesting Request of Firm: N/A

Fate of Firm's Retest Request: N/A

Investigation Report Dated: 30.01.2025

SCN Permission: 287-M

SCN: 06.02.2025

Reply of SCN:

History (Last 03 Years): Product: 02 cases reported including subject case, Firm: 05 cases reported including subject case.

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD: