Health & Population Department
PROVINCIAL QUALITY CONTROL BOARD, PUNJAB.

287 Meeting of PQCB

Date: 08-01-2025

Time: 11:30 AM

Venue

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

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ITEM No. 1

REGULAR CASES

Case No. 1

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

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
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**	Post facto 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

Case is placed before the Board for Decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 2

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

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

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD

Case No. 3

PQCB/ 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

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 5.44 Complies

limit: 4.0-6.9

Identification: Paracetamol identified

Assay:

Stated: 120mg/5ml

Determined 122.781mg/5ml

Percentage: 102.32% Complies

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, 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

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

8. Case is placed before the Board for Decision

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 4

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 VIII O THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We M/S Lisko Pakistan (Pvt) Ltd Petitioner Company" would like to submit instant review petitton A the learned Provincial Quality Control Board. Puniab against the order of committee PQCB dated 20-0 (the "impugned Decision") in which request of re-testing from NIH, Islamabad has been turned down 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 <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 ie 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% propvlene glycol has been completely overlooked in the impugned order anc 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 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, 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.

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

PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 5

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:

Sr.No.	Name of Drug	Batch	Manufacturer	TRA No. and Date
1.	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 VIII O THE PROVINCIAL QUALITY CONTROL BOARD REGULATIONS, 2001

We M/S Lisko Pakistan (Pvt) Ltd Petitioner Company" would like to submit instant review petitton A 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 <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 ie 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.

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, BAHAWALNAGAR, 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. 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.

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**

PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 6

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:

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 petitton A 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 <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 ie 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.

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, BAHAWALNAGAR, 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. 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.

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**

PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 7

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.

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for retesting.

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

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, BAHAWALNAGAR, 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. Share transparent findings, causes and measures against the incident in which DTL Bahawalpur issued standard report for Batch No. 184-24, 185-24 and Batch No. 186-24 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.

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**

PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 8

PQCB/MSS-194360, 194359/2024

Tehsil and District Layyah

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 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 24.5^0C **(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**	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

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:	**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	42nd meeting of committee PQCB dated 30-07-2024 (Order dated 20-09-	Pending
180-24	01-105005912	Multan			

			particles as per USP<1151>)	2024)	

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.

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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.

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**
- **History (2021 onwards): Firm: 110 cases**
- **Product: 87 cases**

Case is placed before the board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 9

No. PQCB/R-479/2021

Tehsil Hassanabdal District Attock

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/s Prays Pharmaceuticals, plot no. 10, street SS-4, National Industrial Zone, RCCI, Rawat Islamabad** through its Managing Partner, Basit Abbasi 2. Basit Abbasi Managing Partner 3. Najam Zaman Production Incharge 4. Shama ur Rehman Quality Control Incharge/Warrantor of M/s **Prays Pharmaceuticals, plot no. 10, street SS-4, National Industrial Zone, RCCI, Rawat Islamabad**

BRIEF FACTS OF THE CASE

i. Provincial Inspector of Drugs, Tehsil Hassan Abdal, District Attock reported that He, on 15-01-2021 inspected the premises of M/s All Pharmacy Shah Jholan Road Hassanabdal, took sample of subject drug along with other drugs on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi The 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	TRA No. & Date	DTL Test Report Result
Cream Beta-C 15g (Betamethasone as Dipropionate 0.05%w/w, Clotrimazole 0.1%w/w) **Mfg Date:** Dec 2020 **Expiry Date:** Dec 2022 **Regn No.** 075674	1177	M/s Prays Pharmaceuticals, plot no. 10, street SS-4, National Industrial Zone, RCCI, Rawat Islamabad	TRA No. 01-741000778/DTL RWP Dated: 08-06-2021	**Specification Applied: MS** **PHYSICAL DESCRIPTION** White coloured, semi solid cream, filled in labelled, collapsible aluminium having white screw cap, further packed in outer labelled carton. **IDENTIFICATION:** Betamethasone Dipropionate identified. Clotrimazole identified

Assay	Stated	Determined	Percentage	Limits	Comme
Betamethasone:	0.05 %w/w	0.031 %w/w	**61.41%**	90-110%	**DOES NOT COMPL**

Clotrimazole	0.1 %w/w	0.081 %w/w	**80.64%**	90-110%	**DOES NOT COMPL**

RESULT: The above sample is **"Substandard"** with regards to **Assay** performed for **Betamethasone and Clotrimazole.**

ii. The Proprietor of M/s Ali Pharmacy Shah Jholan Road Hassanabdal provided invoice/ warranty bearing No. 051008 dated 13-01-2021 issued by M/s United Distributor, Shop# E-59, 1st Floor Umer Plaza, College Road, Rawalpindi.
iii. Warrantor Portion was sent to M M/s United Distributor, Shop# E-59, 1st Floor Umer Plaza, College Road, Rawalpindi who in turn provided invoice/ warranty bearing No. 1173 dated 26-11-2020 issued by M/s Prays Pharmaceuticals Plot # 10, Street SS-4, National Industrial Zone (RCC) Rawat, Islamabad.
iv. A copy of Test/ Analysis report was sent to M/s Prays Pharmaceuticals Plot # 10, Street SS-4, National Industrial Zone (RCC) Rawat, Islamabad and they were directed to provide requisite information in this regard. In respopse, M/s Prays Pharmaceuticals Plot Plot # 10, Street SS-4, National Industrial Zone (RCC) Rawat, Islamabad challenged the test/analysis report and requested to send sample to appellate laboratory for retesting.
v. Retesting request of the firm was placed before the provincial quality control board in its 238th meeting held on 09-02-2022 which was turned down.
vi. 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/DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacture for sale/ Sale of Substandard**

b. **Issuance of false warranty**

3. Show cause was issued to accused person(s) vide dated 05-08-2022

REPLY OF SHOW CAUSE NOTICE:

Firm replied to the show cause notice vide letter Reference no. nil stating that:

Reply to the Show Cause Notice dated 05-08-2022 on behalf of M/s Prays Pharmaceuticals, Plot No.10, Street No.SS-4, National Industrial Zone, RCCI Rawat, Islamabad, through its Managing Partner Mr. Basit Abbasi & M. Ahmed Bilai Adil.

RESPECTFULLY SHEWETH:

That in reply to the show cause Notice dated 05-08-2022, received on 19-08-2022, it is submitted as under;That the facts of the case are that the Provincial Drug inspector took the sample of Beta-C cream 15gm, batch No.1177 manufactured by the petitioner's firm on form No.4 from the premises of M/s Ali Pharmacy, Hassanabdal on 15-01-2021 for test and analysis.That the Drug Inspector sent the sample to the Drug Testing Laboratory on 18 Jan, 2021 which was received by the DTL on 08-02-2021 who vide Test Report declared the subject item as substandard vide test report No.01-74000778/DTL dated 08/06/2021. That it is most respectfully submitted that the submission of sample by the Drug Inspector to the Drug testing lab was in violation of section 19(3) of the drugs Act, 1976, hence illegal and violative of mandatory provisions of law.

That in regard to the test report it is further submitted that the report of analyst was also a time

barred report; therefore the same was in admissible in evidence and cannot be the basis of prosecution. That in similar nature of cases in which the Govt. Analyst had submitted a time barred report, the learned PQCB had pleased to drop the case, therefore justice demands similar treatment in similar nature of case, hence the deviation from earlier decisions of this Learned Board would cause discrimination, which does not warranted under the law. That Hon'ble High Court had declared in its reported judgment i-e 2002 YLR 1621 that Provincial Quality Control Board should perform their duties fairly, justly without the element of discrimination.

That the Hon'ble Supreme Court of Pakistan held in its judgment report in 1996 SCMR 1183 that in a similar circumstances the benefit shall be extended to those who are similarly placed and no discrimination shall be allowed.

That it would be extremely unjust, unfair and illegal to treat two similar cases in two opposite directions such as one is prosecuted and other is issued warning.

That no notice under section 32(3)(b) of the Drugs Act, 1976 was received which is the mandatory requirement of law, otherwise no one have the plea of warranty. That the Govt., Analyst did not mention the full protocols of the tests applied, therefore, the reports were not to be relied upon being not

Admissible in evidence. Reliance was placed on PLD 2003 Lahore 115. That the Govt., analyst had failed to mention the temperature at time of analysis.

That the Govt., Analyst did not analysed the betamethasone "as dipropionate", therefore the conclusion / analysis has no legal value and not reliable.

Prayer under the circumstances explained above it is, therefore, respectfully prayed that this above said case may kindly be dropped or issue warning in the interest of justice and to meet the ends of substantive justice as the report of analyst was a time barred report and the remedial measure had been taken by the manufacture. Any other relief deemed fit in the circumstances of the case may also be granted.

Personnel hearing notice(s) issued to accused person(s) vide dated 01-01-2025.

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	15-01-2021
2	**Sample Sent to DTL (Form-6)**	18-01-2021
3	**Receipt Date in DTL**	08-02-2021
4	**Issuance of DTL Report**	08-06-2021

5	**Time Extension**	232 meeting dated 24-06-2021
6	**DI First Communication with Firm**	26-06-2021
8	**Investigation Report by DI**	23-05-2022
9	**Show Cause Notice Issued**	05-08-2022
10	**History (3 years) :**	Firm’s reported :03
		Product reported: 01

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 10

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 :**	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.**

	Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772				**As per USP <1151> Pharmaceutical Dosage Forms *"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."*** **(DOES NOT COMPL** **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 Glyc Propylene Glycol.** **WHO Working Document** **QAS/23.922/rev3 Dated 31 Oct 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 Character**
2	Suspension Parapol Paediatric Suspension 120ml	083-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial	10097008759/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains:** **Paracetamol USP…. 120mg**

	(Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772		Area, Karachi		**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 COMPL** **pH:** **Limit: 4.0-6.9** **Determined: 5.5 at 23.7°C** **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 Glyc Propylene Glycol.** **WHO Working Docum** **QAS/23.922/rev3 Dated 31 Oct 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 Character
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 COMPL** **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 Glyc Propylene Glycol.** **WHO Working Docume** **QAS/23.922/rev3 Dated 31 Oct 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 Character**
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 COMPL** **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 Glyc**

					Propylene Glycol. **WHO W** **Document** **QAS/23.922/rev3 Dated 31 Oct** **2023** **Ethylene Glycol:** **Diethylene Glycol:** **Limit: NMT 0.1% Determined: Not Detected** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **Determined: 11.21%** **RESULT: The Sample is declared as "SUB-STANDARD" on basis of Physical Character**
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	**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 COMPL** **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 122.83 mg/5ml (102.36%)**

					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 Glyc** **Propylene Glycol.** **WHO Working Docum** **QAS/23.922/rev3 Dated 31 Oct 2023** **Ethylene Glycol:** **Diethylene Glycol:** **Limit: NMT 0.1% Determined: Not Detected** **Limit: NMT 0.1%** **Determined: Not Detected** **Propylene Glycol** **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 COMPL** **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 Glyc** **Propylene Glycol.** **WHO Working Docume** **QAS/23.922/rev3 Dated 31 Oct 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 of Physical Character**
7	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml)	085-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	1009700876/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**

	Mfg. Date : Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772				**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 COMPL** **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 Glyc** **Propylene Glycol.** **WHO Working Docume** **QAS/23.922/rev3 Dated 31 Oct 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	084-	M/S Lisko	10097008760/DTL	**Specs Applied: USP 2024/Others/In house**

	Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772	24	Pakistan (Pvt) Ltd, L-10 D Block No. 21, Federal B Industrial Area, Karachi	dated 15.07.2024	**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 COMPL** **pH:** **Limit: 4.0-6.9** **Determined: 5.5 at 23.5ºC** **IDENTIFICATION: Paracetamol is identified.** **ASSAY OF PARACETAMOL:** **Stated 120 mg/5ml** **Determined 127.29 mg/5ml (106.08%)** **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 Glyc Propylene Glycol.** **WHO Working Docum** **QAS/23.922/rev3 Dated 31 Oct 2023** **Ethylene Glycol:** **Limit: NMT 0.1% Determined: Not** **Diethylene Glycol:** **Limit: NMT 0.1%**

					Detected | **Determined: Not Detected** **Propylene Glycol** **Determined: 10.65%** **RESULT:** **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	**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 COMPL** **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 Glyc** **Propylene Glycol.**

					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 COMPL** **pH:** **Limit: 4.0-6.9** **Determined: 5.5 at 24.0°C** **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 Glyc** **Propylene Glycol.** **WHO Working Docume** **QAS/23.922/rev3 Dated 31 Oct 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 Character**
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 COMPL** **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 Glyc** **Propylene Glycol.** **WHO Working Docume** **QAS/23.922/rev3 Dated 31 Oct 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.
12	Suspension Parapol Paediatric Suspension 120ml (Paracetamol USP 120mg/5ml, 120ml)	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**

	Mfg. Date : Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772				**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 COMPL** **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 Glyc** **Propylene Glycol.** **WHO Working Docum** **QAS/23.922/rev3 Dated 31 Oct** **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 Character**
13	Suspension Parapol Paediatric Suspension	066-24	M/S Lisko Pakistan (Pvt) Ltd, L-10 D Block No. 21,	10097008751/DTL dated 15.07.2024	**Specs Applied: USP 2024/Others/In house** **COMPOSITION: Each 5ml contains:** **Paracetamol USP…. 120mg**

	120ml (Paracetamol USP 120mg/5ml, 120ml) **Mfg. Date :** Aug-2023 **Exp. Date** : Aug-2025 **Reg. No**. 002772		Federal B Industrial Area, Karachi		**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 COMPL** **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 Glyc Propylene Glycol.** **WHO Working Docum** **QAS/23.922/rev3 Dated 31 Oct 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 Character
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 COMPL** **pH:** **Limit: 4.0-6.9** **Determined: 5.5 at 23.8°C** **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 Glyc** **Propylene Glycol.** **WHO Working Docume** **QAS/23.922/rev3 Dated 31 Oct** **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 Character**
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 COMPL** **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 Glyc**

					Propylene Glycol. **WHO Working Docum** **QAS/23.922/rev3 Dated 31 Oct 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 COMPL** **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 Glyc** **Propylene Glycol.** **WHO Working Docum** **QAS/23.922/rev3 Dated 31 Oct** **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 Character

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.

vi. Pursuant to the retest request of the firm, PQCB decided to turn-down the request in its 43rd committee meeting dated 29-08-2024.

2. 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**

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

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

4. 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 ambiguities 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:

5. 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 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 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.

6. The Board after careful perusal of the case record after due deliberation and 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**	30-10-2024
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. 11

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 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.

v. A copy of test report 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.

vi. 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.

vii. Pursuant to firm's retesting request the Committee of Provincial Quality Control Board in its 41sr Committee meeting held on 27-06-2024, after due deliberation and discussion unanimously decided to **Turn Down** the retesting request of the subject drug sample and 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 committee 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 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 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.

7. Keeping in view the facts of the case, the Board after due deliberation and discussion decided to issue **Pend the case.**

8. Personal hearing notice(s) issued to accused person(s) dated 02-01-2025.

Case is placed before the board for decision.

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: 06-06-2024**
- **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: