Health & Population Department
PROVINCIAL QUALITY CONTROL BOARD, PUNJAB.

276 Meeting of PQCB

Date: 29-02-2024

Time: 11:00 AM

Venue

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

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ITEM No. 1

REGULAR CASES (ADULTERATED, SUBSTANDARD, MISBRANDED AND UNREGISTERED)

Case No. 1

PQCB/R-576/2021

(PHFMC, Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Stanley Pharmaceuticals, 84-B, Industrial Estate, Hayatabad, Peshawar** through its Chief Executive Officer/ Warrantor, Abdullah Shah. 2. Abdullah Shah Chief Executive Officer/ Warrantor 3. Imran Khan Production Incharge 4. Umar Kamran Marwat Quality Control Incharge **of M/S Stanley Pharmaceuticals, 84-B, Industrial Estate, Hayatabad, Peshawar.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Punjab Health Facility Management Company (PHFMC), Lahore reported that:-

i. He, on 06-09-2021, inspected premises of PHMC Medicine Store (Store inside District Office PHFMC Ganj Shakar Colony Chak No. 89/6-R District Store PHFMC Sahiwal) and took sample of drug on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 0000106016 dated 09-09-2021.
ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

iii.

Name of drug	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Syrup Broxol DM (Dextromethorphan 6.25mg + Diphenhydramine HCl 5mg/5ml) **Mfg.date:** Jul-2021 **Exp. date:**	E-509	M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan	TRA No. 01-25008152/DTL Dated:-27-11-2021	**Analysis with specifications applied:** Manufacturer Specification (MS) **Composition:** Each 5 ml contains: Dextromethorphan HBr…6.25mg Diphenhydramine HCl…5mg

Jul-2023 **Regn No.** 022854				**Description (MS):** Pink color liquid in amber color sealed glass bottle. (stated volume: 120 ml) **Identification (MS):** Dextromethorphan HBr & Diphenhydramine HCl are identified. **Assay (MS):** Dextromethorphan HBr **Stated** | **Determined** | **Percentage** | **Limit** 6.25mg/5ml | 5.74mg/5ml | 91.76% | 90.0-110.0% Diphenhydramine HCl **Stated** | **Determined** | **Percentage** | **Limit** 5.0mg/5ml | **9.97mg/5ml** | **199.37%** | **90.0-110.0%** **(Does not Comply with Specifications)** **RESULT:** The sample is declared **SUB-STANDARD** on the basis of **ASSAY TEST OF DIPHENHYDRAMINE HCL.**

iv. Store Keeper PHMC Medicine Store (Store inside District Office PHFMC Ganj Shakar Colony Chak No. 89/6-R District Store PHFMC Sahiwal) submitted Invoice/warranty No. 1500042 dated 13-08-2021 issued by M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan as a proof of its purchase of the said drug.

v. Warrantor Portion of the drug sample and a copy of test/analysis report were sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan and they were asked to provide the requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 241st meeting held on 31-03-2022 **allowed** to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

vii.

Name of	**Batch No.**	**Name of Manufacturer**	**NIH Test**	**NIH Test Report Result**

<table>
<tr><th>Drug</th><th></th><th></th><th>Report No.</th><th></th></tr>
<tr><td>Syrup Broxol DM</td><td>E-509</td><td>M/s Stanley Pharmaceuticals (Pvt.) Ltd., 84-B, Industrial State Hayatabad, Peshawar-Pakistan</td><td>096-P/2022 dated 13-06-2022</td><td>Analysis with specifications applied:

Manufacture Specifications

<u>ASSAY:</u>
<table>
<tr><th><u>ASSAY</u></th><th><u>STATED</u></th><th><u>FOUND</u></th><th><u>LIMIT</u></th><th><u>PERCENTAGE</u></th></tr>
<tr><td>Diphenhydramine HCl</td><td>5mg/5ml</td><td>8.52mg/5ml</td><td>90-110%</td><td>170.4%</td></tr>
<tr><td>Dextromethorphan HBr</td><td>6.25mg/5ml</td><td>5.93mg/5ml</td><td>90-110%</td><td>94.88%</td></tr>
</table>
Does not Comply with the Manufacturer’s specifications.

<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of tests performed.</td></tr>
</table>

viii. The Copy of NIH report was sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan.

ix. 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(as amended)/DRAP Act 2012 and Rules framed there under by the way of: -

x. **Manufacture for sale /sale of Substandard drug**
xi. **Issuance of false warranty**

xii. 3. Show cause notice(s) issued to the accused person(s) dated 26-10-2022.

<u>Reply of the firm to Show cause notice vide letter no. Nil dated 02-11-2022:</u>

We M/S Stanley Pharma Peshawar hereby clarified our position regarding to Broxol DM Syrup Batch No: E-509 declared substandard by NIH and DTL Bahawalpur on the basis of Diphenhydramine HCl assay i.e. 170.40% and 199.37% respectively. It is huge difference in assay results of NIH & DTL Bahawalpur i.e. 28.97% which clearly shows the mistake have done by both Laboratories during analysis based on titration.

Moreover, we have manufactured the Broxol DM syrup Batch No. E-509 in high speed 2/800rpm silver son 10000 Liters Mixing Tank capacity at once, not manufactured in portion wise. The competent authority PQCB team also confirmed this type of mixing tank Capacity 10000 Liters conducted PSI regarding Riam suspension batches held on dated 29.08.2022.

According to above said reason the same product Broxol DM syrup Batch No. E-509 is declared of Standard quality DTL Rawalpindi/ DTL Multan/ DTL Faisalabad Punjab.

Kindly consider our above said points and will give us **WARNING** in this regard and close the file.

4. Personal Hearing notice(s) issued to accused person(s) dated 02-12-2022.

Previous Proceeedings & Decision by The Board:

254th meeting held on 13-12-2022

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **254th meeting** held on 13-12-2022 under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Ahmed Awais, Secretary DQCB, District Sahiwal and Dr. M. Sheeraz, Drug Inspector Punjab Health Facilities Management Company were present along with the original case record. No one among the nominated accused persons of M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan appeared before the Board. However, a written request for adjournment was received from the firm vide letter no. Nil dated 09-12-2022 on behalf of the firm. The Board after due deliberation and discussion unanimously decided to **adjourn** the case in best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

6. Personal Hearing notice(s) issued to accused person(s) dated 29-03-2023

258th meeting dated 05-04-2023

7. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Ahmed Awais, Secretary DQCB Sahiwal via zoom meeting and Mr. Sheeraz, Provincial Inspector of Drugs, PHFMC, Lahore was present along with the original case record. Among the nominated accused persons Umar Kamran (Quality Control Manager) of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar was present.

8. The Board after due deliberation and discussion unanimously decided to **left over case** due to time constraints.

9. Personal Hearing notice(s) issued to accused person(s)

259th meeting dated 18-04-2023

10. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **259th meeting** held on **18-04-2023** under the chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, Punjab (Vice Chairperson). Mr. Ahmed Awais, Secretary DQCB Sahiwal via zoom meeting and Mr. Sheeraz, Provincial Inspector of Drugs, PHFMC was present along with the original case record. Among the nominated accused persons Umar Kamran (Quality Control Manager) of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar appeared before the Board and stated that huge difference in assay results of NIH & DTL Bahawalpur which clearly shows the mistake have done by both Laboratories during analysis based on titration. Moreover, they have manufactured the Broxol DM syrup Batch No. E-509 and in high

speed 2/800rpm silverson 10000 Liters Mixing Tank capacity at once, not manufactured in portion wise. According to MS, method for assay of the product is 3-step procedure. The subject product Broxol DM syrup Batch No. E-509 was declared of Standard quality DTL Rawalpindi/ DTL Multan/ DTL Faisalabad.

11. The Board after detailed scrutiny of the record observed that Syrup Broxol DM Batch No E 509 was declared of substandard quality by Drugs Testing Laboratory Bahawalpur and NIH on the basis of assay of diphenhydramine HCl. Government Analyst showed that the firm provided method to DTL Bahawalpur was two step method for assay of diphenhydramine HCl.

12. The Board observed that the firm provided different methods to different Drug testing Laboratories of Punjab. So, the Board after detailed scrutiny of the case record and statement of the accused person observed that in order to dig out the root cause of this defect, the Production and Quality Control & Assurance for subject drug need to be evaluated. Therefore, the Board decided to **pend the case** and to constitute a committee comprising of the followings to conduct **Product Specific Inspection (PSI)** of **M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan** and submit report within fortnight for consideration by the Board:

1	**Prof. Dr Mahmood Ahmed** Member PQCB	Convener
2	**Faheem Ahmed** Pharmacist, PQCB	Facilitator

Inspection was conducted on 28.08.2023 and the following inspection report was received in the office of the Secretary, PQCB on 20.10.2023

INSPECTION REPORT OF M/S STANLEY PHARMACEUTICALS, 84-B, INDUSTRIAL STATE, HAYATABAD PESHAWAR PAKISTAN.

Panel Members:

Prof. Dr. Mahmood Ahmad, Member, PQCB.

Waseem Mahmood Director Operations, PQCB.

Date of Inspection: 28-08-2023

Inspection was conducted with reference to order dated **18-04-2023** in case No **PQCB/R-576/2021.**

Premises:

Unit started in 1995, Total area (Four Acres), covered area (18841 sq feet),

There are three sections i.e Tablet Section, Capsule Section and Oral Liquid Section. Administration block., QC Lab. There are total number of 84 different products are being

manufactured in the mentioned premises. The manufacturer bears a Drug Manufacturing License No. 000434 valid until 15-06-2024.

Product details:

Name of drug Broxol DM Syrup 120 ml

Batch number E-509

Registration number 022854

Date of manufacturing 07-2021

Date of expiry 07-2023

Declared **Substandard** from **DTL Bahawalpur** on the basis of Assay test of Diphenhydramine HCl. {199.37% (Limit 90-110%)

Declared **Substandard quality** from **NIH** on basis of assay test of Diphenhydramine HCl {170.4 % (Limit 90-110%).

Staff

Designation	**Name**
Chief Executive Officer/Warrantor	Abdullah Shah
Production Manager	Imran Khan
QC Manager	Umar Kamran Marwat
QA Manager	Miss Shahnaz

Batch Processing Record of specific product:

1. BMR Record: Available.
2. Testing method: Manufacturer specifications).
3. Batch manufacturing date: 31-07-2021.
4. Line clearance: Available.
5. Batch size: 10000 Liters (83000 bottles)

Observations:

1. The batch size of the Broxol DM Syrup 10000 liters (83000 bottles of 120 ml each). The mentioned Syrup have two active ingredients i.e Diphenhydramine HCl 5 mg/5 ml and Dextromethorphan HBr 6.25 mg/5 ml
2. Testing of products is as per Manufacturer Specifications, however the in-process quality control and finished product quality control procedures demand upgradation

under current guidelines.

3. At the time of inspection, no dispensing Pharmacist was present in the raw material section. The record was only maintained manually however computerized system was available in the said section but the record was not maintained in the system.
4. There was no procedure for the counter verification of the dispensed materials from the raw material store.
5. Process validation record available, conducted on 16-03-2022.
6. According to stance of the manufacturer, product was manufactured according to the manufacturer specifications and Quality Control Manager and Production were of the opinion that product was of specifications. They also provided a copy of report issued by DTL Faisalabad for the same batch No. E-508 declaring it as "Standard Quality"

Recommendations:

1. SOPs must be revised for in-process quality control and finished product quality control to identify any out of specification product before its issuance from the manufacturing unit to the market.
2. A dedicated pharmacist must be ensured in the raw material store to supervise all activities regarding receipt and issuance of raw materials.
3. There must be authentic procedure for the counter verification of the dispensed materials from the raw material store.
4. Process validation must be repeated to ensure the quality of products.
5. Conduct analytical method validation and equipment validation according to current guidelines.
6. Trainings of the qualified staff at frequent intervals is recommended.

Conclusion:

The panel is of the opinion that product namely Broxol DM Syrup, declared substandard from DTL Bahawalpur and subsequently declared substandard from NIH, is due to poor control at the dispensing of raw materials from the raw material store and a weak quality control failed to identify the error during in-process as well as finished product. Supervision of the raw material store and upgradation of quality control procedures under current guidelines is strongly recommended.

M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan submitted following response to Inspection Report vide letter dated 13.11.2023:

Reference your kind Letter No: PQCB/R-576/2021 dated 30.10.2023 received on 13.11.2023.

We M/S Stanley Pharma Peshawar hereby submitted our response regarding Corrective and Preventive actions by the recommendations of inspection committee conducted PSI on dated 28.08.2023.

1. SOP revised for in process Quality control & finished product quality control to identify any out of specifications product before its issuance from manufacturing unit to the market (Annexure 1) attached.
2. A dedicated pharmacist is appointed on dated 02.10.2023 for ensuring the Raw material store to supervise all the activities regarding receipt & issuance of Raw materials (Annexure II) attached and moreover for your kind information at time of inspection the Dispensing pharmacist duty was performed by Production Pharmacist due to his father in Law funeral.

3. We have proper authentic procedure for the counter verification of the dispensed material under the supervision of Dispensing Pharmacist and counter checked by QA inspector of relevant section (Annexure-III) attached.
4. To ensure the quality of product the Process validation was repeated on dated 28.09.2023(Annexure IV) attached.
5. Analytical Method Validation was repeated on dated 07.09.2023 (Annexure V) attached.
6. Training of Qualified staff and supervisors is conducted each and every month, for evidence Training schedule & attendance sheet attached (Annexure VI).

xiv. We M/S Stanley Pharma Peshawar took immediate corrective and preventive actions to control failure of Diphenhydramine HCI assay in Broxol DM Syrup.

Kindly consider our above said justifications and may give us WARNING in this regard.

Summary:

Manufacturing Date: 07.2021

Expiry Date: 07.2023

Sampling Date (Form 4): 06.09.2021

Sent to DTL (Form 6): 09.09.2021

Date of receipt in DTL: 15.09.2021

DTL Report Date (Form 7): 27.11.2021

Time Extension: Granted in 235th meeting dated 30.11.2021

1ST DI Communication with firm on dated: 06.01.2022

Date of Retesting Request of Firm: 10.01.2022

Fate of Retesting Request: Allowed (241meeting dated 31-03-2022) (NIH Substandard).

Investigation Report Dated: 29.07.2022

4. Personal hearing notice(s) issued to the accused persons(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 2

PQCB/R-579/2021

Tehsil & District Pakpattan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan** through its Chief Executive Officer/ Warrantor Abdullah Shah 2. Abdullah Shah Chief Executive Officer/ Warrantor 3. Imran Khan Production Incharge 4. Umar Kamran Marwat Quality Control Incharge Of M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil & District Pakpattan reported that:-

i. He, on 14-09-2021, inspected M/s medicine store O/O PHMC Pakpattan and took sample of drug on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 0000106260 dated 14-09-2021.

ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

iii. Store Keeper O/O PHMC Pakpattan provided Invoice/warranty No. 1500056 dated 01-09-2021 issued by M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan as a proof of its purchase of the said drug.

iv. Warrantor Portion of the drug sample was sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan.

v. A copy of test/analysis report was sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan and they were asked to provide the requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 244th meeting held on 31-05-2022 allowed to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of drug	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Syrup Broxol DM (Dextromethorphan HBr 6.25mg + Diphenhydramine HCl 5mg/5ml, 120ml) **Mfg.date:**	E-517	M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan	TRA No. 01-85000042/DTL Dated: 27-11-2021	**Analysis with specifications applied:** MS **Composition:** Each 5 ml contains: Dextromethorphan HBr…6.25mg Diphenhydramine HCl…5mg

08-2021 **Exp. date:** 08-2023 **Regn No.** 022854				**Description (MS):** Pink color liquid in amber color sealed glass bottle. (Stated volume: 120 ml) **Identification (MS):** Dextromethorphan HBr & Diphenhydramine HCl are identified. **Assay (MS):** Dextromethorphan HBr **Stated** | **Determined** | **Percentage** | **Limit** 6.25mg/5ml | 5.68mg/5ml | 90.87% | 90.0-110.0% Diphenhydramine HCl **Stated** | **Determined** | **Percentage** | **Limit** 5.0mg/5ml | **9.72mg/5ml** | **194.39%** | **90.0-110.0%** **(Does not Comply with Specifications)** **RESULT:** The sample is declared **SUB-STANDARD** on the basis of **ASSAY TEST OF DIPHENHYDRAMINE HCL.**

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Test Report No.**	**NIH Test Report Result**
Cough Syrup Broxol DM 120ml	E-517	M/s Stanley Pharmaceuticals (Pvt.) Ltd., 84-B, Industrial State Hayatabad, Peshawar-Pakistan	0154-P/2022 dated 09-09-2022	**ASSAY:** **ASSAY** | **STATED** | **FOUND** | **LIMIT** | **PERCENTAGE** Diphenhydramine HCl | 5mg/5ml | 8.54mg/5ml | **90-110%** | **170.8%** Dextromethorphan HBr | 6.25mg/5ml | 5.71mg/5ml | 90-110% | 91.42% **Does not Comply with the Manufacturer's specifications.** **CONCLUSION:** The sample is of **Sub-Standard** quality on the basis of tests performed.

vii. The Copy of NIH report was sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan vide letter dated 23-09-2022.

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/DRAP Act 2012 and Rules framed there under by the way of: --

a. **Manufacture for sale/sale of Substandard drug**
b. **Issuance of false warranty**

Summary:

Manufacturing Date: 08-2021

Expiry Date: 08-2023

Sampling Date: 14-09-2021

Sent to DTL (Form 6): 14-09-2021

Date of receipt in DTL: 20-09-2021

DTL Report Date: 27-11-2021

Time extension granted: 235-M dated 30-11-2021

1ST DI Communication with firm on dated: 09-12-2021

Date of Retesting Request of Firm: 14-12-2021

Fate of Retesting Request: allow (244-M dated 31-05-2022)

Sample received in NIH: 09-06-2022

NIH report date: 09-09-2022 (93 days)

Investigation Report Dated: 29-09-2022

3 Show cause notice issued to the accused

4 Personal Hearing Notice issued to accused person(s)

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 3

PQCB/R-547,548/2022

Tehsil & District Okara

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan** through its Chief Executive Officer/ Warrantor Abdullah Shah 2. Abdullah Shah — Chief Executive Officer/ Warrantor 3. Imran Khan — Production Incharge 4. Umar Kamran Marwat — Quality Control Incharge Of M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil & District Okara reported that: -

i. The then Drug Inspector, on 27-08-2022 inspected Main Medicine Store CEO DHA Okara, took subject drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vides memorandum no**.** 138324 & 138325 dated 27-08-2022.
ii. Following drug samples after test/analysis were declared **Substandard** by Government Analyst, Drug Testing Laboratory, Bahawalpur as detailed below: -
iii. Store Keeper Main Medicine Store CEO DHA Okara, provided Invoice/warranty No. 1500948 dated 26-07-2022 issued by M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan as a proof of its purchase of the said drug.
iv. Warrantor Portion of the subject batches of drug samples were sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan.
v. Copies of test/analysis report were sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan and they were asked to provide the requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
vi. Pursuant to firm's retesting request the Provincial Quality Control Board sent the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

S #	Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
1	Syrup Broxol DM (Dextromethorphan HBr 6.25mg + Diphenhydramine	P-288	M/s Stanley Pharmaceutical 84-B,	TRA No. 01-10097000066/DTL Dated: 14-10-2022	**Analysis with specifications applied:** MS **Composition:** Each 5 ml contains:

<table>
<tr>
<td></td>
<td>HCl 5mg/5ml, 120ml)

Mfg.date:

07-2022

Exp. date:

07-2024

Regn No.

022854</td>
<td></td>
<td>Industrial State, Hayatabad Peshawar Pakistan</td>
<td></td>
<td>Dextromethorphan HBr…6.25mg

Diphenhydramine HCl….5mg

<u>Description (MS):</u> Pink color liquid in amber color sealed gla/ss bottle. (Stated volume: 120 ml)

<u>Identification (MS):</u> Dextromethorphan HBr & Diphenhydramine HCl are identified.

<u>Assay (MS):</u> Dextromethorphan HBr

<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>6.25mg/5ml</td><td>6.634mg/5ml</td><td>106.141%</td><td>5.625-6.875mg/5ml</td></tr>
</table>

Diphenhydramine HCl

<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>5.0mg/5ml</td><td>9.996mg/5ml</td><td>199.922%</td><td>4.5-5.5mg/5ml</td></tr>
</table>

(Does not Comply with Specifications)

RESULT: The sample is declared <u>SUB-STANDARD</u> on the basis of <u>ASSAY TEST OF DIPHENHYDRAMINE HCL.</u></td>
</tr>
<tr>
<td>2</td>
<td>Syrup Broxol DM (Dextromethorphan HBr 6.25mg + Diphenhydramine HCl 5mg/5ml, 120ml)

Mfg.date:

07-2022

Exp. date:

07-2024</td>
<td>P-292</td>
<td>M/s Stanley Pharmaceutical

84-B, Industrial State, Hayatabad Peshawar Pakistan</td>
<td>TRA No. 01-10097000067/DTL

Dated: 14-10-2022</td>
<td><u>Analysis with specifications applied</u>: MS

<u>Composition:</u> Each 5 ml contains:

Dextromethorphan HBr…6.25mg

Diphenhydramine HCl….5mg

<u>Description (MS):</u> Pink color liquid in amber color sealed glass bottle. (Stated volume: 120 ml)

<u>Identification (MS):</u> Dextromethorphan HBr & Diphenhydramine HCl are identified.

<u>Assay (MS):</u> Dextromethorphan HBr

<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>6.25mg/5ml</td><td>6.754mg/5ml</td><td>108.071%</td><td>5.625-</td></tr>
</table>
</td>
</tr>
</table>

Regn No. 022854					

			6.875mg/5ml

Diphenhydramine HCl

Stated	**Determined**	**Percentage**	**Limit**
5.0mg/5ml	**10.093mg/5ml**	**201.863%**	**4.5-5.5mg/5ml**

(Does not Comply with Specifications)

RESULT: The sample is declared **SUB-STANDARD** on the basis of **ASSAY TEST OF DIPHENHYDRAMINE HCL.**

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Test Report No.**	**NIH Test Report Result**
Cough Syrup Broxol DM 120ml	P-288	M/s Stanley Pharmaceuticals (Pvt.) Ltd., 84-B, Industrial State Hayatabad, Peshawar-Pakistan	018-P/2023 dated 27-04-2023	**Analysis with specifications applied:** Manufacture Specifications **ASSAY:** **ASSAY** / **STATED** / **FOUND** / **LIMIT** / **PERCENTAGE** **Diphenhydramine HCl** / **5mg/5ml** / **3.35mg/5ml** / 90-110% / **67.114%** Dextromethorphan HBr / 6.25mg/5ml / 5.66mg/5ml / 90-110% / 90.6% **Does not Comply with the Manufacturer's specifications.** **CONCLUSION:** The sample is of **Sub-Standard** quality on the basis of tests performed.
Cough Syrup Broxol DM 120ml	P-292	M/s Stanley Pharmaceuticals (Pvt.) Ltd., 84-B, Industrial State Hayatabad, Peshawar-Pakistan	019-P/2023 dated 27-04-2023	**Analysis with specifications applied:** Manufacture Specifications **ASSAY:** **ASSAY** / **STATED** / **FOUND** / **LIMIT** / **PERCENTAGE** Diphenhydramine HCl / 5mg/5ml / 4.23mg/5ml / 90-110% / **84.62%**

				Dextromethorphan HBr	6.25mg/5ml	5.91mg/5ml	90-110%	94.64%

Does not Comply with the Manufacturer's specifications.

CONCLUSION: The sample is of **Sub-Standard** quality on the basis of tests performed.

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/DRAP Act 2012 and Rules framed there under by the way of: --

a. **Manufacture for sale/sale of Substandard drugs**
b. **Issuance of false warranty**

Summary:

Manufacturing Date: 07-2022

Expiry Date: 07-2024

Sampling Date: 27-08-2022

Sent to DTL (Form 6): 27-08-2022

Date of receipt in DTL: 30-08-2022

DTL Report Date: 14-10-2022

Time extension granted: N/A

1ST DI Communication with firm on dated:22-10-2022

Date of Retesting Request of Firm: 24-10-2022

Fate of Retesting Request: allow (256-M)

Sample received in NIH: 31-01-2023

NIH report dated: 27-04-2023

Investigation Report Dated: 30-05-2023

3 Show cause notice issued to the accused

Firm submitted reply to show cause notice dated 31-07-2023

We have received your Kind letter No. POCB/R-547, 548/2022 dated 21.07.2023 received on 31.07.2023.

We M/S Stanley Pharma Peshawar hereby clarified our position regarding to Broxol DM Syrup Batch No: P-288 declared substandard by NIH and DTL Bahawalpur on the basis of Diphenhydramine HCl assay i.e. 67.114% and 199.922% respectively. it is huge difference in assay results of NIH & DTL Bahawalpur i.e.

132.808% which clearly shows the mistakes have done by both Laboratories during analysis based on titration.

2 We M/S Stanley Pharma Peshawar hereby clarified our position regarding to Broxol DM Syrup Batch No: P-292 declared substandard by NIH and DTL Bahawalpur on the basis of Diphenhydramine HCl assay i.e. 84.62% and 201.863% respectively. it is huge difference in assay results of NIH & DTL Bahawalpur i.e. 117.243% which clearly shows the mistakes have done by both Laboratories during analysis based on titration

3 It is stated for your kind information that Diphenhydramine HCL is acidic salt freely soluble in water, there is no possibility of Assay results of Active Pharmaceutical Ingredient (API) under or above the specified specification in syrup dosage form.

Moreover, we have manufactured the Broxol DM syrup Batch No P-288 & P-292 in high speed 2800rpm silver

son 10000 Liters Mixing Tank capacity at once, not manufactured in portion wise. The competent Authority PQCB team also confirmed this type of mixing tank Capacity 10000 Liters conducted PSI regarding to Riam

Suspension batches held on dated 29.08.2022.

It is informed you that the same product Broxol DM syrup Batch No: P-288 & P-292 are declared of Standard Quality DTL Faisalabad Punjab.

Kindly consider our above said points and may give us WARNING in this regard.

4 Personal Hearing Notice issued to accused person(s)

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 4

PQCB/R-609/2022

Tehsil & District Pakpattan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan** through its Chief Executive Officer/ Warrantor Abdullah Shah 2. Abdullah Shah Chief Executive Officer/ Warrantor 3. Imran Khan Production Incharge 4. Umar Kamran Marwat Quality Control Incharge Of M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil & District Pakpattan reported that:-

i. The then drug Inspector, on 18-08-2022, inspected medicine store O/O PHMC Pakpattan and took sample of drug on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 0000135420 dated 18-08-2022.

ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

iii. Store Keeper O/O PHMC Pakpattan provided Invoice/warranty No. 1500635 dated 22-07-2022 issued by M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan as a proof of its purchase of the said drug.

iv. Warrantor Portion of the drug sample was sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan.

v. A copy of test/analysis report was sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan and they were asked to provide the requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 256th meeting held on 19-01-2023 allowed to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of drug	**Batch No.**	**Name of manufacturer**	**TRA No. & Date**	**DTL Test Report Results**
Syrup Broxol DM (Dextromethorphan HBr 6.25mg + Diphenhydramine HCl 5mg/5ml, 120ml)	P-288	M/s Stanley Pharmaceuticals84-B, Industrial State, Hayatabad Peshawar Pakistan	TRA No. 01-10094000594/DTL Dated: 14-10-2022	**Analysis with specifications applied:** MS **Composition:** Each 5ml contains: Dextromethorphan HBr (BP)…6.25mg Diphenhydramine HCl (BP)…5mg

Mfg. date: 07-2022 **Exp. date:** 07-2024 **Regn No.** 022854				**Description (MS):** Pink color liquid in amber color sealed glass bottle. (Stated volume: 120 ml) **Identification (MS):** Dextromethorphan HBr & Diphenhydramine HCl are identified. **Assay (MS):** Dextromethorphan HBr **Stated** | **Determined** | **Percentage** | **Limit** 6.25mg/5ml | 6.645mg/5ml | 106.317% | 5.625-6.875mg/5ml Diphenhydramine HCl **Stated** | **Determined** | **Percentage** | **Limit** 5.0mg/5ml | **10.183mg/5ml** | **203.665%** | **4.5-5.5mg/5ml** **(Does not Comply with Specifications)** **RESULT:** The sample is declared **SUB-STANDARD** on the basis of **ASSAY TEST OF DIPHENHYDRAMINE HCL.**

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Test Report No.**	**NIH Test Report Result**
Cough Syrup Broxol DM 120ml	P-288	M/s Stanley Pharmaceuticals (Pvt.) Ltd., 84-B, Industrial State Hayatabad, Peshawar-Pakistan	017-P/2023 dated 27-04-2023	**Analysis with specifications applied:** Manufacturer Specifications **ASSAY:** **ASSAY** | **STATED** | **FOUND** | **LIMIT** | **PERCENTAGE** Diphenhydramine HCl | 5mg/5ml | 3.50mg/5ml | 90-110% | **70.032%** Dextromethorphan HBr | 6.25mg/5ml | 5.7mg/5ml | 90-110% | 91.2% **Does not Comply with the Manufacturer's specifications.** **CONCLUSION:**

				The sample is of **Sub-Standard** quality on the basis of tests performed.

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/DRAP Act 2012 and Rules framed there under by the way of: --

a. **Manufacture for sale/sale of Substandard drugs**
b. **Issuance of false warranty**

Summary:

Manufacturing Date: 07-2022

Expiry Date: 07-2024

Sampling Date: 18-08-2022

Sent to DTL (Form 6): 18-08-2022

Date of receipt in DTL: 19-08-2022

DTL Report Date: 14-10-2022

Time extension granted: N/A

1ST DI Communication with firm on dated:24-10-2022

Date of Retesting Request of Firm: 27-10-2022

Fate of Retesting Request: allow (256-M)

Sample received in NIH: 31-01-2023

NIH report dated: 27-04-2023 (87 days)

Investigation Report Dated: 05-07-2023

3 Show cause notice issued to the accused

Firm submitted reply to show cause notice dated 30-08-2023

We have received your Kind letter No. POCB/R-609/2022 dated 22.08.2023 .

We M/S Stanley Pharma Peshawar hereby clarified our position regarding to Broxol DM Syrup Batch No: P-288 declared substandard by NIH and DTL Bahawalpur on the basis of Diphenhydramine HCl assay i.e. 70.032%. is huge difference in assay results of NIH & DTL Bahawalpur i.e. 133.633% which clearly shows the mistakes have done by both Laboratories during analysis based on titration.

3 It is stated for your kind information that Diphenhydramine HCL is acidic salt freely soluble in water, there is no possibility of Assay results of Active Pharmaceutical Ingredient (API) under or above the specified specification in syrup dosage form.

Moreover, we have manufactured the Broxol DM syrup Batc No P-288 in high speed 2800rpm silver

son 10000 Liters Mixing Tank capacity at once, not manufactured in portion wise. The competent Authority PQCB team also confirmed this type of mixing tank Capacity 10000 Liters conducted PSI regarding to Riam

Suspension batches held on dated 28.08.2022.

It is informed you that the same product Broxol DM syrup Batch No: P-288 & P-292 are declared of Standard Quality DTL Faisalabad Punjab.

Kindly consider our above said points and may give us WARNING in this regard.

4 Personal Hearing Notice issued to accused person(s)

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 5

PQCB/MSS-175227, 175228, 175229, 175230, 175231, 175232, 175233 /2023

MSD Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S Lisko Pakistan Pvt Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal 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 Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B Industrial Area Karachi .

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, MSD Lahore reported that:-

i. He on 11-09-2023 inspected the premises of Govt. Sub Sub-Medical Store Depot, Maraka Lahore took samples of subject drugs on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No.175227,175228,175229,175230,175231,175232,175233 Dated 11-09-2023.
ii. The following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Lahore as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	032-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000060/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 130 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)**

				pH: **Determined: 5.4 AT 24.9º C** **(Complies)** **IDENTIFICATION OF PARACETAMOL:** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **ASSAY OF PARACETAMOL:** **Stated = 120mg/5mL** **Determined = 127.22mg/5mL** **Percentage = 106.02%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is SUB-STANDARD, on the basis of Physical description as per USP.**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	033-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000078/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **pH:** **Determined: 5.4 AT 24.4º C** **(Complies)** **IDENTIFICATION OF PARACETAMOL:** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol**

				identified). **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 128.02mg/5mL** **Percentage = 106.68%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**
Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	034-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000079/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023<u>:</u>** **<u>PHYSICAL APPEARANCE:</u>** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY** **<u>pH:</u>** **Determined: 5.3 AT 25.5° C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 131.36mg/5mL** **Percentage = 109.47%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the**

				basis of Physical description as per USP.
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	036-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000067/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **pH:** **Determined: 5.4 AT 24.3º C** **(Complies)** **IDENTIFICATION OF PARACETAMOL:** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **ASSAY OF PARACETAMOL:** **Stated = 120mg/5mL** **Determined = 130.37mg/5mL** **Percentage = 108.64%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is SUB-STANDARD, on the basis of Physical description as per USP.**
Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	037-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000077/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.**

				However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*. **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 24.6º C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 130.75mg/5mL** **Percentage = 108.96%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP**
Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	038-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000072/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023<u>:</u>** **<u>PHYSICAL APPEARANCE:</u>** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 24.4º C** **(Complies)**

				IDENTIFICATION OF PARACETAMOL: **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **ASSAY OF PARACETAMOL:** **Stated = 120mg/5mL** **Determined = 131.84mg/5mL** **Percentage = 109.87%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is SUB-STANDARD, on the basis of Physical description as per USP.**
Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	039-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000076/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **pH:** **Determined: 5.4 AT 25.6° C** **(Complies)** **IDENTIFICATION OF PARACETAMOL:** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **ASSAY OF PARACETAMOL:** **Stated = 120mg/5mL** **Determined = 128.96mg/5mL**

				Percentage = 107.47% **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**

iii. Mr. Zafar Jahanzaib Meer, Pharmacist, Govt. Sub-Medical Store Depot, Maraka Lahore provided warranty/invoice DC no.00037 dated 11-07-2023, no. 00067 dated 01-08-2023, no. 000088 dated 09-08-2023 and no. 000101 Dated 18-08-2023 issued by M/ **Lisko Pharmaceuticals (Pvt) Ltd,**L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

iv. Warrantor Portion was sent to M**/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, and Pakistan.

v. Copies of Test/ Analysis reports were sent to M**/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan. In response, the firm challenged the report and requested for re-testing of the samples from Appellate Laboratory.

vi. Pursuant to the retesting request of the firm, the retesting requests of subject samples were placed in 28th committee meeting. During personal hearing, Firm withdraw their retesting requests.

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated. 06-12-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 12-12-2023 stating that:

During committee meeting, we highlighted ambiguities in all 28 DTL reports. Once again we would

like to highlight and discuss those ambiguities of DTL reports as below:

2. We would first like to highlight 5 major ambiguities regarding statement written by government

analyst:

Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed

Volume=120mL Determined volume = 120 mL.

(1) However, according to USP <1151> Pharmaceutical Dosage Forms;

A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

(11) Our suspension is translucent and not clear due to the presence of small micro Sized particles that can also be seen in our suspension. Although, we strongly claim that our particles can been seen in suspension via naked eye still particle size of solid particles must be considered and in our case, government analyst has ignored this fact before giving conclusive statement. If the solid particles are very small and uniformly dispersed, they may not be visible to naked eye resulting to a translucent appearance for the suspension. USP does not bound / specify suspended particles to be observed only via naked eye. Government analyst just wrote her observation without mentioning mode i.e. Naked eye, microscope, etc. regarding physical appearance of Parapol suspension.

Hence statement of government analyst regarding absence of suspended particles is Baseless. Government analyst has written in every DTL report that our sample is not suspension but she did not specify that if our sample is not suspension than what is it.? She just wrote definition of suspension from USP <1151> but she did not specify that if our sample is not biphasic preparation than what is it.? Government analyst claimed in every DTL report that all the test/s were performed

as per USP (Point no## 6) while it is to be noted that USP does not mention any test to distinguish biphasic preparation with monophasic preparation or any test to check absence or presence of suspended particles in preparation. Government analyst did not mention or consider any factors that affect physical appearance of suspension i.e particle size, shape, refractive index of suspended

Particles as well as the refractive index and viscosity of the liquid medium. Hence, conclusion on physical appearance of suspension cannot be solely determined by the presence of particles but also by the size and distribution of these particles within the liquid.

Here, we would also like to share discussion on above mentioned ambiguities during 28th committee meeting of PQCB. Government analyst was asked to give her stance for which she showed samples of Parapol suspension before committee members. Similarly, we brought Panadol Liquid (GSK) as it is a clear solution and we wanted to present it before the committee members so that honorable members can check physically and compare Parapol sample (Suspension claimed) with Panadol liquid (solution). Honorable committee members were convinced that sample of Parapol is not "clear" rather translucent in appearance.

We also shared reply of technical service manager of USP (Copy attached) before the committee members in which we inquired regarding test to distinguish between biphasic preparation and monophasic preparation. His reply was clear and precise that "I am not aware of any specific test to distinguish between two i.e monophasic and biphasic preparation". We also submitted documents (copies attached) of API purchased from Citi Pharma in which it can be seen that they have supplied us micronized Paracetamol and this further support our stance i.e micronized particles of Paracetamol were present and Dispersed throughout the liquid.

b. We have written in our packaging material to SHAKE WELL BEFORE USE as our product is

suspension and particles may get settle at the bottom with the passage of time but we believe that

Government analyst did not follow instructions to shake our sample before taking out for testing. During the committee meeting, government analyst tried to pour our suspension into beaker without shaking and when honorable committee members asked her to shake it first then she replied that bubbles will form on shaking. This showed her mala fide intentions and we suspect same violation of testing protocols in our case.

c. We believed that government analyst must have conducted pharmacopeia test via USP before

giving final conclusion that samples of Parapol are not suspension and it does not contains solid

Particles. In all DTL reports, government analyst has just wrote her observation and used TA?

PHARMACEUTICAL DIVISION

Suspension definition of USP and did not mention any technique or any apparatus through which she checked presence or absence of particles or to prove her stance. When, honorable committee members asked government analyst to explain her stance against our claim for which she failed to mention any test from official pharmacopeia. She just said that she asked from USP via email. Her own statement during the committee meeting proved that she did not apply any applicable USP test on our product to check presence or absence of solid particles in our sample rather she relied on email which can never be the part of official testing.

We also highlighted one important point before the committee members that USP gives disclaimer statement I footer statement in all their email replies in which it is clearly stated that "this response has been provided for informational purpose only and should not be construed as an official interpretations of USP text or relied on to demonstrated compliance with USP standards or requirements" (Copy attached). While government analyst stated during meeting that reply she got from USP had no such disclaimer remarks and therefore we request honorable committee members to ask analyst to show that reply of USP directly logging into her account.

We are sure of this fact that disclaimer remarks are always present in USP replies and we suspect possibility of alteration in USP reply which will prove mala fide intention of Government analyst. We also request honorable committee members to share true facts with us as well as it is our right to check grounds on the basis of which all our samples were declared sub-standard.

6. During the committee meeting, we submitted formulation of Parapol suspension in which we highlighted presence 2 of suspending agents i.e. Xanthan gum and PVPK-30 and the only reason of these suspending agents in our formulation is to suspend and disperse solid particles throughout the liquid phase and therefore our product also complies definition of suspension as per USP

I.e. biphasic preparation consisting of solid particles dispersed throughout the liquid phase.

7. We strongly claim that our product is suspension and biphasic preparation and the statement regarding physical appearance by government analyst is baseless, yet DTL Lahore did discriminatory act in our case as government analyst declared all samples as sub-standard while DTL Lahore used to declare samples of different firms as misbranded on the basis of physical description in past. We had already submitted evidences in this regard and we are again submitting to prove discriminatory act in our case.

In the light of above facts and ambiguities, we willingly withdraw from re-testing request but

we would again request honorable committee Of PQCB to declare all 28 reports by DTL Lahore as standard and allow it for consumption as the statement regarding physical appearance by government analyst is baseless while other test conducted on our samples are well within limits.

Personnel hearing notice(s) issued to accused person(s) vide dated 09-01-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 04-2023, 07-2023

Expiry Date: 04-2025, 07-2025

Sampling Date: 11-09-2023

Sent to DTL (Form 6): 11-09-2023

Date of receipt in DTL: 12-09-2023

DTL Report Date: 17-10-2023

Time Extension: N/A

1ST DI Communication with firm on dated: 24-10-2023

Date of Retesting Request of Firm: 31-10-2023

Fate of Retesting Request: - withdraw

Investigation Report Dated: 6-11-2023

PROCEEDINGS AND DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (operations) Primary & Secondary Healthcare department /Vice chairperson, PQCB. Hassan Saeed, Secretary DQCB, Lahore and Ubaidullah Anwar Inspector of drugs, MSD , Lahore were present along with original case record. Dr. Sarfaraz (Business unit Head) on behalf of M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

The case was leftover due to time constraints.

Case No. 6

PQCB/MSS-175244, 175245/2023

MSD Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S Lisko Pakistan Pvt Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal 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 Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B Industrial Area Karachi .

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, MSD Lahore reported that:-

i. He on 11-09-2023 inspected the premises of Govt. Sub Sub-Medical Store Depot, Maraka Lahore took samples of subject drugs on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No. 175244,175245Dated 11-09-2023.
ii. The following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Lahore as detailed below: -

Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	019-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000063 /DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **pH:** **Determined: 5.4 AT 25.4º C**

				(Complies) **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 125.1mg/5mL** **Percentage = 104.25%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**
Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	020-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000062/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023<u>:</u>** **<u>PHYSICAL APPEARANCE:</u>** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 25.2° C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 125.53mg/5mL** **Percentage = 104.61%**

				Limit = 90.0%-110.0% of labelled amount **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**

iii. Mr. Zafar Jahanzaib Meer, Pharmacist, Govt. Sub-Medical Store Depot, Maraka Lahore provided warranty/invoice DC no.00037 dated 11-07-2023, no. 00067 dated 01-08-2023, no. 000088 dated 09-08-2023 and no. 000101 Dated 18-08-2023 issued by M/ **Lisko Pharmaceuticals (Pvt) Ltd,**L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

iv. Warrantor Portion was sent to M**/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, and Pakistan.

v. Copies of Test/ Analysis reports were sent to M**/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan. In response, the firm challenged the report and requested for re-testing of the samples from Appellate Laboratory.

vi. Pursuant to the retesting request of the firm, the retesting requests of subject samples were placed in 28th committee meeting. During personal hearing, Firm withdraw their retesting requests.

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated. 06-12-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 12-12-2023 stating that:

During committee meeting, we highlighted ambiguities in all 28 DTL reports. Once again we would

like to highlight and discuss those ambiguities of DTL reports as below:

2. We would first like to highlight 5 major ambiguities regarding statement written by government

analyst:

Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed

Volume=120mL Determined volume = 120 mL.

(1) However, according to USP <1151> Pharmaceutical Dosage Forms;

A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

(11) Our suspension is translucent and not clear due to the presence of small micro Sized particles that can also be seen in our suspension. Although, we strongly claim that our particles can been seen in suspension via naked eye still particle size of solid particles must be considered and in our case, government analyst has ignored this fact before giving conclusive statement. If the solid particles are very small and uniformly dispersed, they may not be visible to naked eye resulting to a translucent appearance for the suspension. USP does not bound / specify suspended particles to be observed only via naked eye. Government analyst just wrote her observation without mentioning mode i.e. Naked eye, microscope, etc. regarding physical appearance of Parapol suspension.

Hence statement of government analyst regarding absence of suspended particles is Baseless. Government analyst has written in every DTL report that our sample is not suspension but she did not specify that if our sample is not suspension than what is it.? She just wrote definition of suspension from USP <1151> but she did not specify that if our sample is not biphasic preparation than what is it.? Government analyst claimed in every DTL report that all the test/s were performed

as per USP (Point no## 6) while it is to be noted that USP does not mention any test to distinguish biphasic preparation with monophasic preparation or any test to check absence or presence of suspended particles in preparation. Government analyst did not mention or consider any factors that affect physical appearance of suspension i.e particle size, shape, refractive index of suspended

Particles as well as the refractive index and viscosity of the liquid medium. Hence, conclusion on physical appearance of suspension cannot be solely determined by the presence of particles but also by the size and distribution of these particles within the liquid.

Here, we would also like to share discussion on above mentioned ambiguities during 28th committee meeting of PQCB. Government analyst was asked to give her stance for which she showed samples of Parapol suspension before committee members. Similarly, we brought Panadol Liquid (GSK) as it is a clear solution and we wanted to present it before the committee members so that honorable members can check physically and compare Parapol sample (Suspension claimed) with Panadol liquid (solution). Honorable committee members were convinced that sample of Parapol is not "clear" rather translucent in appearance.

We also shared reply of technical service manager of USP (Copy attached) before the committee members in which we inquired regarding test to distinguish between biphasic preparation and monophasic preparation. His reply was clear and precise that "I am not aware of any specific test to distinguish between two i.e monophasic and biphasic preparation". We also submitted documents (copies attached) of API purchased from Citi Pharma in which it can be seen that they have supplied us micronized Paracetamol and this further support our stance i.e micronized particles of Paracetamol were present and Dispersed throughout the liquid.

b. We have written in our packaging material to SHAKE WELL BEFORE USE as our product is

suspension and particles may get settle at the bottom with the passage of time but we believe that

Government analyst did not follow instructions to shake our sample before taking out for testing. During the committee meeting, government analyst tried to pour our suspension into beaker without shaking and when honorable committee members asked her to shake it first then she replied that bubbles will form on shaking. This showed her mala fide intentions and we suspect same violation of testing protocols in our case.

c. We believed that government analyst must have conducted pharmacopeia test via USP before

giving final conclusion that samples of Parapol are not suspension and it does not contains solid

Particles. In all DTL reports, government analyst has just wrote her observation and used TA?

PHARMACEUTICAL DIVISION

Suspension definition of USP and did not mention any technique or any apparatus through which she checked presence or absence of particles or to prove her stance. When, honorable committee members asked government analyst to explain her stance against our claim for which she failed to mention any test from official pharmacopeia. She just said that she asked from USP via email. Her own statement during the committee meeting proved that she did not apply any applicable USP test on our product to check presence or absence of solid particles in our sample rather she relied on email which can never be the part of official testing.

We also highlighted one important point before the committee members that USP gives disclaimer statement I footer statement in all their email replies in which it is clearly stated that "this response has been provided for informational purpose only and should not be construed as an official interpretations of USP text or relied on to demonstrated compliance with USP standards or requirements" (Copy attached). While government analyst stated during meeting that reply she got from USP had no such disclaimer remarks and therefore we request honorable committee members to ask analyst to show that reply of USP directly logging into her account.

We are sure of this fact that disclaimer remarks are always present in USP replies and we suspect possibility of alteration in USP reply which will prove mala fide intention of Government analyst. We also request honorable committee members to share true facts with us as well as it is our right to check grounds on the basis of which all our samples were declared sub-standard.

6. During the committee meeting, we submitted formulation of Parapol suspension in which we highlighted presence 2 of suspending agents i.e. Xanthan gum and PVPK-30 and the only reason of these suspending agents in our formulation is to suspend and disperse solid particles throughout the liquid phase and therefore our product also complies definition of suspension as per USP

i.e biphasic preparation consisting of solid particles dispersed throughout the liquid phase.

7. We strongly claim that our product is suspension and biphasic preparation and the statement regarding physical appearance by government analyst is baseless, yet DTL Lahore did discriminatory act in our case as government analyst declared all samples as sub-standard while DTL Lahore used to declare samples of different firms as misbranded on the basis of physical description in past. We had already submitted evidences in this regard and we are again submitting to prove discriminatory act in our case.

In the light of above facts and ambiguities, we willingly withdraw from re-testing request but we would again request honorable committee Of PQCB to declare all 28 reports by DTL Lahore as standard and allow it for consumption as the statement regarding physical appearance by government analyst is baseless while other test conducted on our samples are well within limits.

Personnel hearing notice(s) issued to accused person(s) vide dated 09-01-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 04-2023, 07-2023

Expiry Date: 04-2025, 07-2025

Sampling Date: 11-09-2023

Sent to DTL (Form 6): 11-09-2023

Date of receipt in DTL: 12-09-2023

DTL Report Date: 17-10-2023

Time Extension: N/A

1ST DI Communication with firm on dated: 24-10-2023

Date of Retesting Request of Firm: 31-10-2023

Fate of Retesting Request: - withdraw

Investigation Report Dated: 6-11-2023

PROCEEDINGS AND DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (operations) Primary & Secondary Healthcare department /Vice chairperson, PQCB. Hassan Saeed, Secretary DQCB, Lahore and Ubaidullah Anwar Inspector of drugs, MSD , Lahore were present along with original case record. Dr. Sarfaraz (Business unit Head) on behalf of M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

The case was leftover due to time constraints.

Case No. 7

PQCB/MSS-175222, 175223, 175224, 175225/2023

MSD Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S Lisko Pakistan Pvt Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal 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 Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B Industrial Area Karachi .

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, MSD Lahore reported that:-

i. He on 11-09-2023 inspected the premises of Govt. Sub Sub-Medical Store Depot, Maraka Lahore took samples of subject drugs on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No. 175222,175223,175224,175225.
ii. The following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Lahore as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	026-24	M/S **Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000068/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **pH:**

				Determined: 5.3 at 24.5º C **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 130.25mg/5mL** **Percentage = 108.54%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	027-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000071/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023<u>:</u>** **<u>PHYSICAL APPEARANCE:</u>** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 24.6º C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>**

				Stated = 120mg/5mL **Determined = 129.64mg/5mL** **Percentage = 108.03%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	028-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000073/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023<u>:</u>** **<u>PHYSICAL APPEARANCE:</u>** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 24.8º C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 130.20mg/5mL** **Percentage = 108.50%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**

Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	031-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000070/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*.** **(DOES NOT COMPLY)** **pH:** **Determined: 5.4 AT 24.8° C** **(Complies)** **IDENTIFICATION OF PARACETAMOL:** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **ASSAY OF PARACETAMOL:** **Stated = 120mg/5mL** **Determined = 130.45mg/5mL** **Percentage = 108.71%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is SUB-STANDARD, on the basis of Physical description as per USP.**

iii. Mr. Zafar Jahanzaib Meer, Pharmacist, Govt. Sub-Medical Store Depot, Maraka Lahore provided warranty/invoice DC no.00037 dated 11-07-2023, no. 00067 dated 01-08-2023, no. 000088 dated 09-08-2023 and no. 000101 Dated 18-08-2023 issued by M/ **Lisko Pharmaceuticals (Pvt) Ltd,**L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

iv. Warrantor Portion was sent to M/**S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, and Pakistan.

v. Copies of Test/ Analysis reports were sent to M/**S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan. In response, the firm challenged the report and requested for re-testing of the samples from Appellate Laboratory.

vi. Pursuant to the retesting request of the firm, the retesting requests of subject samples were placed in 28th committee meeting. During personal hearing, Firm withdraw their retesting requests.

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated. 06-12-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 12-12-2023 stating that:

During committee meeting, we highlighted ambiguities in all 28 DTL reports. Once again we would

like to highlight and discuss those ambiguities of DTL reports as below:

2. We would first like to highlight 5 major ambiguities regarding statement written by government

analyst:

Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed

Volume=120mL Determined volume = 120 mL.

(1) However, according to USP <1151> Pharmaceutical Dosage Forms;

A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

(11) Our suspension is translucent and not clear due to the presence of small micro Sized particles that can also be seen in our suspension. Although, we strongly claim that our particles can been seen in suspension via naked eye still particle size of solid particles must be considered and in our case, government analyst has ignored this fact before giving conclusive statement. If the solid particles are very small and uniformly dispersed, they may not be visible to naked eye resulting to a translucent appearance for the suspension. USP does not bound / specify suspended particles to be observed only via naked eye. Government analyst just wrote her observation without mentioning mode i.e. Naked eye, microscope, etc. regarding physical appearance of Parapol suspension.

Hence statement of government analyst regarding absence of suspended particles is Baseless. Government analyst has written in every DTL report that our sample is not suspension but she did not specify that if our sample is not suspension than what is it.? She just wrote definition of suspension from USP <1151> but she did not specify that if our sample is not biphasic preparation than what is it.? Government analyst claimed in every DTL report that all the test/s were performed

as per USP (Point no## 6) while it is to be noted that USP does not mention any test to distinguish biphasic preparation with monophasic preparation or any test to check absence or presence of suspended particles in preparation. Government analyst did not mention or consider any factors that affect physical appearance of suspension i.e particle size, shape, refractive index of suspended

Particles as well as the refractive index and viscosity of the liquid medium. Hence, conclusion on physical appearance of suspension cannot be solely determined by the presence of particles but also by the size and distribution of these particles within the liquid.

Here, we would also like to share discussion on above mentioned ambiguities during 28th committee meeting of PQCB. Government analyst was asked to give her stance for which she showed samples of Parapol suspension before committee members. Similarly, we brought Panadol Liquid (GSK) as it is a clear solution and we wanted to present it before the committee members so that honorable members can check physically and compare Parapol sample (Suspension claimed) with Panadol liquid (solution). Honorable committee members were convinced that sample of Parapol is not "clear" rather translucent in appearance.

We also shared reply of technical service manager of USP (Copy attached) before the committee members in which we inquired regarding test to distinguish between biphasic preparation and monophasic preparation. His reply was clear and precise that "I am not aware of any specific test to distinguish between two i.e monophasic and biphasic preparation". We also submitted documents (copies attached) of API purchased from Citi Pharma in which it can be seen that they have supplied us micronized Paracetamol and this further support our stance i.e micronized particles of Paracetamol were present and Dispersed throughout the liquid.

b. We have written in our packaging material to SHAKE WELL BEFORE USE as our product is

suspension and particles may get settle at the bottom with the passage of time but we believe that

Government analyst did not follow instructions to shake our sample before taking out for testing. During the committee meeting, government analyst tried to pour our suspension into beaker without shaking and when honorable committee members asked her to shake it first then she replied that bubbles will form on shaking. This showed her mala fide intentions and we suspect same violation of testing protocols in our case.

c. We believed that government analyst must have conducted pharmacopeia test via USP before

giving final conclusion that samples of Parapol are not suspension and it does not contains solid

Particles. In all DTL reports, government analyst has just wrote her observation and used TA?

PHARMACEUTICAL DIVISION

Suspension definition of USP and did not mention any technique or any apparatus through which she checked presence or absence of particles or to prove her stance. When, honorable committee members asked government analyst to explain her stance against our claim for which she failed to mention any test from official pharmacopeia. She just said that she asked from USP via email. Her own statement during the committee meeting proved that she did not apply any applicable USP test on our product to check presence or absence of solid particles in our sample rather she relied on email which can never be the part of official testing.

We also highlighted one important point before the committee members that USP gives disclaimer statement I footer statement in all their email replies in which it is clearly stated that "this response has been provided for informational purpose only and should not be construed as an official interpretations of USP text or relied on to demonstrated compliance with USP standards or requirements" (Copy attached). While government analyst stated during meeting that reply she got from USP had no such disclaimer remarks and therefore we request honorable committee members to ask analyst to show that reply of USP directly logging into her account.

We are sure of this fact that disclaimer remarks are always present in USP replies and we suspect possibility of alteration in USP reply which will prove mala fide intention of Government analyst. We also request honorable committee members to share true facts with us as well as it is our right to check grounds on the basis of which all our samples were declared sub-standard.

6. During the committee meeting, we submitted formulation of Parapol suspension in which we highlighted presence 2 of suspending agents i.e. Xanthan gum and PVPK-30 and the only reason of these suspending agents in our formulation is to suspend and disperse solid particles throughout the liquid phase and therefore our product also complies definition of suspension as per USP

i.e biphasic preparation consisting of solid particles dispersed throughout the liquid phase.

7. We strongly claim that our product is suspension and biphasic preparation and the statement regarding physical appearance by government analyst is baseless, yet DTL Lahore did discriminatory act in our case as government analyst declared all samples as sub-standard while DTL Lahore used to declare samples of different firms as misbranded on the basis of physical description in past. We had already submitted evidences in this regard and we are again submitting to prove discriminatory act in our case.

In the light of above facts and ambiguities, we willingly withdraw from re-testing request but we would again request honorable committee Of PQCB to declare all 28 reports by DTL Lahore as standard and allow it for consumption as the statement regarding physical appearance by government analyst is baseless while other test conducted on our samples are well within limits.

Personnel hearing notice(s) issued to accused person(s) vide dated 09-01-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 04-2023, 07-2023

PROCEEDINGS AND DECISI

Expiry Date: 04-2025, 07-2025

Sampling Date: 11-09-2023

Sent to DTL (Form 6): 11-09-2023

Date of receipt in DTL: 12-09-2023

DTL Report Date: 17-10-2023

Time Extension: N/A

1ST DI Communication with firm on dated: 24-10-2023

Date of Retesting Request of Firm: 31-10-2023

Fate of Retesting Request: - withdraw

Investigation Report Dated: 6-11-2023

ON BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (operations) Primary & Secondary Healthcare department /Vice chairperson, PQCB. Hassan Saeed, Secretary DQCB, Lahore and Ubaidullah Anwar Inspector of drugs, MSD , Lahore were present along with original case record. Dr. Sarfaraz (Business unit Head) on behalf of M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

The case was leftover due to time constraints.

Case No. 8

PQCB/MSS-

175235,175236,175237,175238,175239, 175240, 175241 /2023

MSD Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S Lisko Pakistan Pvt Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal 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 Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B Industrial Area Karachi .

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, MSD Lahore reported that:-

i. He on 11-09-2023 inspected the premises of Govt. Sub Sub-Medical Store Depot, Maraka Lahore took samples of subject drugs on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No. 175235,175236,175237,175238,175239, 175240 and 175241 Dated 11-09-2023.
ii. The following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Lahore as detailed below: -

Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	006-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000064/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.*** **(DOES NOT COMPLY** **pH:**

				Determined: 5.5 AT 24.6º C **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 124.67mg/5m** **Percentage = 103.89%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	040-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000075/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023<u>:</u>** **<u>PHYSICAL APPEARANCE:</u>** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.*** **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 24.9º C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>**

				Stated = 120mg/5mL **Determined = 130.63mg/5mL** **Percentage = 108.86%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	003-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000061/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023<u>:</u>** **<u>PHYSICAL APPEARANCE:</u>** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.*** **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 25.0º C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 127.21mg/5mL** **Percentage = 106.01%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**

Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	002-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000066/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.*** **(DOES NOT COMPLY)** **pH:** **Determined: 5.4 AT 24.7º C** **(Complies)** **IDENTIFICATION OF PARACETAMOL:** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **ASSAY OF PARACETAMOL:** **Stated = 120mg/5mL** **Determined = 130.85mg/5mL** **Percentage = 109.04%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is SUB-STANDARD, on the basis of Physical description as per USP.**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	005-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000065/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a***

				biphasic preparation consisting of solid particles dispersed throughout a liquid phase. **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 24.6º C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 130.66mg/5mL** **Percentage = 108.88%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**
Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 04-2023 **Exp. Date**: 04-2025 **Reg** # 002772	293-23	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000069/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023<u>:</u>** **<u>PHYSICAL APPEARANCE:</u>** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.*** **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 24.5º C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>**

				The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 130.67mg/5mL** **Percentage = 108.89%** **Limit = 90.0%-110.0% of labelled amount** **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**
Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 04-2023 **Exp. Date**: 04-2025 **Reg** # 002772	294-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10206000074/DTL dated 17-10-2023 DTL Lahore	**Specification applied: USP 2023<u>:</u>** **<u>PHYSICAL APPEARANCE:</u>** **Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL.** **However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.*** **(DOES NOT COMPLY)** **<u>pH:</u>** **Determined: 5.4 AT 24.5° C** **(Complies)** **<u>IDENTIFICATION OF PARACETAMOL:</u>** **The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).** **<u>ASSAY OF PARACETAMOL:</u>** **Stated = 120mg/5mL** **Determined = 129.28mg/5mL** **Percentage = 107.73%**

				Limit = 90.0%-110.0% of labelled amount **RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Physical description as per USP.**

iii. Mr. Zafar Jahanzaib Meer, Pharmacist, Govt. Sub-Medical Store Depot, Maraka Lahore provided warranty/invoice DC no.00037 dated 11-07-2023, no. 00067 dated 01-08-2023, no. 000088 dated 09-08-2023 and no. 000101 Dated 18-08-2023 issued by M/ **Lisko Pharmaceuticals (Pvt) Ltd,**L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

iv. Warrantor Portion was sent to M/**S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, and Pakistan.

v. Copies of Test/ Analysis reports were sent to M/**S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan. In response, the firm challenged the report and requested for re-testing of the samples from Appellate Laboratory.

vi. Pursuant to the retesting request of the firm, the retesting requests of subject samples were placed in 28th committee meeting. During personal hearing, Firm withdraw their retesting requests.

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated. 06-12-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 12-12-2023 stating that:

During committee meeting, we highlighted ambiguities in all 28 DTL reports. Once again we would

like to highlight and discuss those ambiguities of DTL reports as below:

2. We would first like to highlight 5 major ambiguities regarding statement written by government

analyst:

Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed

Volume=120mL Determined volume = 120 mL.

(1) However, according to USP <1151> Pharmaceutical Dosage Forms;

A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

(11) Our suspension is translucent and not clear due to the presence of small micro Sized particles that can also be seen in our suspension. Although, we strongly claim that our particles can been seen in suspension via naked eye still particle size of solid particles must be considered and in our case, government analyst has ignored this fact before giving conclusive statement. If the solid particles are very small and uniformly dispersed, they may not be visible to naked eye resulting to a translucent appearance for the suspension. USP does not bound / specify suspended particles to be observed only via naked eye. Government analyst just wrote her observation without mentioning mode i.e. Naked eye, microscope, etc. regarding physical appearance of Parapol suspension.

Hence statement of government analyst regarding absence of suspended particles is Baseless. Government analyst has written in every DTL report that our sample is not suspension but she did not specify that if our sample is not suspension than what is it.? She just wrote definition of suspension from USP <1151> but she did not specify that if our sample is not biphasic preparation than what is it.? Government analyst claimed in every DTL report that all the test/s were performed

as per USP (Point no## 6) while it is to be noted that USP does not mention any test to distinguish biphasic preparation with monophasic preparation or any test to check absence or presence of suspended particles in preparation. Government analyst did not mention or consider any factors that affect physical appearance of suspension i.e particle size, shape, refractive index of suspended

Particles as well as the refractive index and viscosity of the liquid medium. Hence, conclusion on physical appearance of suspension cannot be solely determined by the presence of particles but also by the size and distribution of these particles within the liquid.

Here, we would also like to share discussion on above mentioned ambiguities during 28th committee meeting of PQCB. Government analyst was asked to give her stance for which she showed samples of Parapol suspension before committee members. Similarly, we brought Panadol Liquid (GSK) as it is a clear solution and we wanted to present it before the committee members so that honorable members can check physically and compare Parapol sample (Suspension claimed) with Panadol liquid (solution). Honorable committee members were convinced that sample of Parapol is not "clear" rather translucent in appearance.

We also shared reply of technical service manager of USP (Copy attached) before the committee members in which we inquired regarding test to distinguish between biphasic preparation and monophasic preparation. His reply was clear and precise that "I am not aware of any specific test to distinguish between two i.e monophasic and biphasic preparation". We also submitted documents (copies attached) of API purchased from Citi Pharma in which it can be seen that they have supplied us micronized Paracetamol and this further support our stance i.e micronized particles of Paracetamol were present and Dispersed throughout the liquid.

b. We have written in our packaging material to SHAKE WELL BEFORE USE as our product is

suspension and particles may get settle at the bottom with the passage of time but we believe that

Government analyst did not follow instructions to shake our sample before taking out for testing. During the committee meeting, government analyst tried to pour our suspension into beaker without shaking and when honorable committee members asked her to shake it first

then she replied that bubbles will form on shaking. This showed her mala fide intentions and we suspect same violation of testing protocols in our case.

c. We believed that government analyst must have conducted pharmacopeia test via USP before

giving final conclusion that samples of Parapol are not suspension and it does not contains solid

Particles. In all DTL reports, government analyst has just wrote her observation and used TA?

PHARMACEUTICAL DIVISION

Suspension definition of USP and did not mention any technique or any apparatus through which she checked presence or absence of particles or to prove her stance. When, honorable committee members asked government analyst to explain her stance against our claim for which she failed to mention any test from official pharmacopeia. She just said that she asked from USP via email. Her own statement during the committee meeting proved that she did not apply any applicable USP test on our product to check presence or absence of solid particles in our sample rather she relied on email which can never be the part of official testing.

We also highlighted one important point before the committee members that USP gives disclaimer statement I footer statement in all their email replies in which it is clearly stated that "this response has been provided for informational purpose only and should not be construed as an official interpretations of USP text or relied on to demonstrated compliance with USP standards or requirements" (Copy attached). While government analyst stated during meeting that reply she got from USP had no such disclaimer remarks and therefore we request honorable committee members to ask analyst to show that reply of USP directly logging into her account.

We are sure of this fact that disclaimer remarks are always present in USP replies and we suspect possibility of alteration in USP reply which will prove mala fide intention of Government analyst. We also request honorable committee members to share true facts with us as well as it is our right to check grounds on the basis of which all our samples were declared sub-standard.

6. During the committee meeting, we submitted formulation of Parapol suspension in which we highlighted presence 2 of suspending agents i.e. Xanthan gum and PVPK-30 and the only reason of these suspending agents in our formulation is to suspend and disperse solid particles throughout the liquid phase and therefore our product also complies definition of suspension as per USP

i.e biphasic preparation consisting of solid particles dispersed throughout the liquid phase.

7. We strongly claim that our product is suspension and biphasic preparation and the statement regarding physical appearance by government analyst is baseless, yet DTL Lahore did discriminatory act in our case as government analyst declared all samples as sub-standard while DTL Lahore used to declare samples of different firms as misbranded on the basis of physical description in past. We had already submitted evidences in this regard and we are again submitting to prove discriminatory act in our case.

In the light of above facts and ambiguities, we willingly withdraw from re-testing request but we would again request honorable committee Of PQCB to declare all 28 reports by DTL

Lahore as standard and allow it for consumption as the statement regarding physical appearance by government analyst is baseless while other test conducted on our samples are well within limits.

Personnel hearing notice(s) issued to accused person(s) vide dated 09-01-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 04-2023, 07-2023

Expiry Date: 04-2025, 07-2025

Sampling Date: 11-09-2023

Sent to DTL (Form 6): 11-09-2023

Date of receipt in DTL: 12-09-2023

DTL Report Date: 17-10-2023

Time Extension: N/A

1ST DI Communication with firm on dated: 24-10-2023

Date of Retesting Request of Firm: 31-10-2023

Fate of Retesting Request: - withdraw

Investigation Report Dated: 6-11-2023

PROCEEDINGS AND DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (operations) Primary & Secondary Healthcare department /Vice chairperson, PQCB. Hassan Saeed, Secretary DQCB, Lahore and Ubaidullah Anwar Inspector of drugs, MSD , Lahore were present along with original case record. Dr. Sarfaraz (Business unit Head) on behalf of M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

The case was leftover due to time constraints.

Case No. 9

No. PQCB/ MSS-175880, 175881, 175882, 175883, 175884, 175885/2023

MSD Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S Lisko Pakistan Pvt Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal 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 Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B Industrial Area Karachi .

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, MSD Lahore reported that:-

i. He on 11-09-2023 inspected the premises of Govt. Sub Sub-Medical Store Depot, Maraka Lahore took samples of subject drugs on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No. 175880, 175881, 175882, 175883, 175884, 175885 Dated 11-09-2023.
ii. The following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Lahore as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	045-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10194003520/DTL dated 20-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.*

				(DOES NOT COMPLY) **pH:** Determined: 5.4 AT 23.8º C (Complies) **IDENTIFICATION OF PARACETAMOL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **ASSAY OF PARACETAMOL:** Stated = 120mg/5mL Determined = 125.9mg/5mL Percentage = 104.92% Limit = 90.0%-110.0% of labelled amount **RESULT:** The above sample is SUB-STANDARD, on the basis of Physical description as per USP.
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	047-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10194003516/DTL dated 20-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* **(DOES NOT COMPLY)** **pH:** Determined: 5.4 AT 23.3º C (Complies) **IDENTIFICATION OF PARACETAMOL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified).

				ASSAY OF PARACETAMOL: Stated = 120mg/5mL Determined = 131.78mg/5mL Percentage = 109.82% Limit = 90.0%-110.0% of labelled amount **RESULT:** The above sample is SUB-STANDARD, on the basis of Physical description as per USP.
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	050-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10194003515/DTL dated 20-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* **(DOES NOT COMPLY)** **pH:** Determined: 5.3 AT 23.3º C (Complies) **IDENTIFICATION OF PARACETAMOL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **ASSAY OF PARACETAMOL:** Stated = 120mg/5mL Determined = 130.04mg/5mL Percentage = 108.37% Limit = 90.0%-110.0% of labelled amount **RESULT:** The above sample is SUB-STANDARD, on the basis of Physical description as per USP.

Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	049-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10194003517/DTL dated 20-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* **(DOES NOT COMPLY)** **pH:** Determined: 5.4 AT 23.5º C (Complies) **IDENTIFICATION OF PARACETAMOL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **ASSAY OF PARACETAMOL:** Stated = 120mg/5mL Determined = 127.6mg/5mL Percentage = 106.33% Limit = 90.0%-110.0% of labelled amount **RESULT:** The above sample is SUB-STANDARD, on the basis of Physical description as per USP.
Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	046-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10194003513/DTL dated 20-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed*

				throughout a liquid phase. **(DOES NOT COMPLY)** **pH:** Determined: 5.4 AT 23.3º C (Complies) **IDENTIFICATION OF PARACETAMOL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **ASSAY OF PARACETAMOL:** Stated = 120mg/5mL Determined= 129.18mg/5mL Percentage = 107.65% Limit = 90.0%-110.0% of labelled amount **RESULT:** The above sample is SUB-STANDARD, on the basis of Physical description as per USP.
Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg. Date**: 04-2023 **Exp. Date**: 04-2025 **Reg** # 002772	270-23	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10194003518/DTL dated 20-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* **(DOES NOT COMPLY)** **pH:** Determined: 5.4 AT 23.8º C (Complies) **IDENTIFICATION OF PARACETAMOL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major

				peak in standard chromatogram (Paracetamol identified). **ASSAY OF PARACETAMOL:** Stated = 120mg/5mL Determined= 130.15mg/5mL Percentage = 108.46% Limit = 90.0%-110.0% of labelled amount **RESULT:** The above sample is SUB-STANDARD, on the basis of Physical description as per USP.

i. Mr. Zafar Jahanzaib Meer, Pharmacist, Govt. Sub-Medical Store Depot, Maraka Lahore provided warranty/invoice DC no.00037 dated 11-07-2023, no. 00067 dated 01-08-2023, no. 000088 dated 09-08-2023 and no. 000101 Dated 18-08-2023 issued by M/ **Lisko Pharmaceuticals (Pvt) Ltd,**L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan
ii. Warrantor Portion was sent to M/**S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, and Pakistan.
iii. Copies of Test/ Analysis reports were sent to M/**S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan. In response, the firm challenged the report and requested for re-testing of the samples from Appellate Laboratory.
iv. Pursuant to the retesting request of the firm, the retesting requests of subject samples were placed in 28th committee meeting. During personal hearing, Firm withdraw their retesting requests.

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated. 06-12-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 12-12-2023 stating that:

During committee meeting, we highlighted ambiguities in all 28 DTL reports. Once again we would

like to highlight and discuss those ambiguities of DTL reports as below:

2. We would first like to highlight 5 major ambiguities regarding statement written by government

analyst:

Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed

Volume=120mL Determined volume = 120 mL.

(1) However, according to USP <1151> Pharmaceutical Dosage Forms;

A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

(11) Our suspension is translucent and not clear due to the presence of small micro Sized particles that can also be seen in our suspension. Although, we strongly claim that our particles can been seen in suspension via naked eye still particle size of solid particles must be considered and in our case, government analyst has ignored this fact before giving conclusive statement. If the solid particles are very small and uniformly dispersed, they may not be visible to naked eye resulting to a translucent appearance for the suspension. USP does not bound / specify suspended particles to be observed only via naked eye. Government analyst just wrote her observation without mentioning mode i.e. Naked eye, microscope, etc. regarding physical appearance of Parapol suspension.

Hence statement of government analyst regarding absence of suspended particles is Baseless. Government analyst has written in every DTL report that our sample is not suspension but she did not specify that if our sample is not suspension than what is it.? She just wrote definition of suspension from USP <1151> but she did not specify that if our sample is not biphasic preparation than what is it.? Government analyst claimed in every DTL report that all the test/s were performed

as per USP (Point no## 6) while it is to be noted that USP does not mention any test to distinguish biphasic preparation with monophasic preparation or any test to check absence or presence of suspended particles in preparation. Government analyst did not mention or consider any factors that affect physical appearance of suspension i.e particle size, shape, refractive index of suspended

Particles as well as the refractive index and viscosity of the liquid medium. Hence, conclusion on physical appearance of suspension cannot be solely determined by the presence of particles but also by the size and distribution of these particles within the liquid.

Here, we would also like to share discussion on above mentioned ambiguities during 28th committee meeting of PQCB. Government analyst was asked to give her stance for which she showed samples of Parapol suspension before committee members. Similarly, we brought Panadol Liquid (GSK) as it is a clear solution and we wanted to present it before the committee members so that honorable members can check physically and compare Parapol sample (Suspension claimed) with Panadol liquid (solution). Honorable committee members were convinced that sample of Parapol is not "clear" rather translucent in appearance.

We also shared reply of technical service manager of USP (Copy attached) before the committee members in which we inquired regarding test to distinguish between biphasic preparation and monophasic preparation. His reply was clear and precise that "I am not aware of any specific test to distinguish between two i.e monophasic and biphasic preparation". We also submitted documents (copies attached) of API purchased from Citi

Pharma in which it can be seen that they have supplied us micronized Paracetamol and this further support our stance i.e micronized particles of Paracetamol were present and Dispersed throughout the liquid.

b. We have written in our packaging material to SHAKE WELL BEFORE USE as our product is

suspension and particles may get settle at the bottom with the passage of time but we believe that

Government analyst did not follow instructions to shake our sample before taking out for testing. During the committee meeting, government analyst tried to pour our suspension into beaker without shaking and when honorable committee members asked her to shake it first then she replied that bubbles will form on shaking. This showed her mala fide intentions and we suspect same violation of testing protocols in our case.

c. We believed that government analyst must have conducted pharmacopeia test via USP before

giving final conclusion that samples of Parapol are not suspension and it does not contains solid

Particles. In all DTL reports, government analyst has just wrote her observation and used TA?

PHARMACEUTICAL DIVISION

Suspension definition of USP and did not mention any technique or any apparatus through which she checked presence or absence of particles or to prove her stance. When, honorable committee members asked government analyst to explain her stance against our claim for which she failed to mention any test from official pharmacopeia. She just said that she asked from USP via email. Her own statement during the committee meeting proved that she did not apply any applicable USP test on our product to check presence or absence of solid particles in our sample rather she relied on email which can never be the part of official testing.

We also highlighted one important point before the committee members that USP gives disclaimer statement I footer statement in all their email replies in which it is clearly stated that "this response has been provided for informational purpose only and should not be construed as an official interpretations of USP text or relied on to demonstrated compliance with USP standards or requirements" (Copy attached). While government analyst stated during meeting that reply she got from USP had no such disclaimer remarks and therefore we request honorable committee members to ask analyst to show that reply of USP directly logging into her account.

We are sure of this fact that disclaimer remarks are always present in USP replies and we suspect possibility of alteration in USP reply which will prove mala fide intention of Government analyst. We also request honorable committee members to share true facts with us as well as it is our right to check grounds on the basis of which all our samples were declared sub-standard.

6. During the committee meeting, we submitted formulation of Parapol suspension in which we highlighted presence 2 of suspending agents i.e. Xanthan gum and PVPK-30 and the only reason of these suspending agents in our formulation is to suspend and disperse solid particles throughout the liquid phase and therefore our product also complies definition of suspension

as per USP

i.e biphasic preparation consisting of solid particles dispersed throughout the liquid phase.

7. We strongly claim that our product is suspension and biphasic preparation and the statement regarding physical appearance by government analyst is baseless, yet DTL Lahore did discriminatory act in our case as government analyst declared all samples as sub-standard while DTL Lahore used to declare samples of different firms as misbranded on the basis of physical description in past. We had already submitted evidences in this regard and we are again submitting to prove discriminatory act in our case.

In the light of above facts and ambiguities, we willingly withdraw from re-testing request but we would again request honorable committee Of PQCB to declare all 28 reports by DTL Lahore as standard and allow it for consumption as the statement regarding physical appearance by government analyst is baseless while other test conducted on our samples are well within limits.

Personnel hearing notice(s) issued to accused person(s) vide dated 09-01-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 04-2023, 07-2023

Expiry Date: 04-2025, 07-2025

Sampling Date: 11-09-2023

Sent to DTL (Form 6): 11-09-2023

Date of receipt in DTL: 12-09-2023

DTL Report Date: 17-10-2023

Time Extension: N/A

1ST DI Communication with firm on dated: 24-10-2023

Date of Retesting Request of Firm: 31-10-2023

Fate of Retesting Request: - withdraw

Investigation Report Dated: 6-11-2023

PROCEEDINGS AND DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (operations) Primary & Secondary Healthcare department /Vice chairperson, PQCB. Hassan Saeed, Secretary DQCB, Lahore and Ubaidullah Anwar Inspector of drugs, MSD , Lahore were present along with original case record. Dr. Sarfaraz (Business unit Head) on behalf of M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

The case was leftover due to time constraints.

Case No. 10

No. PQCB/ MSS-175875, 175876/2023

MSD Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S Lisko Pakistan Pvt Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal 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 Limited, L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B Industrial Area Karachi .

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, MSD Lahore reported that:-

i. He on 11-09-2023 inspected the premises of Govt. Sub Sub-Medical Store Depot, Maraka Lahore took samples of subject drugs on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No. 175875,175876 Dated 11-09-2023.

ii. The following drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Lahore as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	039-24	M/S **Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10194003519/DTL dated 20-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* (DOES NOT COMPLY) **pH:**

				Determined: 5.4 AT 23.2º C (Complies) **IDENTIFICATION OF PARACETAMOL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **ASSAY OF PARACETAMOL:** Stated = 120mg/5mL Determined = 128.5mg/5mL Percentage = 107.08% Limit = 90.0%-110.0% of labelled amount **RESULT:** The above sample is SUB-STANDARD, on the basis of Physical description as per USP.
Suspension Parapol 120ml(Paracetamol USP 120 mg/5ml) **Mfg. Date**: 07-2023 **Exp. Date**: 07-2025 **Reg** # 002772	041-24	**M/S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	TRA #01-10194003514/DTL dated 20-10-2023 DTL Lahore	**Specification applied: USP 2023:** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.* **(DOES NOT COMPLY)** **pH:** Determined: 5.4 AT 23.3º C (Complies) **IDENTIFICATION OF PARACETAMOL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **ASSAY OF PARACETAMOL:** Stated = 120mg/5mL Determined = 129.06mg/5mL

				Percentage = 107.55% Limit = 90.0%-110.0% of labelled amount **RESULT:** The above sample is SUB-STANDARD, on the basis of Physical description as per USP.

i. Mr. Zafar Jahanzaib Meer, Pharmacist, Govt. Sub-Medical Store Depot, Maraka Lahore provided warranty/invoice DC no.00037 dated 11-07-2023, no. 00067 dated 01-08-2023, no. 000088 dated 09-08-2023 and no. 000101 Dated 18-08-2023 issued by M/ **Lisko Pharmaceuticals (Pvt) Ltd,**L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan
ii. Warrantor Portion was sent to M/**S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, and Pakistan.
iii. Copies of Test/ Analysis reports were sent to M/**S Lisko Pharmaceuticals (Pvt) Ltd,** L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan. In response, the firm challenged the report and requested for re-testing of the samples from Appellate Laboratory.
iv. Pursuant to the retesting request of the firm, the retesting requests of subject samples were placed in 28th committee meeting. During personal hearing, Firm withdraw their retesting requests.

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated. 06-12-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 12-12-2023 stating that:

During committee meeting, we highlighted ambiguities in all 28 DTL reports. Once again we would

like to highlight and discuss those ambiguities of DTL reports as below:

2. We would first like to highlight 5 major ambiguities regarding statement written by government

analyst:

Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed

Volume=120mL Determined volume = 120 mL.

(1) However, according to USP <1151> Pharmaceutical Dosage Forms;

A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.

(DOES NOT COMPLY)

(11) Our suspension is translucent and not clear due to the presence of small micro Sized particles that can also be seen in our suspension. Although, we strongly claim that our particles can been seen in suspension via naked eye still particle size of solid particles must be considered and in our case, government analyst has ignored this fact before giving conclusive statement. If the solid particles are very small and uniformly dispersed, they may not be visible to naked eye resulting to a translucent appearance for the suspension. USP does not bound / specify suspended particles to be observed only via naked eye. Government analyst just wrote her observation without mentioning mode i.e. Naked eye, microscope, etc. regarding physical appearance of Parapol suspension.

Hence statement of government analyst regarding absence of suspended particles is Baseless. Government analyst has written in every DTL report that our sample is not suspension but she did not specify that if our sample is not suspension than what is it.? She just wrote definition of suspension from USP <1151> but she did not specify that if our sample is not biphasic preparation than what is it.? Government analyst claimed in every DTL report that all the test/s were performed

as per USP (Point no## 6) while it is to be noted that USP does not mention any test to distinguish biphasic preparation with monophasic preparation or any test to check absence or presence of suspended particles in preparation. Government analyst did not mention or consider any factors that affect physical appearance of suspension i.e particle size, shape, refractive index of suspended

Particles as well as the refractive index and viscosity of the liquid medium. Hence, conclusion on physical appearance of suspension cannot be solely determined by the presence of particles but also by the size and distribution of these particles within the liquid.

Here, we would also like to share discussion on above mentioned ambiguities during 28th committee meeting of PQCB. Government analyst was asked to give her stance for which she showed samples of Parapol suspension before committee members. Similarly, we brought Panadol Liquid (GSK) as it is a clear solution and we wanted to present it before the committee members so that honorable members can check physically and compare Parapol sample (Suspension claimed) with Panadol liquid (solution). Honorable committee members were convinced that sample of Parapol is not "clear" rather translucent in appearance.

We also shared reply of technical service manager of USP (Copy attached) before the committee members in which we inquired regarding test to distinguish between biphasic preparation and monophasic preparation. His reply was clear and precise that "I am not aware of any specific test to distinguish between two i.e monophasic and biphasic preparation". We also submitted documents (copies attached) of API purchased from Citi Pharma in which it can be seen that they have supplied us micronized Paracetamol and this further support our stance i.e micronized particles of Paracetamol were present and Dispersed throughout the liquid.

b. We have written in our packaging material to SHAKE WELL BEFORE USE as our product is

suspension and particles may get settle at the bottom with the passage of time but we believe that

Government analyst did not follow instructions to shake our sample before taking out for testing. During the committee meeting, government analyst tried to pour our suspension into beaker without shaking and when honorable committee members asked her to shake it first then she replied that bubbles will form on shaking. This showed her mala fide intentions and we suspect same violation of testing protocols in our case.

c. We believed that government analyst must have conducted pharmacopeia test via USP before

giving final conclusion that samples of Parapol are not suspension and it does not contains solid

Particles. In all DTL reports, government analyst has just wrote her observation and used TA?

PHARMACEUTICAL DIVISION

Suspension definition of USP and did not mention any technique or any apparatus through which she checked presence or absence of particles or to prove her stance. When, honorable committee members asked government analyst to explain her stance against our claim for which she failed to mention any test from official pharmacopeia. She just said that she asked from USP via email. Her own statement during the committee meeting proved that she did not apply any applicable USP test on our product to check presence or absence of solid particles in our sample rather she relied on email which can never be the part of official testing.

We also highlighted one important point before the committee members that USP gives disclaimer statement I footer statement in all their email replies in which it is clearly stated that "this response has been provided for informational purpose only and should not be construed as an official interpretations of USP text or relied on to demonstrated compliance with USP standards or requirements" (Copy attached). While government analyst stated during meeting that reply she got from USP had no such disclaimer remarks and therefore we request honorable committee members to ask analyst to show that reply of USP directly logging into her account.

We are sure of this fact that disclaimer remarks are always present in USP replies and we suspect possibility of alteration in USP reply which will prove mala fide intention of Government analyst. We also request honorable committee members to share true facts with us as well as it is our right to check grounds on the basis of which all our samples were declared sub-standard.

6. During the committee meeting, we submitted formulation of Parapol suspension in which we highlighted presence 2 of suspending agents i.e. Xanthan gum and PVPK-30 and the only reason of these suspending agents in our formulation is to suspend and disperse solid particles throughout the liquid phase and therefore our product also complies definition of suspension as per USP

i.e biphasic preparation consisting of solid particles dispersed throughout the liquid phase.

7. We strongly claim that our product is suspension and biphasic preparation and the statement regarding physical appearance by government analyst is baseless, yet DTL Lahore did discriminatory act in our case as government analyst declared all samples as sub-standard

while DTL Lahore used to declare samples of different firms as misbranded on the basis of physical description in past. We had already submitted evidences in this regard and we are again submitting to prove discriminatory act in our case.

In the light of above facts and ambiguities, we willingly withdraw from re-testing request but we would again request honorable committee Of PQCB to declare all 28 reports by DTL Lahore as standard and allow it for consumption as the statement regarding physical appearance by government analyst is baseless while other test conducted on our samples are well within limits.

Personnel hearing notice(s) issued to accused person(s) vide dated 09-01-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 04-2023, 07-2023

Expiry Date: 04-2025, 07-2025

Sampling Date: 11-09-2023

Sent to DTL (Form 6): 11-09-2023

Date of receipt in DTL: 12-09-2023

DTL Report Date: 17-10-2023

Time Extension: N/A

1ST DI Communication with firm on dated: 24-10-2023

Date of Retesting Request of Firm: 31-10-2023

Fate of Retesting Request: - withdraw

Investigation Report Dated: 6-11-2023

PROCEEDINGS AND DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (operations) Primary & Secondary Healthcare department /Vice chairperson, PQCB. Hassan Saeed, Secretary DQCB, Lahore and Ubaidullah Anwar Inspector of drugs, MSD, Lahore were present along with original case record. Dr. Sarfaraz (Business unit Head) on behalf of M/s Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan

The case was leftover due to time constraints.

Case No. 11

PQCB/MSS-176620,176621,176622/2023

District Headquarter Hospital Kasur, District Kasur

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-Pakistan** 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-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, District Headquarter Hospital Kasur, District Kasur reported that:

i. She, on 27-09-2023, inspected the premises of Main Medicine Store District Headquarter Hospital Kasur, District Kasur, took four 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 Lahore vide memorandum no. 176620, 176621 & 176622 all dated 27-09-2023.

ii. The following drug samples after test/analyses were declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Sr. No.	Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
1	Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg Date:** July 2023 **Expiry Date:** July 2025	058-24	M/S Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21 Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	01-10194003647/DTL dated 23-10-2023	**Analysis with specifications applied: USP 2023** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation **free from any suspended solid particles** in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120 mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*. **(DOES NOT COMPLY)** **pH:**

	Regn No. 002772				Determined: 5.4 at 24.8º C (Complies) **<u>IDENTIFICATION OF PARACETAMOL:</u>** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **<u>ASSAY OF PARACETAMOL:</u>** Stated= 120 mg/5 mL Determined= 128.85 mg/5 mL Percentage= 107.37% Limit= 90.0%-110.0% of labelled amount **<u>RESULT:</u>** The above sample is **<u>SUB-STANDARD</u>**, on the basis of Physical description as per USP.
2.	Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg Date:** July 2023 **Expiry Date:** July 2025 **Regn No.** 002772	061-24	M/S Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21 Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	01-10194003645/DTL dated 23-10-2023	**Analysis with specifications applied: USP 2023** **<u>PHYSICAL APPEARANCE:</u>** Pink coloured clear viscous liquid preparation **free from any suspended solid particles** in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120 mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*. **(DOES NOT COMPLY)** **<u>pH:</u>** Determined: 5.3 at 24.9º C (Complies) **<u>IDENTIFICATION OF PARACETAMOL:</u>** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **<u>ASSAY OF PARACETAMOL:</u>** Stated= 120 mg/5 mL Determined= 128.86 mg/5 mL Percentage= 107.39%

					Limit= 90.0%-110.0% of labelled amount **RESULT:** The above sample is **SUB-STANDARD**, on the basis of Physical description as per USP.
3.	Suspension Parapol 120ml (Paracetamol USP 120 mg/5ml) **Mfg Date:** July 2023 **Expiry Date:** July 2025 **Regn No.** 002772	060-24	M/S Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21 Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	01-10194003646/DTL dated 23-10-2023	**Analysis with specifications applied: USP 2023** **PHYSICAL APPEARANCE:** Pink coloured clear viscous liquid preparation **free from any suspended solid particles** in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed volume=120 mL. Determined volume = 120 mL. However, according to USP <1151> Pharmaceutical Dosage Forms; *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase*. **(DOES NOT COMPLY)** **pH:** Determined: 5.4 at 24.8º C (Complies) **IDENTIFICATION OF PARACETAMOL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Paracetamol identified). **ASSAY OF PARACETAMOL:** Stated= 120 mg/5 mL Determined= 131.30 mg/5 mL Percentage= 109.42% Limit= 90.0%-110.0% of labelled amount **RESULT:** The above sample is **SUB-STANDARD**, on the basis of Physical description as per USP.

iii. Storekeeper Main Medicine Store District Headquarter Hospital Kasur, District Kasur provided invoice/warranty bearing No. 000198 dated 13-09-2023 issued by M/S Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan as a proof of its purchase of subject drug samples.

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

v. Copies of test/analyses reports were sent to M/S Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan with directions to explain their position and provide

requisite information in this regard. In response, the firm challenged the test/analysis reports and requested to re-test the above-mentioned drug samples from Appellate Laboratory, National Institute of Health, Islamabad.

Previous Proceedings & Decision by the Committee:

29th meeting held on 30-11-2023

2. The subject request for retesting of the drug sample was placed before the Committee Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **29th meeting** held on **30-11-2023** under the chair of Additional Secretary (Drug Control) Co-Convener of Committee, Provincial Quality Control Board, Punjab. Dr. Sarfaraz Business Unit Head of M/S Lisko Pharmaceuticals (Pvt) Ltd appeared before the committee of Provincial Quality Control Board to plead the case. The Secretary PQCB apprised that Drug Testing Laboratory report conveyed by the Provincial inspector of Drugs to manufacturer vide letter No210/DI dated 02-11-2023. Manufacturer requested for retesting vide letter no. Nil dated 01-11-2023.

3. The office of the Secretary Provincial Quality Control Board asked the firm to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. PQCB-MSS176620,176622,176621 dated 20-11-2023 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 batches. The firm appeared before the committee and submitted withdrawal request vide letter no Nil dated 30-11-2023. 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. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 29-12-2023

Firm replied to the show cause notice vide letter dated 16-01-2024

We appeared before the honorable committee members of PQCB in 29" committee meeting on 30-11-2023 and give our stance in detail related to above DTL reports by DTL Lahore. Once again, we would like to give our stance and reservations in the reports of DTL Lahore regarding our product:

1. *We submitted our formulation of suspension at the time of registration and after considering our formulation, we were given registration of " **Suspension** Parapol 120mg/5ml" having DRC no# 002772 from DRAP (formerly known as Ministry of Health, Pakistan) on 26 Sep 1977. It's **been registered with DRAP for last 46 years** and by the grace of Almighty, we are regularly supplying this product in market and government health institutions for last 46 years.*
2. *Here we would like to draw your attention towards no. of reports of Parapol suspension declared standard in last 6 financial years from different DTLs of Punjab. **We have 479 standard reports of Parapol suspension of same formulation** in which government analysts of all DTLs declared our samples standard after checking physical characteristics, assay and applying other*

applicable pharmacopeia tests

Sr. no.	*Financial Year*	*No. of batches tested in* ***DTL Lahore***	*No. of batches tested in* ***DTL Rawalpindi***	*No. of batches tested in* ***DTL Multan***	*No. of batches tested in* ***DTL Bahawalpur***	*No. of batches tested in* ***DTL Faisalabad***	*Total standard reports of Parapol suspension in single financial year*
1	*2018-19*	*11*	*10*	*17*	*21*	*22*	*81*
2	*2019-20*	*6*	*8*	*24*	*18*	*24*	*80*
3	*2020-21*	*149*	*1*	*9*	*8*	*8*	*175*
4	*2022-23*	*61*	*6*	*13*	*8*	*3*	*91*
5	*2023-24*	*0*	*0*	*0*	*3*	*0*	*3*
Total no. of batches declared standard by DTL		*226*	*25*	*63*	*58*	*54*	***426***
Total no. of standard reports by DTL		*233*	*28*	*80*	*76*	*62*	***479***

Above claim of standard reports can be verified from all DTLs and we can produce its evidence in personal hearing as well.

3. *DTL Lahore has issued* ***233 standard reports*** *of Parapol suspension in last 6 financial years. In all the standard reports, it was mentioned that "the above sample of suspension Parapol is of standard quality". Supplied Batches that were declared standard and batches that were declared sub-standard can be compared that both are same in appearance and have same physical characteristics. DTL Lahore kept declaring our product Parapol susp as standard till 30" August 2023 (TRA no # 0110194003122 and 01-10194003123) and now all of sudden, government analyst of DTL Lahore started declaring our samples as sub-standard on the basis of physical description while all other parameters are well within limit.*
4. *As discussed in the 28" committee meeting, we would again like to draw your attention towards the Very important point that some of the batches that are declared sub-standard by DTL Lahore on the Dasis of physical description were declared standard quality by other DTLs of Punjab i.e DTL Bhawalpur, DTL Faisalabad and DTL Multan (reports attached) with the*

statement ***"Sample of Parapol Suspension is of standard quality with regards to tests: Physical test, identification & assay test performed".*** *Details are as below:*

Batch No.	***Standard Report by another DTL***	***Substandard Report by DTL Lahore***
294-23	***DTL Bahawalpur*** *TRA No. 01-10097004530 dated 27-07-2023*	***DTL Lahore*** *TRA No. 01-10206000074 dated 17-10-2023*
033-24	***DTL Bahawalpur*** *TRA No. 01-10097004752 dated 28-08-2023*	***DTL Lahore*** *TRA No. 01-10206000078 dated 17-10-2023*
041-24	***DTL Multan*** *TRA No. 01-105004272 dated 15-09-2023*	***DTL Lahore*** *TRA No. 01-10194003514 dated 20-10-2023*
046-24	***DTL Faisalabad*** *TRA No. 01-68025999 dated 06-10-2023*	***DTL Lahore*** *TRA No. 01-10194003513 dated 20-10-2023*

During 28th committee meeting, we highlighted ambiguities in all 28 DTL reports. Once again we would like to highlight and discuss those ambiguities of DTL reports as below:

a. *We would first like to highlight 5 major ambiguities regarding statement written by government analyst:*

> *Pink coloured clear viscous liquid preparation free from any suspended solid particles in amber colored plastic bottle having label pasted on it, with a sealed white plastic screw cap. Claimed*
>
> *Volume=120mL Determined volume = 120 mL.*
>
> *(1) However, according to USP <1151> Pharmaceutical Dosage Forms;*
>
> *A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase.*
>
> *(DOES NOT COMPLY)*

i. ***Our suspension is translucent and not clear*** *due to the presence of small micro Sized particles that can also be seen in our suspension. Although, we strongly claim that our particles can been seen in suspension via naked eye still particle size of solid particles must be considered and in our case, government analyst has ignored this fact before giving conclusive statement.* ***If the solid particles are very small and uniformly dispersed, they may not be visible to naked eye resulting to a translucent appearance*** *for the suspension.*

ii. ***USP does not bound / specify suspended particles to be observed only via naked eye.*** *Government analyst just wrote her observation without mentioning mode i.e. Naked eye,*

microscope, etc. regarding physical appearance of Parapol suspension. Hence statement of government analyst regarding absence of suspended particles is Baseless.

iii. *Government analyst has written in every DTL report that our sample is not suspension but she did not specify that* ***if our sample is not suspension than what is it.?*** *She just wrote definition of suspension from USP <1151> but she did not specify that if our sample is not biphasic preparation than what is it.?*

iv. *Government analyst claimed in every DTL report that all the test/s were performed as per USP (Point no## 6) while it is to be noted that* ***USP does not mention any test to distinguish biphasic preparation with monophasic preparation or any test to check absence or presence of suspended particles in preparation.***

v. *Government analyst did not mention or consider any* ***factors that affect physical appearance of suspension i.e particle size, shape, refractive index of suspended particles as well as the refractive index and viscosity of the liquid medium.*** *Hence, conclusion on physical appearance of suspension cannot be solely determined by the presence of particles but also by the size and distribution of these particles within the liquid.*

Here, we would also like to share discussion on above mentioned ambiguities during 28th committee meeting of PQCB. Government analyst was asked to give her stance for which she showed samples of Parapol suspension before committee members. Similarly, we brought Panadol Liquid (GSK) as it is a clear solution and we wanted to present it before the committee members so that honorable members can check physically and compare Parapol sample (Suspension claimed) with Panadol liquid (solution). ***Honorable committee members were convinced that sample of Parapol is not "clear" rather translucent in appearance.***

We also shared ***reply of technical service manager of USP*** *before the committee members in which we inquired regarding test to distinguish between biphasic preparation and monophasic preparation. His reply was clear and precise that "I am not aware of any specific test to distinguish between two i.e monophasic and biphasic preparation". We also submitted documents (copies attached) of API purchased from Citi Pharma in which it can be seen that they have supplied us micronized Paracetamol and this further support our stance i.e micronized particles of Paracetamol were present and Dispersed throughout the liquid.*

b. *We have written in our packaging material to* ***SHAKE WELL BEFORE USE*** *as our product is suspension and particles may get settle at the bottom with the passage of time but* ***we believe that Government analyst did not follow instructions to shake our sample before taking out for testing****. During the committee meeting, government analyst tried to pour our suspension into beaker without shaking and when honorable committee members asked her to shake it first then she replied that bubbles will form on shaking. This showed her mala fide intentions and we suspect same violation of testing protocols in our case.*

c. We believed that government analyst must have conducted pharmacopeia test via USP before giving final conclusion that samples of Parapol are not suspension and it does not contain solid

Particles. In all DTL reports, government analyst has just written her observation and used TA?

PHARMACEUTICAL DIVISION Suspension definition of USP <1151> and did not mention any ***technique or any apparatus through which she checked presence or absence of particles or*** *to prove her stance. When, honorable committee members asked government analyst to explain her stance against our claim for which she failed to mention any test from official pharmacopeia. She just said that* ***she asked from USP via email. Her own statement during the committee meeting proved that she did not apply any applicable USP test on our product*** *to check presence or absence of solid particles in our sample rather* ***she relied on email which can never be the part of official testing****.*

*We also highlighted one important point before the committee members that **USP gives disclaimer statement I footer statement in all their email replies** in which it is clearly stated that "**this response has been provided for informational purpose only and should not be construed as an official interpretation of USP text or relied on to demonstrated compliance with USP standards or requirements"**. While government analyst stated during meeting that reply she got from USP had no such disclaimer remarks and therefore **we request honorable committee members to ask analyst to show that reply of USP directly logging into her account**.*

We are sure of this fact that disclaimer remarks are always present in USP replies and we suspect possibility of alteration in USP reply which will prove mala fide intention of Government analyst. We also request honorable committee members to share true facts with us as well as it is our right to check grounds on the basis of which all our samples were declared sub-standard.

*6. During the 28th committee meeting, we submitted formulation of Parapol suspension in which we highlighted **presence of 2 suspending agents i.e. Xanthan gum and PVPK-30** and the only reason of these suspending agents in our formulation is **to suspend and disperse solid particles throughout the liquid phase** and therefore our product also complies definition of suspension as per USP i.e biphasic preparation consisting of solid particles dispersed throughout the liquid phase.*

*7. We strongly claim that our product is suspension and biphasic preparation and the statement regarding physical appearance by government analyst is baseless, **yet DTL Lahore did discriminatory act in our case** as government analyst declared all samples as sub-standard while **DTL Lahore used to declare samples of different firms as misbranded on the basis of physical description in past**. We had already submitted evidences in this regard and we are again submitting to prove discriminatory act in our case.*

*In the light of above facts and ambiguities, we willingly withdraw from re-testing request but **we would again request honorable committee of PQCB to declare all 3 reports by DTL Lahore as standard and allow it for consumption** as the statement regarding physical appearance by government analyst is baseless while other test conducted on our samples are well within limits.*

We once again request honorable committee members of PQCB to decide this case on merit and do justice with best of their expertise and technical knowledge.

4. Personal hearing notice(s) issued to accused person(s) dated 20-02-2024

5. Cases are placed before the Board for decision.

Summary:

(For Batch No. 058-24, 061-24 & 060-24)

Manufacturing Date: July 2023

Expiry Date: July 2025

Sampling Date (Form 4): 27-09-2023

Sent to DTL (Form 6): 27-09-2023

Date of receipt in DTL: 28-09-2023

DTL Report Date (Form 7): 23-10-2023

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 02-11-2023

Retesting Request of Firm: Yes (01-11-2023)

Fate of Retesting Request: Withdrawn by firm on 30-11-2023; Withdrawal accepted in 29th Committee Meeting Dated 30-11-2023

Investigation Report Dated: 20-11-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 12

PQCB/MSS--175630/2023

THQ Bhalwal, 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-Pakistan** 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-Pakistan.

Provincial Inspector of Drugs, Tehsil Bhalwal, District Sargodha reported that:

i. She, on 14-09-2023, inspected the premises of Main Medicine Store Tehsil Headquarter Hospital Bhalwal, District Sargodha, took following drug sample on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Rawalpindi vide memorandum no. 175630 dated 27-09-2023.
ii. The following drug samples after test/analyses were 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
Suspension Parapol 120ml (Paracetamol: 120 mg/5ml) **Mfg Date:** July 2023 **Expiry Date:** July 2025 **Regn No.**	053-24	M/S Lisko Pharmaceuticals (Pvt) Ltd, L-10 D Block no. 21 Shaheed Rashid Minhas Road Federal B Industrial Area, Karachi, Pakistan	01-75007523/DTL dated 17-10-2023	**Analysis with specifications applied: USP 2023** **PHYSICAL APPEARANCE:** Pinkish Red colored liquid, filled in amber coloured glass 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:** Determined: 5.39 (Complies the test) Limit: 4.0 – 6.9 **IDENTIFICATION:**

002772				Paracetamol Identified. (Complies the test) **ASSAY:** Stated: 120 mg/5 mL Determined: 123.207 mg/5 mL Percentage: 102.67% (Complies the test) Limit: 90 %-110 % **RESULT: The above sample is "Substandard", on the basis of Physical description as per USP.**

iii. Main Medicine Store Tehsil Headquarter Hospital Bhalwal, District Sargodha provided invoice/warranty bearing No. 000167 dated 09-09-2023 issued by M/S Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan as a proof of its purchase.

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

v. A copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to the request of M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan the Committee of PQCB in its 29th Committee Meeting of the Board held on 30-11-2023 decided to accept the firm's request for withdrawal of the retesting request of the subject drug sample

2. In this way You have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under by the way of: -

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

b. **Issuance of false warranty**

3. Showcause Notice(s) issued to accused person(s) dated 29-12-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 16-01-2024 stating that:

With reference to show cause notices received on 11-1-2024 (letter no# MSS-175630/2023), we would like to give our stance with supportive documents related to our case in which DTL Lahore has declared samples of Parapol susp 120mg/5ml as s sub-standard on the basis of physical description.

Details of sub-standard batches of Parapol suspension 120mg/5ml from DTL Rawalpindi are as below:

S. No.	*LAB/DTL*	*BATCH NO:*	*TRA NO.*	*DATE OF RESULT*

1	*Rawalpindi*	*053-24*	*01-75007523/DTL*	*17-10-2023*

We appeared before the honorable committee members of P¿CB in 29" committee meeting on 30-11-2023 and give our stance in detail to above DTL reports by DTL Rawalpindi. Once again, we would like to give our stance and reservations in the reports of DTL Lahore regarding our product:

1 We submitted our formulation of suspension at the time of registration and after considering our

formulation, we were given registration of "Suspension Parapol 120mg/5ml" having DRC no#

002772 from DRAP (formerly known as Ministry of Health, Pakistan) on 26" Sep 1977. It's been registered with DRAP for last 46 years and by the grace of Almighty, we are regularly supplying this product in market and government health institutions for last 46 years.

2. Here we would like to draw your attention towards no. of reports of Parapol suspension declared

Standard in last 6 financial years from different DTLs of Punjab. ***We have 479 standard reports of***

Parapol suspension of same formulation *in which government analysts of all DTLs declared our*

samples standard after checking physical characteristics, assay and applying other applicable

Pharmacopeia tests.

S. no.	*Financial Year*	*No. of batches tested in* ***DTL Lahore***	*No. of batches tested in* ***DTL Rawalpindi***	*No. of batches tested in* ***DTL Multan***	*No. of batches tested in* ***DTL Bahawalpur***	*No. of batches tested in* ***DTL Faisalabad***	*Total standard reports of Parapol suspension in single financial year*
1	*2018-19*	*11*	*10*	*17*	*21*	*22*	*81*
2	*2019-20*	*6*	*8*	*24*	*18*	*24*	*80*
3	*2020-21*	*149*	*1*	*9*	*8*	*8*	*175*
4	*2022-23*	*61*	*6*	*13*	*8*	*3*	*91*
5	*2023-24*	*0*	*0*	*0*	*3*	*0*	*3*

Total no. of batches declared standard by DTL	*226*	*25*	*63*	*58*	*54*	***426***
Total no. of standard reports by DTL	*233*	*28*	*80*	*76*	*62*	***479***

Above claim of standard reports can be verified from all DTLs and we can produce its evidence in personal hearing as well.

*DTL Rawalpindi has issued **28 standard reports** of Parapol suspension in last 6 financial year. In all the standard reports, it was mentioned that "the above sample of **suspension Parapol** is of standard Quality". Supplied Batches that were declared standard and batches that were declared sub-standard can be compared that both are same in appearance and have same physical characteristics. **DTL Rawalpindi kept declaring our product Parapol susp as standard till 4h Oct 2023** (TRA no # 01-74008418 and 01-74008420) and now all of sudden, government analyst of DTL Rawalpindi started declaring our samples as sub-standard on the basis of physical description while all the samples complies in assay results.*

During 28th committee meeting, we highlighted ambiguities in DTL reports. Once again we would

like to highlight and discuss those ambiguities of DTL reports as below:

2. We would first like to highlight major ambiguities regarding statement written by government

Analyst "Clear viscous solution".

*(i) Our suspension is translucent and not clear due to the presence of small micro Sized particles that can also be seen in our suspension. Although, we strongly claim that our particles can been seen in suspension via naked eye still particle size of solid particles must be considered and in our case, government analyst has ignored this fact before giving conclusive statement. **If the solid particles are very small and uniformly dispersed, they may not be visible to naked eye resulting to a translucent appearance** for the suspension.*

*(ii) **USP does not bound / specify suspended particles to be observed only via naked eye**. Government analyst just wrote her observation without mentioning mode i.e. Naked eye, microscope, etc. regarding physical appearance of Parapol suspension.*

Hence statement of government analyst regarding absence of suspended particles is Baseless.

(iii) Government analyst claimed in every DTL report that all the test/s were performed

*as per USP (Point no## 6) while it is to be noted that **USP does not mention any test to distinguish biphasic preparation with monophasic preparation or any test to check absence or presence of suspended particles in preparation.***

*(iv) Government analyst did not mention or consider any **factors that affect physical appearance of suspension i.e particle size, shape, refractive index of suspended Particles as well as the refractive index and viscosity of the liquid medium**.*

Hence, conclusion on physical appearance of suspension cannot be solely determined by the presence of particles but also by the size and distribution of these particles within the liquid.

Here, we would also like to share discussion on above mentioned ambiguities during 28th committee meeting of PQCB. Government analyst was asked to give her stance for which she showed samples of Parapol suspension before committee members. Similarly, we brought Panadol Liquid (GSK) as it is a clear solution and we wanted to present it before the committee members so that honorable members can check physically and compare Parapol sample (Suspension claimed) with Panadol liquid (solution). ***Honorable committee members were convinced that sample of Parapol is not "clear" rather translucent in appearance****.*

We also shared ***reply of technical service manager of USP (Copy attached)*** *before the committee members in which we inquired regarding test to distinguish between biphasic preparation and monophasic preparation. His reply was clear and precise that "****I am not aware of any specific test to distinguish between two i.e monophasic and biphasic preparation****". We also submitted documents (copies attached) of* ***API purchased from Citi Pharma*** *in which it can be seen that they have supplied us micronized Paracetamol and this further support our stance* ***i.e micronized particles of Paracetamol were present and Dispersed throughout the liquid.***

b. We have written in our packaging material to ***SHAKE WELL BEFORE USE*** *as our product is*

suspension and particles may get settle at the bottom with the passage of time but ***we believe that***

Government analyst did not follow instructions to shake our sample before taking out for testing*. During the 28th committee meeting, government analyst tried to pour our suspension into beaker* ***without shaking*** *and when honorable committee members asked her to shake it first then she replied that bubbles will form on shaking. This showed her mala fide intentions and we suspect same violation of testing protocols in our case.*

c. We believed that government analyst must have conducted pharmacopeia test via USP before

giving final conclusion that samples of Parapol are not suspension and it does not contains solid

Particles. In all DTL reports, government analyst has just wrote her observation and used Suspension definition of USP <1151> and did not mention any ***technique or any apparatus through which she checked presence or absence of particles*** *or to prove her stance. When, honorable committee members asked government analyst to explain her stance against our claim for which she failed to mention any test from official pharmacopeia. She just said that* ***she asked from USP via email. Her own statement during the committee meeting proved that she did not apply any applicable USP test on our product*** *to check presence or absence of solid particles in our sample rather she relied on email which can never be the part of official testing.*

We also highlighted one important point before the 28th committee members that ***USP gives disclaimer statement/footer statement in all their email replies*** *in which it is clearly stated that "****this response has been provided for informational purpose only and should not be construed as an official interpretations of USP text or relied on to demonstrated compliance with USP standards or requirements"*** *(Copy attached). While government analyst stated*

during meeting that reply she got from USP had no such disclaimer remarks and therefore ***we request honorable committee members to ask analyst to show that reply of USP directly logging into her account.***

We are sure of this fact that disclaimer remarks are always present in USP replies and we suspect possibility of alteration in USP reply which will prove mala fide intention of Government analyst. We also request honorable committee members to share true facts with us as well as it is our right to check grounds on the basis of which all our samples were declared sub-standard.

6. During the 28th committee meeting, we submitted formulation of Parapol suspension in which we highlighted ***presence 2 of suspending agents i.e. Xanthan gum and PVPK-30*** *and the only reason of these suspending agents in our formulation is to* ***suspend and disperse solid particles throughout the liquid phase*** *and therefore our product also complies definition of suspension as per USP<1151> i.e biphasic preparation consisting of solid particles dispersed throughout the liquid phase.*

5. We strongly claim that our product is suspension and biphasic preparation and the statement regarding physical appearance by government analyst is baseless, yet ***DTL Lahore and DTL Rawalpindi did discriminatory act in our case*** *as government analyst declared all samples as sub-standard while* ***DTL Lahore used to declare samples of different firms as misbranded on the basis of physical description in past****. We had already submitted evidences in this regard and we are again submitting to prove discriminatory act in our case.*

In the light of above facts and ambiguities, we willingly withdraw from re-testing request ***but we would again request honorable committee Of PQCB to declare all 28 reports by DTL Lahore as standard and allow it for consumption*** *as the statement regarding physical appearance by government analyst is baseless while other test conducted on our samples are well within limits.*

4. Personal Hearing notice(s) issued to accused person(s) dated 20-02-2024.

Summary:

Manufacturing Date: 07-2023

Expiry Date: 07-2025

Sampling date (Form-4): 14-09-2023

Date of receipt in DTL: 21-09-2023

DTL Report date: 17-10-2023

Date of Retesting Request of Firm: Withdraw Retesting Request in 29th Meeting dated 30-11-2023.

Investigation Report dated: 15-11-2023

PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 13

PQCB/SM-05-02/2023

DHQ Hospital, Sheikupura

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad** through its Chief Operating Officer Nadeem Panjtan 2. Nadeem Panjtan Chief Operating Officer 3. Mudassar Nawaz Production In-charge 4. Shaukat Iqbal Quality Control In-charge/ Warrantor **of M/S Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, DHQ Hospital, Sheikhupura reported that: -

i. She, on 05-10-2022, inspected the premises of Drug Complex, DHQ Hospital Sheikhupura, Lahore-Sargodha Road, near Jinnah Park Sheikhupura and recovered and seized below mentioned drug on Form No.05 as detailed below:

Sr.NO.	Name of drugs	Batch No.	Name of Manufacturer	Quantity	Reason of Seizure
1.	Visolact (Lactated ringer's Injection) 1000 ml U.S.P. Reg.# 078034	F21032	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23 Industrial Triangle Kahuta Road, Islamabad, Pakistan.	01 Infusion	Visible black colour particulate matter with approximately 2 inches in size. Stocking/ Purchasing/ Manufacturing/ Manufacture for sale of Adulterated Drugs (containing free-floating visible black color particulate matter)

ii. Drug Complex, DHQ Hospital Sheikhupura, Lahore-Sargodha Road, near Jinnah Park Sheikhupura provided delivery challan no. 149000001488, dated 30-06-2022 provided by MSD/ DGHS, Punjab. Government Medical Store Depot provided invoice/ warranty/ Delivery Challan number 702965 dated 04-07-2021 issued by M/s Vision Pharmaceuticals (Pvt.) Ltd. 22-23, Industrial Triangle, Kahuta Road, Islamabad.

iii. M/s Vision Pharmaceuticals (Pvt.) Ltd. 22-23, Industrial Triangle, Kahuta Road, Islamabad were directed to explain their position and provide requisite information in this regard.

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 and Rules framed there under by the way of :-

a. **Manufacture for sale/Sale of Adulterated drug**
b. **Issuance of false warranty**

REPLY OF THE FIRM:

Refer to your Letter No. PQCB/SM-05-02/2023, Dated 08/06/2023 regarding Show Cause Notice received us on 16-06-2023 in which Provincial Inspector of Drugs. DHO Hospital, Sheikhupura during aforementioned inspection, undersigned identified only one bottle of infusion Visolact 1000ml Batch No F21032 which is intact transparent plastic bottle bearing green color label, closed with company plastic seal containing transparent solution and black color free floating particulate matter with approximately 2 inches in size (Adulteration) This aforementioned drug was seized and recorded on form -5 in contravention with provision of Drug act 1976 of the DRAP Act, 2012 and rules framed therein. The seizure was affected for the stocking/manufacturing//manufacturing for sale of adulterated drugs.

1. Vision Pharmaceuticals (Pvt) Ltd producing Visolact 1000ml (Infusion Ringer Lactate) in LDPE through BFS technology, which is very safe and automatic process and there is no human contact with the product during filling process
2. So many steps involved like raw water filtration through multimedia, softening of water. Double RO process, D-ionization, Distillation and filtration "Solution of Infusion Ringer lactate passing through filters of 1.2µ (0.66 0.45)µ and finally 0.2u" before filling process, after filling LDPE Bottles are sterilized through Autoclave
3. BET is verified at all stages, Distillation Process, after collection of bulk water, ready for manufacturing process", filing tanks and filing nozzles are also verified for BET before filling process
4. After sterilization of filled LOPE Botties, randomly collected Bottles are analyzed for chemical and microbiological analysis including BET
5. It is not possible that after involving so many steps filled LDPE Bottles become contaminated
6. All bottles 100% checked optically for intactness & particles through optical inspection in white and black background with florescence light lamps having LUX 6000 to 8000, leaked test of all bottles also verified by leak test machine.
7. Optical checkers are experienced and well trained; regular eye sight is also checked for all optical checkers as per GMP guidelines and their data is well maintained
8. Our QC/QA lab is ISO 17025 Accredited which is a certification for validity of tests' That renders the authenticity of our tests.
9. We have produced approx. 8700 to 8800 in each batch and such black particulate matter as mentioned, not observed in any other institution/hospital ever, nor it was ever complained by any other institution/hospital
10. According to Report of Test/Analysis by Government Analyst, Punjab DTL Lahore sample collected & submitted to DTL Lahore of the same batch is of standard Quality
11. We have supplied numbers of batches of same product all over the country and all batches are clear from all different DTL, this shows that our system is as per GMP standard and validated.
12. Similarly, its retain sample are of standard quality and comply to specifications
13. Single bottle left in the stock, that was complained for black particle, may be a damaged bottle due to mishandling of bottle during storage that cause any puncture in the bottle.
14. Due to puncher or pin hole black particle and other contamination produce in the bottle.
15. It is clearly mention at the label of bottle (Caution: Do not use if the solution is turbid, contains foreign matter or the bottle is leaking) in both English and Urdu
16. We are confident on our product that is particulate free, pyrogenic free and sterile product.
17. We have already requested to the Drugs Inspector to provide us sample containing black color particle in infusion bottles for Investigation but still not provided.

Summary:

Sampling date: 05-10-2022

Date of Retesting Request of Firm: No

Investigation Report dated: 13-02-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 14

PQCB/R-872/2019

Data Gunj Baksh Town, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan** through its Chief Operating Officer, Nadeem Panjatan 2. Nadeem Panjatan — Chief Operating Officer 3. Imran Khan — Production Incharge 4. Muhammad Irfan Bhatti — Quality Control Incharge 5. Waheed Shah — Warrantor of M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Data Gunj Baksh Town, District Lahore reported that: -

i. His predecessor, on 28-09-2019, inspected the premises of Main Medicine Store office of the CEO (DHA) 24-Cooper Road Lahore, took five different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide memorandum no. 49647 dated 29-09-2019.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Tablet. MEDICLOP [Metoclopramide HCl BP … 10mg] **Mfg Date:** May 2019 **Expiry Date:** Apr 2022	19E355	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.	01-139002850/DTL dated 13-11-2019	**Analysis with specifications applied: BP 2019** **PHYSICAL DESCRIPTION:** PINK COLOURED ROUND TABLET WITH BEVELLED EDGES, HAVING A LINE OF BISECTION ON ONE SIDE AND THE OTHER SIDE PLAIN IN BLISTER PACKING OF TEN UNITS. **DISINTEGRATION TEST:** All six units comply the limit of NMT 15 minutes.

Regn No. 033758				**IDENTIFICATION:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (METOCLOPRAMIDE HCl IDENTIFIED). **ASSAY OF METOCLOPRAMIDE HCl:** Stated Potency: 10 mg / Tab Determined Potency: **7.82 mg / Tab** Percentage: **78.2%** **(DOES NOT COMPLY** Limit: 90.0 – 110.0% of the Label Claim **RESULT:** The above sample is **SUBSTANDARD,** on the basis of ASSAY performed as per BP.

iii. Main Medicine Store office of the CEO (DHA) 24-Cooper Road Lahore provided warranty bearing No. 510883 dated 06-09-2019 issued by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan as a proof of its purchase.

iv. A copy of test/analysis report was sent to M/S Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan with directions to explain their position and provide requisite information in this regard.

Retesting Request of the Firm:

- Two batches **19E355** (subject batch) and **19E338** of the same subject drug i.e., Tablet Mediclop sampled on same Form-4 from the premises of Main Medicine Store office of the CEO (DHA) 24-Cooper Road Lahore by the Drug Inspector Data Gunj Baksh Town Lahore were declared of substandard quality by DTL Lahore on same date i.e., 13-11-2019
- Drug Inspector conveyed the substandard DTL report of both batches on same date i.e., 24-12-2019 to the firm M/s Global Pharmaceuticals.
- Firm submitted retesting request of the batches vide letter dated **10-01-2020**.
- Drug Inspector Data Gunj Baksh Town Lahore conveyed **retest request of both batches** to the office of the PQCB vide letter dated 25-01-2020

- Retesting request of batch no. **19E338 was addressed and the sample was sent to NIH** for retest, which was then declared of Standard Quality by NIH while the retest request of the subject i.e., **19E355 is still lying unaddressed** and the sample expired in April 2022.

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

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

b. **Issuance of false warranty**

c. **Disobey the Lawful Authority by providing wrong information as well as delaying in provision of names of the responsible persons [23 (1) (f) of The Drug Act 1976]**

6. Show-cause notice(s) issued to accused person(s)

Firm replied to the show cause notice vide letter no. REF/GP/006/PQCB/24 dated 10-01-2024

Following submissions are made for your kind attention please;

1. *We received Drug inspector Data Gunj Baksh Letter No. DI/DGBT/278 dated 24-12-2019 in which DTL Lahore declared the said batch substandard based on Assay against Report TRA #01-139002850/DTL dated 13-112019 and Global pharmaceuticals* ***challenged the Government Analyst Report within Stipulated time for retesting in NIH****.*
2. *We received PQCB letter No. PQCB/P-1204-11/2019 dated 13-05-2020 for submission of evidences against TRA # 01-139002850/DTIL and accordingly we submit evidences against our letter No. REF/GP/O62/PQCB/20 dated 18-06-2020.*
3. *We did not receive* ***any letter of Personal hearing from PQCB*** *after this letter.*
4. *Meanwhile our same product Mediclop tablet 10mg batch No. 19E355 was also declared substandard on the basis of Assay supplied to PKLI whose* ***challenge was accepted by PQCB in 218th Meeting*** *held on 27-02-2020 and we received* ***NIH Report of the same batch of "Standard Quality"***
5. ***We noticed the confusion*** *created by PQCB by Putting same Case No. i.e PQCB/P- 1204-1 1/2019 on both cases, one from PKLI Lahore TRA #01-143001444/DTL on 02-11-2019 and 2nd from Data Gunj Baksh Town, Lahore TRA #01-139002850/DTL on 13-11-2019.*
6. *It is also worth mentioning that same Batch # 19E355 was reported of "Standard Quality" by appellate Lab NIH.*
7. *Mediclop tablet 10mg* ***same Batch # 19E355 was tested by DTL Bahawalpur and Rawalpindi*** *on 05-07-2019 and 24-07-2019 respectively using British Pharmacopeia Monograph and Specifications. Both DTL Reports reported the said batch "Pass of Standard Quality w.r.t Assay"*
8. *We have also supplied* ***hundreds of batches in different institution of Punjab*** *and no problem observed by any DTL with respect to Assay.*

Pray:

Based upon above mentioned reasons we request that the declaration of substandard as made in the test report is actually contrary not only to our test reports, DTL Rawalpindi and DTL Bahawalpur and also contrary to appellate Lab (NIH) report. Moreover, ***PQCB did not respond our letter No. REF/GP/062/PQCB/20 Dated 18-06-2020****. Now it is hereby requested to* ***drop the said case*** *in our favor keeping in view the NIH Report of the* ***same batch reported of standard Quality****. We request that the needful be done at the earliest. We are looking forward to help you*

if you have any query.

7. Personal hearing notice(s) issued to accused person(s) dated 20-01-2024

8. Case is placed before the Board for decision.

Summary:

Manufacturing Date: May 2019

Expiry Date: Apr 2022

Sampling Date (Form 4): 28-09-2019

Sent to DTL (Form 6): 29-09-2019

Date of receipt in DTL: 30-09-2019

DTL Report Date (Form 7): 13-11-2019

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 24-12-2019

Retesting Request of Firm: Yes (10-01-2020)

Fate of Retesting Request: Not addressed

Investigation Report Dated: 16-02-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 15

PQCB/R-669/2022

Iqbal Town District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Umer Usman Surgical Cotton Industries, Faisalabad Road, Kot Sai Singh Jhang Sadar Pakistan** through its Chief Executive Officer, Adnan Latif 2. Adnan Latif Chief Executive Officer/ Quality Control Incharge/ Warrantor 3. Muhammad Nadeem Production Incharge of M/s Umer Usman Surgical Cotton Industries, Faisalabad Road, Kot Sai Singh Jhang Sadar Pakistan. 4. Manzoor Ahmad s/o Saeed Muhammad Proprietor 5. Zulqarnain s/o Manzoor Ahmad Qualified Person of **M/s Hasnat Medical Store, situated at Barf Wala Karkhana Road, Main Bazar Gulgasht Colony District Faisalabad**.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Iqbal Town District Faisalabad reported that: -

i. He, on 28-09-2022, inspected the business premises of M/s Hasnat Medical Store, situated at Barf Wala Karkhana Road, Main Bazar Gulgasht Colony District Faisalabad, took two different types of drug samples on Form No 04 dated 28-09-2022 from M/s Hasnat Medical Store, situated at Barf Wala Karkhana Road, Main Bazar Gulgasht Colony District Faisalabad and sent the subject drug sample to Drugs Testing Laboratory Faisalabad vide memorandum no. 142276 dated 29-09-2022.

ii. The subject 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	DTL Test Report Result
Banadages. Umer Usman Surgical Bandage [Umer Usman Surgical Bandage Type II, 10cm X 3m +/- 5%]	27C22194	M/s Umer Usman Surgical Cotton Industries, Faisalabad Road, Kot Sai Singh Jhang Sadar Pakistan.	01-68018902/DTL dated 19-Nov-2022	**Results of test/Analysis with specifications applied:** BP 1993 **DESCRIPTION:** Cotton cloth of plain weave bleached to a good white, in one continuous length containing no joins, clean reasonably free from weaving defects, leaf and shell and edges are evenly cut, parallel with the warp threads and reasonably free from loose threads.

Mfg Date March 2022 **Expiry Date** March 2025 **Regn No.** 016002				**<u>THREADS PER STATED LENGTH:</u>** **<u>Warps:</u>** **Stated:** 135 – 163 per 10cm (BP 1993) <u>+</u> 5% of BP Limit (F.6-6/2005-Reg-II (South) **Determined:** 142.7 per 10cm (Complies) **<u>Wefts:</u>** **Stated:** 84 – 96 per 10cm (BP 1993) <u>+</u> 5% of BP Limit (F.6-6/2005-Reg-II (South) **Determined:** 84.64 per 10cm (Complies) **<u>WEIGHT PER UNIT AREA:</u>** **Stated:** NLT 33 g/m^2 (BP 1993) **Determined:** 41.254 g/m^2 (Complies) **<u>FLUORESCENCE TEST:</u>** **Stated:** Not more than a few isolated fibers show an intense blue fluorescence when examined under UV light (365 nm) {BP 1993} **Determined: All fibers show intense blue fluorescence (Does not Comply)** **<u>RESULT:</u> Given sample is Sub-Standard with regards to Fluorescence Test.**

iii. The Drug Inspector, Iqbal Town, District Faisalabad, locked & sealed the premises of M/s Hasnat Medical Store, situated at Barf Wala Karkhana Road, Main Bazar Gulgasht Colony District Faisalabad under section 18 [(1)(h)] of the Drugs Act 1976 due to contraventions of Section 23 of the Drugs Act 1976 (as amended)/ DRAP Act 2012 and Rules framed there under. Following different types of articles/drug samples on Form-5 recovered & seized as detailed below:

Sr. No.	Name of drug	Batch No.	Manufactured by	Quantity	Reason of seizure	Reason of seizure
1	Myzid 200mg/ 5ml Susp.	D5B26	M/s KSH Pharmaceutical North Peshawar	04 Pack	Misbranded Drugs (Price masked by Blue Ball Point & re-written as 220 on	

					outer carton/ pack)	
2	Amoxil 500mg/ Cap.	3G3U	M/s GlaxoSmith Kline Karachi	50 Caps.	Misbranded Drugs	
3	Neuxam 0.5mg/ Tab.	CTF342	M/s StandPharm Pak. Lahore	90 Tabs.	Violation of Schedule B & D W/O Invoice/ Warranty	
4	Neuxam 0.25mg/ Tab.	CTE330	M/s StandPharm Pak. Lahore	50 Tabs.	-do-	
5	Brolite 3mg/ Tab.	CTF359	M/s StandPharm Pak. Lahore.	60 Tabs	-do-	
6	Lexotanil 3mg/ Tab.	P07982	M/s Martin Dow Limited Karachi	150 Tabs.	-do-	
7	Sedonil 3mg/ tab.	253	M/s Adamjee Pharma Karachi	90 Tabs	-do-	
8	Nervin 0.5mg/ Tab.	NV264	M/s Werrick Pharma Islamabad	50 Tabs	-do-	
9	Tonoflex-P 37.5mg +325 mg/ Tab.	041H	M/s Sami Pharma Karachi	39 Tabs	-do-	
10	Tonoflex-P 37.5mg +325 mg/ Tab.	064H	M/s Sami Pharma Karachi	40 Tabs	-do-	
11	Tonoflex 50mg/ Cap.	004H	M/s Sami Pharma Karachi	20 Caps.	-do-	
12	Tramal 50 mg/ Cap.	GAD001	M/s Searle Company Karachi	20 Caps.	-do-	
13	Tramal 37.5+325 mg/ Tab.	CDD028	M/s Searle Company Karachi	20 Tabs.	-do-	
14	Dexamethasone 0.5mg/Tab.	RW-0622H	M/s Venus Pharma Lahore	200 Tabs.	-do-	

Exhibiting/ Stocking for Sale/ Selling the Allopathic drugs in following contraventions of Drugs Act 1976 (as Amended):

1. **Misbranded Drugs** (Price masked by Blue Ball Point & re-written as 220 on outer carton/ pack)
2. **Violation of Schedule "B & D"** (Without Sale/ Purchase Record of Controlled & Prescription Drugs)
3. **Violation of Schedule "H"** (Thermolabile/ Temp. sensitive Drugs stored/ stocked out of Refrigerator)
4. Without Invoice/ Warranties
5. Dirty Dusty & Un-Hygienic Premises

15	Kanadex 0.5 mg/ Tab.	D4-74	M/s ISIS Pharmaceutical Works Karachi	20 Tabs.	-do-	
16	Hyzonate 250mg Inj.	1236	M/s Amson Vaccine & Pharma Islamabad	5 Packs	-do-	
17	Hyzonate 500mg Inj.	098	M/s Amson Vaccine & Pharma Islamabad	4 Packs	-do-	
18	Optachlor 0.5% 10ml E/D	FM0475	M/s Remington Pharmaceutical Industries Lahore	5 Packs	Violation of Schedule H, W/O Invoice / Warranty	
19	Metachlor 5ml Eye Drops	M2634	M/s Remington Pharmaceutical Industries Lahore	8 Packs	Violation of Schedule H, W/O Invoice / Warranty	

Premises of M/s Hasnat Medical Store, situated at Barf Wala Karkhana Road, Main Bazar Gulgasht Colony District Faisalabad was ordered to be <u>de-sealed on 06-10-2022</u> by the Drug Court Faisalabad

iv. Proprietor of M/s Hasnat Medical Store, situated at Barf Wala Karkhana Road, Main Bazar Gulgasht Colony District Faisalabad provided Invoice/Warranty No. 00747 dated 24-04-2022 issued by M/s Medicare Enterprises, 50-Alam Block Medical Housing Scheme Lahore as a proof of its purchase of the subject drug.

v. Warrantor portion of drug sample was sent to M/s Medicare Enterprises, 50-Alam Block Medical Housing Scheme Lahore who in-turn provided Invoice/Warranty No. U.U/119 dated 24-04-2022 issued by M/s Umer Usman Surgical Cotton Industries, Faisalabad Road, Kot Sai Singh Jhang Sadar as a proof of its purchase of the subject drug.

vi. A copy of test/analysis report was sent to M/s Umer Usman Surgical Cotton Industries, Faisalabad Road, Kot Sai Singh Jhang Sadar Pakistan with directions to provide the requisite information and to explain their position in this regard.

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

1. **M/s Umer Usman Surgical Cotton Industries, Faisalabad Road, Kot Sai Singh Jhang Sadar Pakistan** through its Chief Executive Officer, Adnan Latif 2. Adnan Latif Chief Executive Officer/ Quality Control Incharge/ Warrantor	a. Manufacture for sale/Sale of Substandard Medical Device/ Drug b. Issuance of false warranty

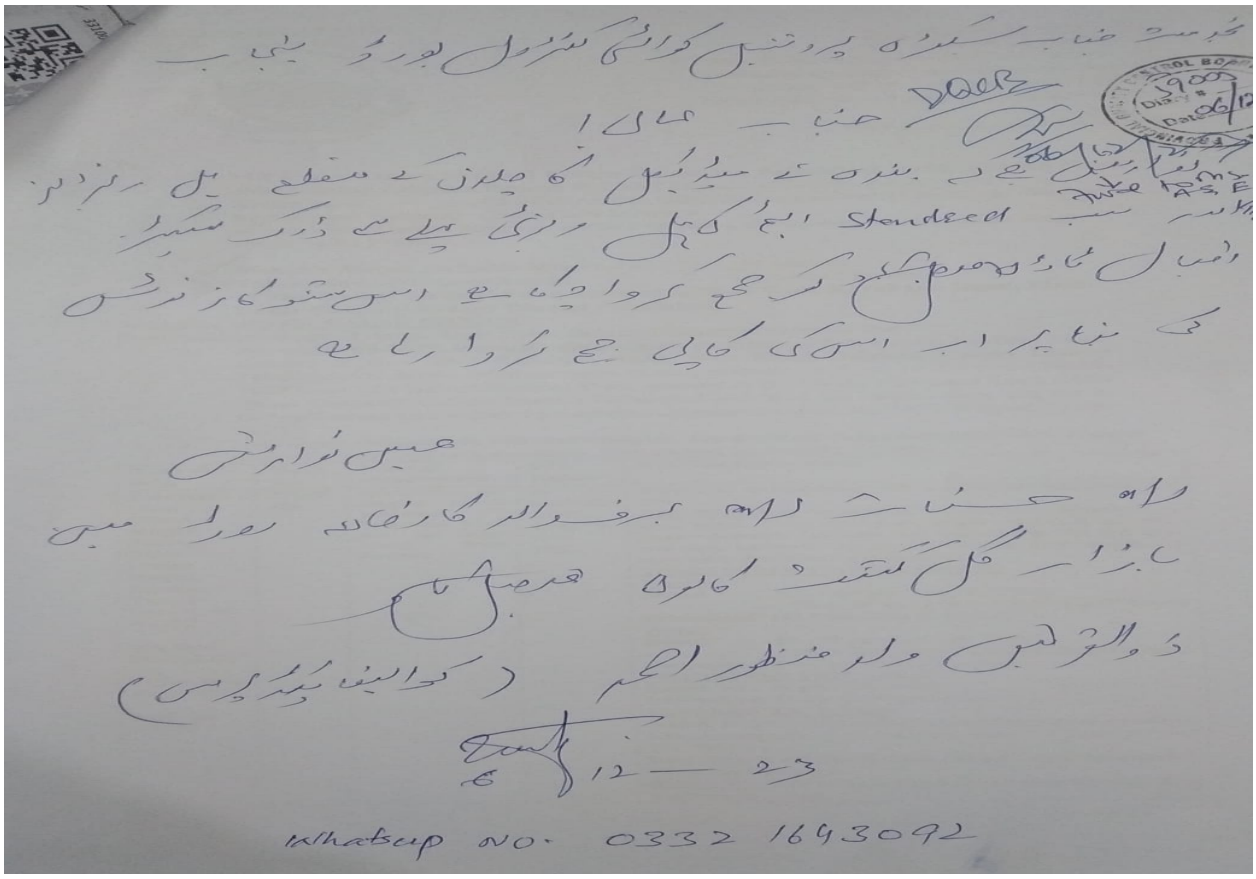
3. Muhammad Nadeem Production Manager of M/s Umer Usman Surgical Cotton Industries, Faisalabad Road, Kot Sai Singh Jhang Sadar Pakistan	
1. Manzoor Ahmad s/o Saeed Muhammad Proprietor 2. Zulqarnain s/o Manzoor Ahmad Qualified Person of **M/s Hasnat Medical Store, situated at Barf Wala Karkhana Road, Main Bazar Gulgasht Colony District Faisalabad**	1. **Misbranded Drugs** (Price masked by Blue Ball Point & re-written as 220 on outer carton/ pack) 2. **Violation of Schedule "B & D"** (Without Sale/ Purchase Record of Controlled & Prescription Drugs) 3. **Violation of Schedule "H"** (Thermolabile Drugs stored/ stocked out of Refrigeration) 4. **Without Invoice/ Warranties** 5. **Dirty Dusty & Un-Hygienic Premises**

3. Show-cause notice(s) issued to accused person(s) dated 13-11-2023

Firm replied to the show cause notice vide letter no. US-2278 received on 28-12-2023

With the reference of your letter no. PQCB/R-669/2022 dated 13-11-2023, show cause about the substandard cotton bandage batch # 27C22194. Our sample is of standard quality in all parameters except one which is Fluorescence test. ***We want to explain the reason of positive test in person and want personal hearing of this case****. The names of* ***technical staff and management are correct*** *as nominated by drug inspector. We shall be very thankful to you for this kindness.*

Qualified Person Zulqarnain submitted following reply dated 06-12-2023



4. Personal hearing notice(s) issued to accused person(s) dated 22-01-2024

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: March-2022

Expiry Date: March-2025

Sampling Date (Form 4): 28-09-2022

Sent to DTL (Form 6): 29-09-2022

Date of receipt in DTL: 30-09-2022

DTL Report Date (Form 7): 19-11-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 10-02-2023

Retesting Request of Firm: No

Investigation Report Dated: 15-08-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 16

PQCB/R-796/2019

Data Gunj Baksh Town, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Dr. Raza Pharma (Pvt.) Ltd., Plot 44-C, Industrial Estate Hayatabad, Peshawar -Pakistan** through its Managing Director, Naeem Shahzad 2. Naeem Shahzad — Managing Director/ Warrantor 3. Shahzad Afzal — Production Manager 4. Muhammad Aslam Khan — Quality Control Manager of M/s Dr. Raza Pharma (Pvt.) Ltd., Plot 44-C, Industrial Estate Hayatabad, Peshawar - Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Data Gunj Baksh Town, District Lahore reported that: -

i. His predecessor, on 02-08-2019, inspected the premises of M/s Fountain House Pharmacy, Fountain House Institute of Mental Health, 37 Lower Mall Lahore, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 47041 dated 08-08-2019.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Tablet. VITAL [VITAMIN A BP … 5000IU, VITAMIN D BP …. 400IU, VITAMIN B1 BP … 5MG, VITAMIN B2 BP …. 5MG, VITAMIN B12 BP 25mcg, VITAMIN C BP …120MG, VITAMIN EBP … 100MG, FOLIC ACID B.P. … 1MG, PANTOTHENIC ACID BP …	2250	M/s Dr. Raza Pharma (Pvt.) Ltd., Plot 44-C, Industrial Estate Hayatabad, Peshawar –Pakistan.	01-143001051/DTL dated 14-11-2019	**Analysis with specifications applied: USP 2019** **PHYSICAL DESCRIPTION:** Plum brown color oblong tablet in a n opaque white sealed plastic bottle with screw cap. **IDENTIFICATION:** The retention time of the major peaks in the sample chromatogram corresponds to the retention time of the major peaks in standard chromatogram (Nicotinamide, Riboflavin, Thiamine & Ascorbic Acid Identified). ASSAY OF NICOTINAMIDE: (HPLC) Stated Potency: 20 mg / tab

10MG, NIACINAMIDE B.P. … 20MG and Minerals] **Mfg Date:** March 2019 **Expiry Date:** Sep 2020 **Regn No.** 019679				Determined Potency: 19.54 mg / tab Percentage: 97.7% Limit: 90 – 150% of Label Claim **ASSAY OF THIAMINE: (HPLC)** Stated Potency: 5 mg / tab Determined Potency: 2.48 mg / tab Percentage: **49.6% (NOT COMPLY)** Limit: 90 – 150% of Label Claim ASSAY OF RIBOFLAVIN: (HPLC) Stated Potency: 5 mg / tab Determined Potency: 4.65 mg / tab Percentage: 93.0% Limit: 90 – 150% of Label Claim ASSAY OF ASCORBIC ACID: (HPLC Method-3) Stated Potency: 120 mg / tab Determined Potency: 108.06 mg / tab Percentage: 90.1% Limit: 90 – 110% of Label Claim **DISSOLUTION TEST:** Limit: NLT 85% (Q=75%)

				The average release of pooled sample of six units is 88.9% **RESULT:** The sample is **SUB-STANDARD,** on the basis of ASSAY OF VITAMIN-B1 performed as per USP.

iii. M/s Fountain House Pharmacy, Fountain House Institute of Mental Health, 37 Lower Mall Lahore provided invoice/warranty bearing No. 3253 dated 25-06-2019 issued by M/s Kins Pharma, 358, K-1, Wapda Town Lahore as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Kins Pharma, 358, K-1, Wapda Town Lahore who provided invoice/warranty bearing No. M/s Kin 4917 dated 15-06-2019 issued by M/s Dr. Raza Pharma (Pvt.) Ltd., Plot 44-C, Industrial Estate Hayatabad, Peshawar -Pakistan.

v. A copy of test/analysis report was sent to M/S Dr. Raza Pharma (Pvt.) Ltd., Plot 44-C, Industrial Estate Hayatabad, Peshawar -Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis reports of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

Previous Proceedings & Decision by the Board:

12th Committee Meeting held on 25-08-2020

Pursuant to firm's request, the Provincial Quality Control Board in its 12th Committee Meeting held on 25-08-2020, decided to **turn down** the firm's request for retesting of the subject sample on the grounds that in the last meeting of PQCB (223rd –M held on 28-07-2020) the firm itself furnished a request for adjournment and now when called for a personal hearing did not appeared before the Committee of the Board. As the sample is near Expiry, the request for retesting may not be meaningful.

232nd meeting held on 24-06-2021:

Firm's review petition against retesting request orders, has also been turned down in 232nd meeting held on 24-06-2021 on the basis of being time-barred. (Firm requested for retesting on 11th Day.)

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

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

    b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 17-02-2023

Firm submitted written reply to the show cause notice vide letter no. DRP/PQCB/012/23 dated 06-03-2023

1. That M/S Dr. Raza Pharma (Pvt.) Ltd., Hayatabad Peshawar has great respect with highest possible level of compliance to all the prevailing law regulating Pharmaceutical industry and has always worked within the legal framework of the DRAP Act 2012/ Drug Act 1976 and Rules framed there-under in order to ensure delivery of high quality effective and safe drugs to the patients at National level.

2. That we received letter No. DIDGBT/260 dated 6/12/2019 from PDI/Drug Controller, Data Ganj Bakhsh Town, Lahore, with copy of test report as above, to which we responded vide letter No DRP/DIGB/01/19 dated 17-12-2019.

3. That we had raised specific legal and factual issues with regards to non-provision of warrantor's portion of sample as required by the law and of the test report being time-barred and being contrary to the approved and applicable company specifications which had provided to the laboratory on request. The test report thus did not qualify as a test report under section 22 of the law; the report being beyond sixty days prescribed period of time and being illegal on account of showing application of USP as such ***Drug was not covered under its allopathic monographs but under it dietary supplements chapter****; on account whereof, the Drug was registered under Dr Raza Specs which were also declared on the label of the drug.*

That, the test report was accordingly in breach of the definition of 'specifications' as given in law and the Drugs (Specifications) Rules, 1978.

4. That, whilst repudiating and rejecting the test report, and on the basis of our own test results of the batch, ***we challenged and controvert the test report of DTL under Section 22(4) of the Drugs Act, 1976, within stipulated time of 10 days****.*

Regarding merits of the Test Report, our serious legal and technical concerns are as follows:

i. *The Drug Inspector took sample from the retail premises on 02.08.2019 almost* ***after 05 months from the manufacturing date*** *of the drug but* ***did not mention the storage conditions*** *at the time of sampling.*
ii. *The Government Analyst failed to fulfill the test/analysis protocols on Form. 07* ***by applying USP Specifications and identify only 04 water soluble vitamins*** *which is controversial with Manufacturer's Specifications (as mentioned on label).*
iii. ***The DTL report is Time Barred*** *U/s 22 (2) of the Drugs act, 1976, and we also found serious discrepancies in the Test Method applied by the Govt. Analyst. Our concerns are as follows.*
iv. ***Tablet Vital contains 21 ingredients*** *(consisting of Fats & Water Soluble Vitamins & Minerals) and is being manufactured under in house specifications (Manufacturer's Specifications)*
v. ***Mobile Phase may not be prepared as per USP method*** *for water soluble Vitamins or it may not be freshened.*
vi. *The Preparation of* ***Sample and Standard solutions need proper mixing and also proper heating and chilling for specific time****, variation may change the results.*
vii. ***Centrifugation*** *is also an important factor, which may alter the results of vitamins, if not properly performed.*
viii. *Most importantly,* ***the Sample and Standard solutions should be used within 3 hours of their preparation****, otherwise results may be altered.*

We analyzed our ***QC retained sample which complies as per Manufacturer's Specification*** *and assay result found within prescribed Limit.*

In view of above-mentioned facts, ***it is requested that case may please be considered as dropped case" on merit*** *and in accordance with law. Every citizen of Pakistan is entitled to be dealt in accordance with law and due process as per requirement of 1973 Constitution of Islamic Republic of Pakistan.*

4. Personal hearing notice(s) issued to accused person(s) dated 24-07-2023

Previous Proceedings and Decision by The Board:

265th meeting held on 03-08-2023

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs

Act 1976 in its **265th meeting** held on **03-08-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Ms Hassan Saeed, Secretary DQCB, District Lahore and Mr. Raheem Ahmad, Drug Inspector Data Gunj Baksh Town District Lahore was present along with the original case record. No one among the nominated accused persons of M/s Dr. Raza Pharma (Pvt.) Ltd., Plot 44-C, Industrial Estate Hayatabad, Peshawar –Pakistan was present.

6. Secretary PQCB apprised the Board that the firm has submitted written request for adjournment vide letter no. DR/PQCB/23 dated 02-08-2023 stating that the nominated technical staff is unavailable due to their personal commitments. The Board, after due deliberation and detailed discussion, unanimously decided to **adjourn the case** of **M/s Dr. Raza Pharma (Pvt.) Ltd., Plot 44-C, Industrial Estate Hayatabad, Peshawar –Pakistan** and to provide another opportunity of personal hearing in the best interest of justice.

7. Personal hearing notice(s) issued to accused person(s) dated 12-09-2023

Previous Proceedings and Decision by The Board:

268th meeting held on 21-09-2023

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **268th meeting** held on **21-09-2023** under the Chairmanship of Special Secretary (Operations) Vice-Chairperson PQCB, Primary & Secondary Healthcare Department Punjab. Ms Hassan Saeed, Secretary DQCB, District Lahore was present along with the original case record. Among the nominated accused persons, Shahzad Afzal (Production Manager) of M/s Dr. Raza Pharma (Pvt.) Ltd., Plot 44-C, Industrial Estate Hayatabad, Peshawar –Pakistan appeared before the Board and submitted that their subject sample is registered with "Dr. Raza Specs." As it comes under "Dietary Supplements Chapter" whereas the application of USP 2019 for its analysis by the DTL Lahore shows the application of allopathic monograph of USP, hence, breaching the definition of "Specifications" as per Drugs (Specifications) Rules 1978. He further submitted that variation of assay of Thiamine is incomprehensible as their QC retained portion of the sample was complying all parameters as per manufacturer's specifications. He requested the Board for a lenient view in the subject case assuring more vigilance in observing protocols while manufacturing the sample in the future.

9. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject sample Tablet. Vital, Batch No. 2250 has been declared substandard by the Drugs Testing Laboratory, Lahore on the basis of non-compliance of assay of the Thiamine (Vitamin B1) with the stated limits. The assay of the Thiamine is determined to be 49.6% which is considerably lesser than the limit of 90-150% as specified in the USP 2019. The Board further observed that assay of rest of the tested vitamins i.e., Nicotinamide, Riboflavin & Ascorbic Acid are complying the official limits being 97.7%, 93.0% & 90.1% respectively, whereas rest of the parameters such as physical description of the sample and dissolution test are also complying the specified criteria.

10. The Board after giving due heed to firm's arguments, was of the view that failure of the subject sample to comply the assay specifications of Vitamin B1 (Thiamine) only, while complying the assay of rest of the tested ingredients, enforces the need to rule out any deviation in the quality control or assurances procedures and hence, needs an inspection of the subject sample's practiced production & quality control standards. Therefore, the Board after due deliberation and detailed discussion decided to **pend the case** and conduct **Product Specific Inspection (PSI)** of **M/s Dr. Raza Pharma (Pvt.) Ltd., Plot 44-C, Industrial Estate Hayatabad, Peshawar –Pakistan.** For this purpose, the Board constituted a committee comprising of following members with directions to submit report for consideration by the Board after conducting product specific inspection:

1	Prof. Dr. Mehmood Ahmad	**Convener**

2	Mr. Rana Abdul Mateen (DDC PQCB)	**Member**

11. The Board further directed the committee to submit report within 90 days otherwise, secretary PQCB would be authorized to change the committee members.

PRODUCT SPECIFIC INSPECTION REPORT OF

M/S DR. RAZA PHARMA, 44-C, HAYATABAD INDUSTRIAL ESTATE, PESHAWAR-PAKISTAN

DATE OF INSPECTION:

Inspection was conducted on 14-10-2023 with reference to PQCB Order No. **PQCB/ R-796/2019** dated 04-10-2023. Sample of drug was taken by Provincial Inspector of drugs, Data Gunj Bakhsh, District Lahore from the premises of M/S Fountain House Pharmacy, Fountain House Institute of Mental Health, 37 Lower Mall Lahore

BRIEF ABOUT MANUFACTURING UNIT:

A National pharmaceutical company duly certified with **ISO 9001:2015 and 45001:2018** Certified company and also complied with the latest **cGMP** Standards.

Manufacturing Unit	M/s Dr. Raza Pharma
Location/Address	44-C, Hayatabad Industrial Estate Peshawar
DML No. and Validity (Date of DML renewal)	000387 14-06-2019
Approved Sections	Oral Syrup Liquid, Tablet, Capsule and Dry Suspension sections
Management	1. **Mr. Naeem Shahzad** **Director**
Firm's Representatives	1. **Mr. Muhammad Aslam Khan** Quality Control Manger 2. **Mr. Shahzad Afzal** Production Manger 3. **Mr. Naveed Khan** Q.A. Manger

Batch Processing Record of Specific Product

1. Batch Number: 2250
2. BMR Record: Available.
3. Retention Sample Analysis record: Available
4. Ambient Stability Study Data: Available
5. list of Equipment: Available
6. Vendor Qualification of Raw Material: Available
7. QC Equipment list & its Calibration Certificates: Available

OBSERVATIONS:

1. The production was temporarily halt due to renovation and extension by adding new sections, including small and large volume Injectables, Ointments, Sachets, Lyophilized etc. to the existing facility, with prior approval from the Drugs Regulatory Authority of Pakistan.
2. Firm provided the ambient stability study Data (0 month, 1st month, 3rd month, 6th month, 9th month & 12th month) of Tablet Vital, Batch No. 2250 along with chromatograms which showed the assay of Vitamin B1 (Thiamine) Iron within the Pharmacopoeial Limit (90-150%).
3. Firm has been improved the RAW Material Sources.
4. Firm used the working standards for the test/analysis of Products.

RECOMMENDATIONS

The following recommendations has been made for ascertain the quality of drugs:

- The firm has to make the **Policy for Quality Control** of APIs
- Firm has to perform **pre-formulation test/analysis** of hygroscopic/heat/light sensitive Vitamins raw material.
- Firm has to establish a **separate in process Quality Control Lab for QA Department** that lies in production area to check the Disintegration, Tablet Hardness, Tablet Friability, Thickness and weight variation after every 30 minutes.
- The firm has to **purchase Primary Standards** of APIs.
- **Data loggers** should be available for temperature and humidity control records at all critical areas.
- **Root cause analysis for fail batches** and market complaints should be conducted by the firm.

CONCLUSION

After careful evaluation of record and physical verification of the plant and equipment involved at the time of production, the panel is of the opinion that the drug in question declared as substandard **due to storage condition of Vitamin B1** (as it can degrade faster & lose effectiveness when exposed to excessive Heat, Light, Oxygen in the air or Humidity) and **use of working standards** at the stage of QC analysis of the product. The firm is advised to follow strictly the Good Manufacturing Processes with letter and spirit. Moreover, the quality control department should be improved and instruments should be routinely validated and validation record be maintained.

M/s Dr. Raza Pharma submitted following response in terms of Corrective & Preventive Actions vide letter no. DR/PQCB/23 dated 08-12-2023

It is hereby confirmed, that after PSl recommendations, we have taken the corrective & preventive actions as per details below:

CORRECTIVE AND PREVENTIVE ACTION ("CAPA") *With reference to Product Specific Inspection (PSI) Report conducted by the Honourable Board Committee members on 14.10.20230rder No. PQCB/ R-796/2019 dated 04.10.2023 in case of drug sample Tablet VITAL (Multivitamins) having Batch No.2250 manufactured by M/s Dr. Raza Pharma, Plot 44-C, Industrial Estate Hayatabad, Peshawar -Pakistan.*

BRIEF INTRODUCTION ABOUT MANUFACTURING UNIT:

M/s. Dr. Raza Pharma is one of the leading and trusted manufacturers of allopathic drugs, incorporated under the companies Ordinance, 1984 and started production in 1995, after obtaining Drug Manufacturing License (000387) and also certified with ISO 9001:2015 and 45001:2018. Its firm commitment to quality and adherence to CGMP guidelines is the hall mark of the company to meet the highest standards and expectations of the patient's /healthcare providers.

Reference to PSI report Recommendations, we are pleased to submit the report after thoroughly working on the short comings raised by Honorable members & following improvements have been done to improve the quality in future.

1. ***Policy for Quality Control of APIs (strict compliance adhered***

   *Firm already follow the **WHO Good Practices** for Pharmaceutical Quality Control Laboratories vide WHO Technical Report Series, No. 957, 2010*

2. ***Pre-Formulation Test/Analysis (strict compliance adhered)***

   *Firm's quality control laboratory already performed **pre-formulation test/analysis** of all hygroscopic/heat/light sensitive Vitamins raw material and issues the analysis certificate for formulation of dosage form.*

3. ***IPQC Lab. for QA Department (strict compliance adhered)***

   *Firm already planned the **IPQC Lab** for QA department in the Tablet and Capsule sections layout map which will be established after the approval from DRAP as the production of **Firm is halt due to renovation and extension** by adding new sections, including small and large volume Injectable, Ointments, Sachets, Lyophilized etc. to the existing facility, with prior approval from the Drugs Regulatory Authority of Pakistan.*

4. ***Primary Standards of APIs (strict compliance adhered)***

   *Firm has started working positively to **purchase the Primary Standards** of Active Pharmaceutical Ingredients.*

5. ***Data loggers (strict compliance adhered)***

   *Firm has acquired the **quotations from different vendors** to purchase the WHO approved Data Loggers which will be installed at all critical areas of unit.*

6. ***Root cause analysis for fail batches (strict compliance adhered)***

   *QA department of the firm has already performed **the root cause analysis for fail batches** of products timely and updated the method of analysis with intimation to DRAP.*

***PRAYER**:*

*In view of CAPA against the PSI report recommendations, it is submitted that firm already provided the all-relevant documents in the said case and **will adhere to the strict compliance of cGMP** in future. Therefore, it is humble requested before the Honorable Board for taking lenient view in the subject case and drop the proceedings against the firm in the interest of Justice.*

12. Personal hearing notice(s) issued to accused person(s) dated 20-02-2024

13. Case is placed before the Board for decision.

Summary:

Manufacturing Date: March 2019

Expiry Date: Sep-2020

Sampling Date (Form 4): 02-08-2019

Sent to DTL (Form 6): 08-08-2019

Date of receipt in DTL: 08-08-2019

DTL Report Date (Form 7): 14-11-2019

Time Extension: Granted on 15-11-2019 (213-M)

1ST DI Communication with firm on dated: 06-12-2019

Retesting Request of Firm: Yes (17-12-2019)

Fate of Retesting Request: Turned Down in 12th Committee Meeting dated 25-08-2020

Firm's Review Petition against Turn Down Orders: 23-10-2020

Fate of Firm's Review Petition: Turn Down on 24-06-2021 (232-M)

Investigation Report Dated: 11-01-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 17

No. PQCB/ SM-22-12/2023 &

R-720/2022

Tehsil Gujar Khan, District Rawalpindi

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/s Shine Laboratories, 9 Km from Sohawa main GT Road Missa Kaswal Gujjar Khan District Rawalpindi** through its owner Hassan Raza Sohail 2. Hassan Raza Sohail — Owner 3. Saad Ahmed — Supervisor 4. Hafiz Muhammad Imran — Production Incharge 5. Bilal Masood — Quality Control Incharge Of M/s Shine Laboratories, 9 Km from Sohawa main GT Road Missa Kaswal Gujjar Khan District Rawalpindi

BRIEF FACTS OF THE CASE

Provincial Inspector of Tehsil Gujar Khan, District Rawalpindi reported that: -

His predecessor, on 22-08-2022, inspected the premises of M/s Shine Laboratories, 9 Km from Sohawa main GT Road Missa Kaswal Gujjar Khan District Rawalpindi recovered & seized six different types of items/articles including finished therapeutic good/labels/raw material Requisition/batch manufacturing sheet/raw material/ ledgers on Form-5. The Raw Material Store was locked & sealed due to following contraventions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 along with FIA official and seized following drugs/material etc.

Sr. No.	Name of drug	Batch No.	Manufactured by	Quantity	Reason of seizure
1.	Resipifit Liquid 1000ml	RP0011	Purported to be manufactured by M/s Shield Nutrascience Lahore	12 bottles*1000ml	Unregistered (registration no. is not printed on outer label, case under investigation are taken on Form-5)
2.	Outer labels of Resipifit liquid, Batch no. RP0012 printed Mfg. date 01/2022 Exp. Date 01/2024.				
3.	Raw material requisition (SL-Po-REQ-01) of Resipifit liquid, batch no. RP0012 dated 08-2-2022 recovered and seized and of dated 2-3-3033 without batch number (Qty. 02)				

4.	Resipifit 200 liter dated 15-05-2020, 150 Lit at 11-05-2020, 100 lit 18-05-2020, 500 Liters at 26-2-2021, 300 lit at 8-6-2021, 84 lit at 15-09-2021, 43 lit at 14-09-2021 duly signed by different officials of the M/s Shine laboratories. Above batch manufacturing sheet of product Resipifit qty. 107) which are signed and stamped with thumb impression of Saad Ahmed in presence of witness.
5.	M/S shine Laboratories having two sections of oral liquid and oral solid all sealed under 18(1) section of Drug Act 1976. The product at sr. 1 by M/s shield nutra sciences Lahore but being recovered from M/s shine laboratories along with finished product, labels and raw material bromohexane HCl.
6.	White color fine powder packed packed in polythene bag in a raw material stated to be bromohexine HCl by saad ahmad qty. app 1.5 kg
7.	Two ledges of blue color containing batch manufacturing record of different product.

i. The drug inspector Tehsil Gujar Khan, District Rawalpindi also took following drug samples on Form No 04 dated 22-08-2022 and sent to Drugs Testing Laboratory Rawalpindi vide Memorandum no. 0000137948 dated 24-08-2022 for the purpose of test/analysis.

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Syrup Respifit Liquid 1000ml (each ml contains Bromohexine hydrochloride 2%, Chlorpheniramine maleate 1%, Aminophylline: 2%, Guaifenesine: 2.5%, Ambroxol hydrochloride: 2%, Menthol 3%) **Mfg. Date**: 02-2021 **Exp. Date**: 02-2023 **Reg** # -------	RP0011	M/S Shield Nutra science, 59 km, mureed kay road, Lahore	01-74005526 / DTL dated: 06-12-2022	**Result of test/ analysis with specifications applied:------** **PHYSICAL DESCRIPTION:** Light Yellow liquid filled in white colored plastic bottle, with affixed label, sealed with aluminium sheet and red coloured plastic screw cap. **Manufacturing specifications is not mentioned on the label of the bottle.** **(Does not comply)** **The drug registration number is not printed on the label of the bottle.** **(Does not comply)** **Note: testing/ analysis was not performed, as there is no official monograph available for this product.** **Note:** Requests for the provision of the method of test/analysis were sent

				from DTL Rawalpindi Letter no. LR/MRS/2022/1098 and second reminder was provided by the manufactures. **Result : the above sample is misbranded as defined under clause (i) and (vi) of sub-section (s) of section 3 of the Drugs Act 1976.**

ii. A copy of test/analysis report of the subject drug sample was sent to M/s **Shine Laboratories, 9 Km from Sohawa main GT Road Missa Kaswal Gujjar Khan District Rawalpindi** with directions to explain their position and provide requisite information in this regard.
iii. The Provincial Inspector of Drugs, Gujar Khan declared the product as manufacturing of Misbranded therapeutic goods and manufacturing of spurious/un-registered /un-Enlisted therapeutic goods and requested to grant permission for registration of FIR under section 23/27 of The Drugs Act 1976 (as amended), DRAP Act 2012 along with FIA official

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacture for Sale/ Sale of spurious/un-registered /un-Enlisted therapeutic goods.**
ii. **Manufacture for Sale/ Sale of Misbranded therapeutic goods.**

3. Showcause was issued to accused person(s) vide dated. 04/01/2024

Personnel hearing notice(s) issued to accused person(s) vide dated 20-02-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 02-2021

Expiry Date: 02-2023

Sampling Date: 22-08-2022

Sent to DTL (Form 6): 24-08-2022

Date of receipt in DTL:01-09-2022

DTL Report Date: 06-12-2022

Time Extension: granted in 253rd meeting

1ST DI Communication with firm on dated: 26-12-2022

PROCEEDING & DECISION BY THE BOARD:

Investigation Report Dated: 17-10-2023

Case No. 18

SM-86-06/2018

(Tehsil and District Layyah)

ATTENDANCE

BRIEF FACTS OF THE CASE:

1. Provincial Inspector of Drugs, Tehsil and District Layyah inspected the premises of M/S Zeeshan Pharmacy, Aslam More, Layyah on 06-03-2018 and recovered/seized stock of eight drugs, four of which were unregistered drugs manufactured by M/S Everest Pharmaceuticals Pvt. Ltd.
2. For the said unregistered drugs, M/S Zeehsan Pharmacy provided the invoice/warranties issued by M/S MAARK Pharmaceuticals (Pvt.) Ltd., Lahore, who in turn provided invoice/warranties issued by M/S Everest Pharmaceuticals,124, Industrial Triangle, Kahuta Road, Islamabad as proof of purchase.
3. The Drug Inspector requested for grant of permission of prosecution/registration of FIR against the below mentioned accused persons who had contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed thereunder

    i. **Ch. Muhammad Usman (Owner/Warrantor)**
    ii. **Dr. Kamran Izhar (Partner)**
    iii. **Noor Muhammad Mahar (Partner)**
    iv. **Muhammad Arshad (Production In charge)**
    v. **Mian Ishtiaq Ahmed (Quality Assurance Manager)**
    vi. **Imtiaz Ahmed (Quality Control Manager)**

    Of M/S Everest Pharmaceuticals Pvt. Ltd 124, Industrial Triangle, Kahuta Road, Islamabad for the offence of

    a. **Illegal import of raw material**
    b. **Illegal manufacturing/Manufacturing for sale of Allopathic unregistered drugs.**
    c. **Issuance of false warranty**

4. Show cause/Personal Hearing Notice was issued to the accused dated 09-08-2018.
5. Provincial Quality Control Board, Punjab granted permission for immediate registration of FIR against the accused at the concerned Police Station/FIA Crime Circle in its 191st meeting dated 16-08-2018
6. FIR C-27/2020 was registered at the crime circle FIA on 02-02-2020.
7. In which the report u/s 173 Cr. PC. Was handed over to Drug Inspector Tehsil Layyah, FIA recommended the cancellation of FIR.
8. On which Drug Inspector Layyah required guidance on 24-07-2021.

File No	Premises Inspected	Drug/ Medicine name and batch no	Offence	Name of accused

SM-86-06/2018	M/S Zeeshan Pharmacy, Aslam More, Layyah	i. Tab Escam 20mg Batch 174 ii. Tab Sambol 1500mcg Batch 282 iii. Tab Xubi Batch 222 iv. Syrup Zink Batch 194	a. Illegal import of raw material b. Illegal manufacturing/Manufacturing for sale of Allopathic unregistered drugs. c. Issuance of false warranty	Accused persons of M/S Everest Pharmaceuticals Pvt. Ltd 124, Industrial Triangle, Kahuta Road, Islamabad as mentioned above

PREVIOUS PROCEEDINGS AND DECISION BY THE COMMITTEE:

2. The subject issue Everest pharma in which cancellation report received from P.S FIA/CCC Lahore was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **22nd meeting** held on 21-06-2023 under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab.
3. The said issue discussed by the committee, Drug Inspectors of respective areas were also present at the time of discussion and files were thoroughly scrutinized regarding the FIRs and challan u/s 173 Cr. PC. The Committee after due deliberation and discussion, unanimously decided to place the complete cases before the board in upcoming meeting.

PERVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

4. The subject issue of M/S Everest pharma Islamabad in which cancellation report received from P.S FIA/CCC Lahore and Investigation Agency Circle Multan vide letter no. 2720 dated 17-04-2023 was placed before the Provincial Quality Control Board (PQCB) Punjab in its 264th meeting held on 14-07-2023 under the Chairmanship of Special Secretary, (Operations) Primary & Secondary Healthcare Department, Punjab (Vice Chairperson).
5. The said issue discussed by the Board; Drug Inspectors of respective areas were also present at the time of discussion. The Board after due deliberation and discussion unanimously decided to direct the Drug Inspectors of the concerned areas to get information or details of the undertrial case of said Firm in Drug Court Islamabad from concerned Federal Inspector of Drug.
6. The Board further decided to call any relevant officer of DRAP, the one who is well informed about the status of cases of M/S Everest Pharma Islamabad in Board meeting while placing other cases of said firm before the Board.
7. Drug Inspector Layyah requested The Federal Inspector of Drugs, Islamabad to provide information about the current status of cases against M/S Everest Pharmaceuticals Pvt. Ltd via letter No. 1011/609/DC/LYA dated nil, a copy of which was received in the office of Secretary Provincial Quality Control Board, Punjab on 21-09-2023.
8. Drug Inspector Layyah communicated to the office of the Secretary PQCB through letter no. 1012/617/DC/LYA dated 27-09-2023 that he telephonically contacted the Federal Inspector of Drugs Islamabad and was informed that the status of the said cases will be apprised to the Board personally by the Legal Consultant Drug Regulatory Authority of Pakistan.

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

9. The issue was placed before the Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **269th** meeting held on **03-10-2023** under the chairmanship of Chairperson, Secretary Primary & Secondary Health Department. Mr. Shahid Zafar, Provincial Inspector of Drugs, Tehsil and District Layyah appeared before the Board and asked for guidance regarding the case.
10. The Board sought the legal opinion of Deputy Director (Legal Affairs) Drug Regulatory Authority of Pakistan

(**"DRAP"**), Islamabad, who was present in the meeting and stated that Federal Investigation Agency has not touched the merits of the case. Federal Investigation Agency merely relied on FIR No. 5/18 in FIA Corporate Crime Circle, Islamabad as a primary FIR registered by Drug Regulatory Authority Pakistan and principle of double jeopardy. However, it is straight law that double jeopardy is only a Judicial function and not a function of executive Investigation Agencies which cannot be disrupted by any Investigation Agency. The law has by now settled that the Investigation Agencies have to merely collect the facts regarding any offence without expressing any opinion regarding them. The principle of double jeopardy will only be applied by Courts in a case when the offense constituted by same facts has been tried by a competent Court and its decision attains finality. He also apprised that the DRAP sought advice from the Ministry of Law and Justice, Government of Pakistan on the doctrine of Double Jeopardy. The said Ministry of Law advised that the Double Jeopardy is a defence that prevents an accused person from being tried again on the same (or similar) charges following a valid acquittal or conviction. This Doctrine aims at providing finality to Criminal adjudication's and protects an individual against double punishments on same or similar charges. The Pre-conditions for attracting the Doctrine of Double Jeopardy are reproduced as under;

i. There must have been an early trial of the accused.
ii. The accused must be seeking protection against a second trial for the offence charged.
iii. The fact alleged in the early trial were the same sought to be proved in the second procedure/trial.
iv. The trial must have been conducted by a Court of competent jurisdiction.
v. The trial must have ended in a judgment of conviction or acquittal.

Reliance is placed on 2014 MLD 2013 Lahore, 2012 PLD 189 Quetta, and 2014 PLD 148 Lahore.

11. That the Deputy Director (Legal Affairs), DRAP also apprised the Board that the Registration Board of DRAP in its 285th Meeting held on 17th & 18th March, 2022 disagreed with findings of FIA, Lahore and observed as under;

> **"17. It has to be noted at the outset that determination as to if double jeopardy applies to a particular set of facts, is a judicial function which cannot be usurped by any investigating agency. The law has by now been settled that the investigating agencies have to merely collect facts regarding an offence without expressing any opinion regarding them. A perusal of both the Inquiry Report as well as the Investigation Reports show that it has not been denied that the offence complained of have been committed by the nominated accused; both the said Reports have not collected any facts which would show that the nominated accused have no role in the commission of offences. Therefore, both the Inquiry Report as well as the Investigation Report are strongly disagreed with as they have usurped the judicial function by diluting the trichotomy of powers to determine the FIRs as violating the doctrine of protection from double jeopardy.**
>
> **18. Even otherwise, both the Inquiry Report as well as the Investigation Report have wrongly applied the doctrine of protection against double jeopardy. A perusal of both the FIRs evinces that the same were lodged under different enactments of law having different procedure and forum for initiating proceedings thereunder, although both the sets of offences have been committed by the petitioners in one go that is to say that the accused acted in such a manner which constituted offences punishable under two separate and distinct enactments i.e. one under the Customs Act and the other under the Pakistan Penal Code along with the drug laws. Both are different and distinct pieces of legislation, therefore, acts and omissions of the accused committed by them cannot be**

said to be same offences.

24. The Board for the aforementioned reasons strongly disagreed with the findings/conclusions by both the Inquiry Report and the Investigation Report and decided the following:

a. **For the cases in which permission for prosecution has already been granted, the concerned FID is directed to file prosecution against the accused within 15 days with intimation to the Board;**
b. **For the cases in which permission for prosecution has not been granted, show cause notice be promptly issued through all means including through registered posts/courier service, Special Messengers/ Dispatch Riders and E-mails and WhatsApp for the accused persons whose IDs are available. Furthermore, show cause notices should be published in prominent Print Media in the reputable English & Urdu Newspapers. The published notices shall be pasted by area FID in front of residence of accused person and relevant Drug Courts".**

12. Legal Consultant, Drug Regulatory Authority, Pakistan provided the orders of Drug Court Islamabad dated 08-06-2023 wherein Dr. Kamran Izhar was acquitted by the Court under application 265-K Cr. P. C in FIR No. 05/2018.
13. Keeping in view the facts of the case and the legal advice of Deputy Director (Legal Affairs), Drug Regulatory Authority Pakistan, the Board after due deliberation and discussion unanimously decided to direct the concerned Drug Inspector to complete his independent investigation of the case and send it to the Board at the earliest for further consideration.
14. Drug Inspector, Tehsil and District Layyah submitted complete investigation report and requested for grant of permission of prosecution vide letter No. 1012/690/DC, LYA dated 29-11-2023 against the below mentioned accused persons who had contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed thereunder

i. **M/S Everest Pharmaceuticals Pvt. Ltd., 124, Industrial Triangle, Kahuta Road, Islamabad** through its **Owner Ch. Muhammad Usman.**
ii. **Ch. Muhammad Usman Owner/Warrantor**
iii. **Dr. Kamran Izhar Partner**
iv. **Noor Muhammad Mahar Partner**
v. **Muhammad Arshad Production In charge**
vi. **Mian Ishtiaq Ahmed Quality Assurance Manager**
vii. **Imtiaz Ahmed Quality Control Manager**

Of M/S Everest Pharmaceuticals Pvt. Ltd 124, Industrial Triangle, Kahuta Road, Islamabad for the offence of

a. **Illegal import of raw material**
b. **Illegal manufacturing/Manufacturing for sale of Allopathic unregistered drugs.**
c. **Issuance of false warranty**

PREVIOUS PROCEEDINGS AND DECISION OF THE BOARD

15. The case was placed before the Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its 274th meeting held on 21-12-2023 under the chairmanship of Special Secretary,

Operations Primary and Secondary Healthcare Department, Punjab (Vice Chairperson). No one among the nominated accused persons of M/S Everest Pharmaceuticals Pvt. Ltd. 124, Industrial Triangle, Kahuta Road, Islamabad appeared before the Board.

16. The Chief Drugs Controller, Punjab apprised the Board that personal hearing notices were delivered at the manufacturing unit of the firm through GMP Auditor, Rawalpindi but the security guards at the premises refused to receive the notices.
17. Keeping in view the facts of the case, the Board after due deliberation and discussion decided to pend the case and directed the concerned Provincial Inspector of Drugs and GMP Auditor, Rawalpindi to ensure the service of personal hearing notices to the accused persons of M/S Everest Pharmaceuticals Pvt. Ltd at their residential addresses by way of registered posts/ courier service/ special Messengers/ dispatch riders/ WhatsApp and e-mails, if available, of the accused and also directed that the notices shall be pasted by area Inspector of Drugs in front of residences of accused persons and relevant Drug Courts.

The case is placed before the Board.

PROCEEDINGS AND DECISION OF THE BOARD

Case No. 19

SM-87-06/2018

(Tehsil and District Layyah)

ATTENDANCE

BRIEF FACTS OF THE CASE

1. Provincial Inspector of Drugs, Tehsil and District Layyah inspected the business premises of M/S Muslim Traders TDA Colony Layyah and seized unregistered drug manufactured by M/S Everest Pharmaceuticals Pvt. Ltd on Form 5 on 06-03-2018.
2. The Drug Inspector requested for grant of permission of prosecution/registration of FIR against the below mentioned accused persons who had contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed thereunder

    i. Muhammad Usman
    ii. Dr. Kamran Izhar
    iii. Noor Muhammad Mahar
    iv. Mian Ishtiaq
    v. Imtiaz Ahmad
    vi. Muhammad Arshad

    Of M/S Everest Pharmaceuticals Pvt. Ltd 124, Industrial Triangle, Kahuta Road, Islamabad for the offence of

    a. Illegal import of raw material
    b. Illegal Manufacturing/Manufacturing for sale of un-registered drugs
    c. Issuance of false warranty

3. Show cause/personal hearing notice(s) issued to the accused.
4. Provincial Quality Control Board, Punjab granted permission for immediate registration of FIR against the accused at the concerned Police Station/FIA Crime Circle in its 191st meeting dated 16-08-2018.
5. The Drug Inspector requested the Deputy Director FIA Multan Region for registration of FIR vide letters No. 871/DC/LYA dated 26-09-2018 and No. 1011/1012-16/DC/LYA dated 29-10-2018 but an FIR was not registered.
6. The Drug Inspector requested for guidance/advice from the Chairman, provincial Quality Control Board, Punjab regarding the case vide his letter No. 1011/1892/DC, LYA dated 07-12-2021.

SM No	Premises Inspected	Drug/ Medicine name and batch no	Offence	Name of accused
SM-87-06/2018	Muslim Traders TDA Colony	i. Tablet Maintain Batch No. 053	a. Illegal import of raw material b. Illegal	Accused persons of M/S Everest Pharmaceuticals Pvt. Ltd 124,

	Layyah	ii. Tablet Dut-Plus Batch No. 094 iii. Tablet Zycin 250mg Batch No. 059 iv. Tablet Somat-N Batch No. 089 v. Tablet Rabzol-D Batch No. 347	Manufacturing/Manufacturing for sale of un-registered drugs c. Issuance of false warranty	Industrial Triangle, Kahuta Road, Islamabad as mentioned above

PREVIOUS PROCEEDINGS AND DECISION OF THE BOARD

7. The issue was placed before the Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **270th** meeting held on **19-10-2023** under the chairmanship of Special Secretary, Operations Primary and Secondary Healthcare Department, Punjab (Vice Chairperson).Drug Inspector, Tehsil and District Layyah did not appear before the Board.
8. The Secretary, Provincial Quality Control Board, Punjab apprised the Board that in 269th meeting of the board. Legal Consultant, Drug Regulatory Authority, Pakistan had given his legal opinion in the matter, who provided the orders of Drug Court Islamabad dated 08-06-2023 wherein Dr. Kamran Izhar was acquitted by the Court under application 265-K Cr. P. C in FIR No. 05/2018.
9. However, it is straight law that double jeopardy is only a Judicial function and not a function of executive Investigation Agencies which cannot be disrupted by any Investigation Agency. The law has by now settled that the Investigation Agencies have to merely collect the facts regarding any offence without expressing any opinion regarding them. The principle of double jeopardy will only be applied by Courts in a case when the offense constituted by same facts has been tried by a competent Court and its decision attains finality. He also apprised that the DRAP sought advice from the Ministry of Law and Justice, Government of Pakistan on the doctrine of Double Jeopardy. The said Ministry of Law advised that the Double Jeopardy is a defense that prevents an accused person from being tried again on the same (or similar) charges following a valid acquittal or conviction. This Doctrine aims at providing finality to Criminal adjudication's and protects an individual against double punishments on same or similar charges. The Pre-conditions for attracting the Doctrine of Double Jeopardy are reproduced as under;

    i. There must have been an early trial of the accused.
    ii. The accused must be seeking protection against a second trial for the offence charged.
    iii. The fact alleged in the early trial were the same sought to be proved in the second procedure/trial.
    iv. The trial must have been conducted by a Court of competent jurisdiction.
    v. The trial must have ended in a judgment of conviction or acquittal.

(Reliance is placed on 2014 MLD 2013 Lahore, 2012 PLD 189 Quetta, and 2014 PLD 148 Lahore).

10. That the Deputy Director (Legal Affairs), DRAP also apprised the Board in 269th meeting of PQCB that the Registration Board of DRAP in its 285th Meeting held on 17th & 18th March, 2022 disagreed with findings of FIA, Lahore and observed as under;

> **"17. It has to be noted at the outset that determination as to if double jeopardy applies to a particular set of facts, is a judicial function which cannot be usurped by any investigating agency. The law has by now been settled that the investigating agencies have to merely collect facts regarding an offence without expressing any opinion regarding them. A perusal of both the Inquiry Report as well as the Investigation Reports show that it has not been denied that the offence complained of have been committed by the nominated accused; both the said Reports have not collected any facts which would show that the nominated accused have no role in the commission of offences. Therefore, both the Inquiry Report as well as the Investigation Report are strongly disagreed with as they have usurped the judicial function by diluting the trichotomy of powers to determine the FIRs as violating the doctrine of protection from double jeopardy.**
>
> **18. Even otherwise, both the Inquiry Report as well as the Investigation Report have wrongly applied the doctrine of protection against double jeopardy. A perusal of both the FIRs evinces that the same were lodged under different enactments of law having different procedure and forum for initiating proceedings thereunder, although both the sets of offences have been committed by the petitioners in one go that is to say that the accused acted in such a manner which constituted offences punishable under two separate and distinct enactments i.e. one under the Customs Act and the other under the Pakistan Penal Code along with the drug laws. Both are different and distinct pieces of legislation, therefore, acts and omissions of the accused committed by them cannot be said to be same offences.**
>
> **24. The Board for the aforementioned reasons strongly disagreed with the findings/conclusions by both the Inquiry Report and the Investigation Report and decided the following:**
>
> a. **For the cases in which permission for prosecution has already been granted, the concerned FID is directed to file prosecution against the accused within 15 days with intimation to the Board;**
> b. **For the cases in which permission for prosecution has not been granted, show cause notice be promptly issued through all means including through registered posts/courier service, Special Messengers/ Dispatch Riders and E-mails and WhatsApp for the accused persons whose IDs are available. Furthermore, show cause notices should be published in prominent Print Media in the reputable English & Urdu Newspapers. The published notices shall be pasted by area FID in front of residence of accused person and relevant Drug Courts".**

11. Keeping in view the facts of the case and the legal advice of Deputy Director (Legal Affairs), Drug Regulatory Authority Pakistan, the Board after due deliberation and discussion unanimously decided to direct the concerned Drug Inspector to complete his independent investigation of the case and send it to the Board at the earliest for further consideration
12. Drug Inspector, Tehsil and District Layyah submitted complete investigation report and requested for grant of permission of prosecution vide letter No. 1011/710/DC, LYA dated 18-12-2023 against the below mentioned accused persons who had contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed thereunder

i. **M/S Everest Pharmaceuticals Pvt. Ltd., 124, Industrial Triangle, Kahuta Road, Islamabad** through its

Owner Ch. Muhammad Usman.

ii. **Ch. Muhammad Usman** **Owner/Warrantor**

iii. **Dr. Kamran Izhar** **Partner**

iv. **Noor Muhammad Mahar** **Partner**

v. **Muhammad Arshad** **Production In charge**

vi. **Mian Ishtiaq Ahmed** **Quality Assurance Manager**

vii. **Imtiaz Ahmed** **Quality Control Manager**

Of M/S Everest Pharmaceuticals Pvt. Ltd 124, Industrial Triangle, Kahuta Road, Islamabad for the offence of

a. **Illegal import of raw material**
b. **Illegal manufacturing/Manufacturing for sale of Allopathic unregistered drugs.**
c. **Issuance of false warranty**

Case is placed before the Board.

PROCEEDINGS AND DECISION OF THE BOARD

Case No. 20

PQCB R-884/2021

(Karor Lal Ehsan, District Layyah)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Hamaz Pharmaceuticals Pvt Ltd., 13-Km, Bosan Road, Multan, Pakistan,** through its Managing Director Imran Manzoor 2. Imran Manzoor — Managing Director 3. Aamir Manzoor — Director 4. Rana Muhammad Ashraf — Production Incharge 5. Muhammad Ashraf Araein — Quality Control Incharge/Warrantor of **M/s Hamaz Pharmaceuticals Pvt Ltd., 13-Km, Bosan Road, Multan, Pakistan.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Karor Lal Esan, District Layyah reported that: -

i. The then Drug Inspector, on 08-04-2021, inspected the business premises of M/s Anayatiya Medical Store, Adda Anayat Shah Mor, Chak No. 242-B/TDA, Tehsil Karor, District Layyah and took 05 different types of drug samples on Form No.04 and sent to Drug Testing Laboratory Multan for the purpose of test/analysis. The subject sample was
ii. The subject drug sample, sent vide memorandum no. 89193 dated 11-04-2021, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Multan as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report TRA No. & Date**
Tablet Estadol Extra [Paracetamol: 500mg, Caffeine: 65mg] **Mfg. date: 08-2022** **Exp. date: 08-2023** **Reg # 021329**	24003	M/s Hamaz Pharmaceuticals Pvt Ltd., 13-Km, Bosan Road, Multan, Pakistan	01-89003401/DTL, date: 11-08-2021
Specification applied: BP 2020 **DESCRIPTION**: White to off-white round tablet engraved “HAMAZ” above the line of bisection on one side & plain on the other side in ALU-PVC blister of 10 units packed in a labelled outer carton. Each outer carton contains ten blisters of 10 units each i.e., (10*10=100 Tablets). **WEIGHT VARIATION:**			

Average Weight: 650.05 mg

Limits: ± 5% (NMT 2 Tablets)

None deviate from ± 10% **(COMPLIES)**

Dissolution Test: Does not comply with the specifications as described below:

Tolerance Limit: NLT 75%(Q)of the labeled amount of Paracetamol and Caffeine is dissolved in 45 mints

LEVEL	UNITS	% RELEASE OF PARACETAMOL						AVERAGE	REMARKS
S1	6	No Unit is less than 80% (Q+5%)						S1	Does not comply
		U#1	U#2	U#3	U#4	U#5	U#6		
Determined	%	39.4	39.8	40.0	48.3	49.9	55.2		

LEVEL	UNITS	% RELEASE OF CAFFEINE						AVERAGE	REMARKS
S1	6	No Unit is less than 80% (Q+5)						S1	Does not comply
		U#1	U#2	U#3	U#4	U#5	U#6		
Determined	%	40	41.4	44.7	45.5	46.8	49.9		

* As the criteria of S3 i.e NMT 2 units are < Q-15%, And no unit is < Q-25% is achieved. So, the results conform at S1 Stage. **The quantity Q, is specified amount of dissolved active substance, expressed as percentage on the label claim.

IDENTIFICATION: Paracetamol and Caffeine Identified

Analytical Method: HPLC

Assay	Stated	Determined	Percentage	Limits	Comments
Paracetamol	500 mg/Tablet	511.25 mg/Tablet	102.25%	95-105%	Complies
Caffeine	65 mg/Tablet	65.49 mg/Tablet	100.75%	95-105%	Complies

RESULT: The above sample is **Sub-Standard**, on the basis of the **Dissolution** performed.

iii. M/s Anayatiya Medical Store, Adda Anayat Shah Mor, Chak No. 242-B/TDA, Tehsil Karor, District Layyah provided invoice/ warranty no. **0** dated 11-03-2021 issued by M/S Hakim sons Medicine Company, Eid Ghah Road, Layyah, as a proof of purchase.
iv. Warrantor portion was sent to M/S Hakim sons Medicine Company, Eid Ghah Road, Layyah.
v. M/S Hakim sons Medicine Company, Eid Ghah Road, Layyah provided invoice/warranty no. **523501**, dated: 20-01-2021 issued by M/S Rayyan Pharma, 1st Floor, Khugani Tower, Medicine Market, Multan, who in turn provided invoice/warranty no. **804** dated: 19-01-2021 issued by M/s Hamaz Pharmaceuticals, Business City Plaza, Hall # 1, 2nd Floor, Bosan Road, Multan, Pakistan, Pakistan, as a proof of purchase of subject drug sample.
vi. A copy of test/analysis report was sent M/s Hamaz Pharmaceuticals Pvt Ltd., 13-Km, Bosan Road, Multan, Pakistan to explain their position and provide requisite information in this regard.

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(as amended)/DRAP Act 2012 and Rules framed there under by the way of: -

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

3. Show cause notice(s)/ Personal Hearing notice issued to the accused vide 08-01-2024.

Case is placed before the board for decision

Summary of the case:

- **Mfg. date:08-2020**
- **Exp. Date: 08-2023**
- **Sampling date (Form 4): 08-04-2021**
- **Sent to DTL (Form 6): 11-04-2021**
- **Date of receipt in DTL: 14-04-2021**
- **DTL Report Date (Form 7): 11-08-2021 (Time barred=on 120th day)**
- **DTL Time Extension: Yes, in 232nd meeting dated: 24-06-2021****
- **DI 1st intimation to firm: 24-12-2019**
- **Retesting request if any: No**
- **Investigation report Dated: 25-10-2023**

****NOTE**:

Time extension for analysis of subject sample was granted to GA DTL Multan in 232nd meeting, dated 24-06-2021. The name of sender was erroneously written as Karor Pacca instead of Karor Lal Esan in request letter by DTL, for the correction of which the Director DTL requested vide letter no.5298/DTLM, dated 06-10-2021. The request was not entertained at that time. Henceforth, the request for post-facto approval for correction is placed before the Board.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 21

PQCB/R-683/2021

Tehsil Chunian, District Kasur

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan** through its Director, Imran Manzoor 2. Imran Manzoor Director 3. Muhammad Ashraf Production Manager s/o Muhammad Din 4. Muhammad Ashraf Arain Quality Control Manager/Warrantor s/o Muhammad Ibrahim of M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Chunian, District Kasur reported that: -

i. His predecessor, on 12-03-2021, inspected the business premises of M/s Zafar Medical Store, Khalid Market, Chunian Kasur, took two different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide memorandum no. 87063 dated 12-03-2021.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**TRA No. & Date**	**DTL Test Report Result**
Syrup. CLOPREL [METOCLOPRAMIDE AS HCl 5mg/5ml] **Mfg Date:** Aug 2020 **Expiry Date:**	CL002	M/S Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan.	01-73007880/DTL dated 06-05-2021	**Analysis with specifications applied: USP 2020** **PHYSICAL DESCRIPTION:** LIGHT GREEN COLORED LIQUID CLAIMED TO BE SYRUP IN AMBER GLASS BOTTLE, SEALED WITH WHITE COLORED ALUMINIUM SCREW CAP. CLAIMED VOLUME= 50ml. **pH:** Limit: 2.0 – 5.5

Aug 2022 **Regn No.** 048921				Determined: 4.27 at 24.8°C **IDENTIFICATION:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (METOCLOPRAMIDE HCl IDENTIFIED) **ASSAY OF METCLOPRAMIDE:** Stated: 5 mg / 5mL Determined: 4.244 mg / 5mL Percentage: **84.88% (DOES NOT COMPLY)** Limit: 90.0%–110.0% OF LABEL **RESULT:** The above sample is **SUB-STANDARD,** on the basis of ASSAY of METOCLOPRAMIDE performed as per USP.

iii. M/s Zafar Medical Store, Khalid Market, Chunian Kasur provided invoice/ warranty bearing No. 000773 dated 28-01-2021 issued by M/s Haseeb Traders, Outside Kot Peeran Katcheri Road, Kasur as a proof of its purchase of the subject drug sample.

iv. Warrantor portion of drug sample was sent to M/s Haseeb Traders, Outside Kot Peeran Katchri Road, Kasur who provided invoice/ warranty bearing No. 827 dated 21-01-2021 issued by M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan as a proof of its purchase of the subject drug sample.

v. A copy of test/analysis report was sent to M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis reports of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

Previous Proceedings of the Board: (Regarding Retesting Request)

249th meeting held on 23-08-2022

2. The subject request for retesting of the drug sample was placed before the Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **249thmeeting** held on **23-08-2022** chairmanship of Vice Chairperson, Provincial Quality Control Board (PQCB) Mr. Noor Mahar Advocate and Mr. Ashraf Quality Control Manager of Hamaz Pharmaceuticals appeared before Board to plead the case. The Secretary PQCB apprised the Board that Drug Testing Laboratory report conveyed by the Provincial inspector of Drugs to manufacturer vide letter no..758A/DI/Chu dated 06-06-2021, (2) letter No..806A/DI/Chu dated 21-08-2021, (3) letter No..822A/DI/Chu dated 21-10-2021, (4) letter No..837A/DI/Chu dated 13-11-2021 and (5) letter No..958/DI/Chu dated 16-05-2022 but only one letter was received by firm 837A/DI/Chu dated 13-11-2021and Manufacturer requested for retesting vide letter no: Hamaz/DDHOKSR/0001 Dated 18-11-2021 which was forwarded to Provincial Quality control Board on 18-07-2022 which was received in the office of PQCB on 27-07-2022 about 8 months delay

3. The Board thoroughly evaluated the DTL test report and observed that the subject product fails to comply on the basis of Assay test of the active pharmaceutical ingredient which is remarkably less (84.88%) than the lower admissible limit of Manufacturer's Specifications (97-103%). The Board further scrutinized the all the relevant data submitted by the Government Analyst regarding the test /analysis and observed that Government Analyst has fulfilled all requirements of the test protocol as described in the Manufacturer's Specifications, as specified by the firm in its label claim. The test was performed on 21 CFR part 11 compliance HPLC with Audit trail. Moreover, after revamping, the Drug Testing Laboratories of the Punjab are testing the drug samples according to the International Standard of the test / analysis and all these laboratories are ISO Certified and are in process of WHO accreditation.

4. Contrarily, the data submitted by the firm in controversion to the Government Analyst report regarding the Assay test of subject drug was insufficient. The Board observed that firm has neither provided the Column used in HPLC rare and Standard used for preparation of solution.

5. Considering the above facts in view, the Board after due deliberation and discussion, unanimously decided to **Turn Down** the request by the Firm for retesting of the subject drug sample. The Board further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

6. The Board further **Decided to forward the matter to Director DTL, Lahore** to probe the delaying correspondence by the area Drug Inspector to the office of PQCB and submit the report for the consideration by the Board.

Probe Report of Case No. PQCB/R-445-05/2021 of Syp. Cloprel, Batch No. CL002, Manufactured by M/S Hamaz Pharmaceuticals (Pvt) Ltd Multan.

Facts of the Case

1. The then Drug Inspector, Mr. Laiq ur Rehman, Tehsil Chunian District Kasur took the sample of Syp. Cloprel 50ml, B.No. CL002, Mfg. by Hamaz Pharmaceuticals (Pvt) Ltd Multan on form-4 0n 12-03-2021.
2. The said sample was sent to DTL Lahore vide memorandum 000087063 on 12-03-2021 and **Form-06 is not available** in file.
3. After 2 days, Drug Inspector, Laiq ur Rehman, Tehsil Chunian District Kasur wrote to Mr. Abdul Latif (Prop.) M/S Zafar Medical Store Khalid Market Chunian and directed him to provide original warranty of said samples vide letter No. 710A/DI/Chu dated 14-03-2021.
4. The said sample was declared substandard by DTL Lahore vide TRA No. 01-73007880/DTL, Dated 06-05-2021.
5. Drug Inspector, Laiq ur Rehman, Tehsil Chunian District Kasur wrote to Mr. Abdul Latif (Prop.) M/S Zafar Medical Store Khalid Market Chunian was intimated about result of said sample and again directed to provide invoice/warranty vide letter no. 749A/Di/Chu dated 18-05-202, who provided the bill no. 000773 dated 28-01-2021.
6. Drug Inspector, Laiq ur Rehman, Tehsil Chunian District Kasur wrote to Mr. Munir Hussain (Warrantor) Haseeb Traders Kasur vide no. 750A/Di/Chu dated 19-05-2021 and sent the warrantor portion, who replied on 28-05-2021 and provided invoice no. 827 Dated 21-01-2021 of the manufacturer M/S Hamaz Pharmaceuticals (Pvt) Ltd Multan.
7. The manufacturer M/s Hamaz Pharmaceuticals (Pvt) Ltd Multan was written by dug inspector Mr. Liaq ur Rehman for provision of information of substandard drug
    a. vide no.758A/Di/Chu, dated 06-06-2021 **Not having any postal proof** and
    b. again, written vide no.806A/Di/Chu, dated 21-08-2021 **Not having any postal proof**,
    c. again, written vide no.822A/Di/Chu, dated 21-10-2021 **Not having any postal proof**,

d. Again, written vide no.837A/Di/Chu, dated 13-11-2021 **having TCS receipt CN 40605574470**,
e. who replied on 25-05-2022 and challenged the test analysis report.

8. The firm M/S Hamaz Pharma replied vide HAMAZ / DDHOKSR/0001 on 18-11-2022 (**within 5 days of last letter by DI**) and **challenged the test analysis report.**
9. The appeal of retesting of sample was not forwarded to chairman, PQCB By Drug Inspector Mr. Laiq Ur Rehman and a letter vide no.914A/Di/Chu, dated 24-02-2022 through registered post was written to firm with direction to provide proof that firm submitted appeal to PQCB, which **unjustified and not as per legal procedure. (Delay of about 3 months)**
10. Again, Drug Inspector Mr. Laiq Ur Rehman sent a letter vide no.958A/Di/Chu, dated 16-05-2022 through registered post was written to firm with direction to provide complete information of drug / firm and proof that firm submitted appeal to PQCB, which is **wrong / unjustified and not as per legal procedure. (Delay of about 3 months)**
11. The firm M/S Hamaz Pharma replied vide HAMAZ / CL002/DDHOKSR/0002 on 27-05-2022 and provided the name of director /QC manager / Production Manager and **again requested for retesting / challenged the test analysis report.**

Mr. Laiq Ur Rehman Drug inspector transferred and Mr. Akhtar Ali was posted on 15-06-2022 and received record of this case file on 21-06-2022.

12. The current drug Inspector Mr. Akhtar Ali wrote letter to Secretary PQCB vide No. 03/DI/Chu /22 dated 18-07-2022 **(about after one month of taking charge) and intimated regarding retesting stance of the firm but only one month left from the expiry of drug i.e., 08/2022.**
13. The Secretary PQCB directed and call upon personal hearing of both Drug Inspectors Tehsil Chunian vide No. PQCB/P-455-5/2021, dated 11-08-2022.
14. The current drug Inspector Mr. Akhtar Ali wrote letter / reply to Secretary PQCB on personal hearing dated 15-08-2022 and disclosed that matter has already been informed to the board.
15. The then Drug inspector Mr. Laiq ur Rehman wrote letter / reply to Secretary PQCB on personal hearing dated 15-08-2022 and admitted that he wrote to the firm to produce evidence of retesting.

Findings of Probe:

The undersigned after perusal of record file of case on 21-12-2022 and personal hearing of Mr. Akhtar Ali, current Drug Inspector, Tehsil Chunian. The undersigned is of opinion that following officers / official are responsible for negligence in official duty and not followed the defined lawful procedure during investigation of case.

1. The then Drug Inspector, Mr. Laiq ur Rehman, Tehsil Chunian (remained posted at said post from 01-09-2020 to 30-05-2022) who
    a. Not provided copy of Form-6
    b. Delay of about 5 months in sending re-testing appeal to PQCB, as not properly posted letters to firm with proof of postal receipt
    c. Proceeded wrongly investigation of case.
2. In said case, negligence in official duty is on the part of officer Ex-drug inspector Mr. Laiq ur Rehman, Tehsil Chunian District Kasur.

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

a. **Manufacture for sale/ Sale of Substandard drug**
b. **Issuance of false warranty**

8. Show-cause notice(s) issued to accused person(s) dated 06-02-2023

Firm replied to the show cause notice vide letter no. HAMAZ/CL-002/MKT/0002S received on 28-02-2023

1. *We are in receipt of the Show Cause Notice No. POCB/R-683/202 1 dated 06-02-2023 whereunder you have directed M/s Hamaz Pharmaceuticals (Pvt.) Ltd. (the "Company") to show cause as to why any legal action may not be taken against the Company including but not limited to the initiation of prosecution before the Honorable Drug Court and cancellation of the Drug Manufacturing License and Drug Registration, for allegedly violating the provisions of the Drugs Act, 1976 and the DRAP Act, 2012 along with the rules framed thereunder.*
2. *We hereby **acknowledged that we have supplied stocks** of Cloprel Syrup Smg/5ml (Metoclopramide as HCI 5mg/5ml) to M/s. Haseeb Traders Kasure. Kot Perian, Kachari Road, Kasure-Pakistan vide invoice warranty No. 827 dated 2 1.01.202 1.*
3. *Drug Testing Laboratory (DTL), Lahore, vide report 01-73007880/DTL dated 06.05.2021 has allegedly declared that Cloprel Syrup Smg/5ml (Metoclopramide HCI Smg/5ml) Batch No. CL002 is Substandard on the basis of Assay of Metoclopramide performed as per USP and **we challenged this report and requested for RETESTING**.*
4. *Without prejudice to the foregoing and despite the complete innocence of the Company and its officials as, please note the following information as per your requirement:*

   Mr. Aamir Manzoor (Director) CNIC No. 36302-069345

   Mr. Shahzad Ahmed Khan (Production In-charge) CNIC No. 36103-1658536-3

   Mr. Muhammad Ashraf (Quality Control In-charge) CNIC No. 36302-5179576-3

5. *As per our in-house testing the batch No.CL002 of **Cloprel Syrup is up to the standards** and there is no offence committed by our firm /s 23/27 of Drug Act 1976 (as amended) /DRAP act 2012 and rules framed there under.*
6. *In view of the foregoing, it is respectfully requested that the titled show cause notice and any subsequent proceedings **may kindly be withdrawn** for prosecution, cancellation & suspension of drug manufacturing license and Drug Registration Certificate or any other legal action(s) against our firm rather we would humbly request this honorable board to **please review your decision on retesting** and oblige.*

4. Personal hearing notice(s) issued to accused person(s) dated 20-02-2024

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: March-2022

Expiry Date: March-2025

Sampling Date (Form 4): 12-03-2021

Sent to DTL (Form 6): 12-03-2021

Date of receipt in DTL: 12-03-2021

DTL Report Date (Form 7): 06-05-2021

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 10-02-2023

Retesting Request of Firm: No

Investigation Report Dated: 15-08-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 22

PQCB/R-740/2021

Sheikh Zayed Hospital, Rahim Yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Hamaz Pharmaceuticals Pvt Ltd., 13Km Bosan Road, Multan** through its Managing Director Amir Khan. 2. Amir Khan — Managing Director 3. Rana Muhammad Ashraf — Production Incharge 4. Muhammad Ashraf Arain — Quality Control Incharge/Warrantor Of M/s Hamaz Pharmaceuticals, 13Km Bosan Road, Multan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sheikh Zayed Hospital, Rahim Yar Khan reported that:-

i. He, on 18-05-2021, inspected the premises of M/s Central Pharmacy (Main Medicine Store), Sheikh Zayed Medical College/Hospital Rahim Yar Khan, took sample on Form 4 and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 340/DI-SZH-RYK dated 18.05.2021 for the purpose of test/analysis.
ii. The 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.	Name of Manufacturer	DTL Report	DTL Test Report Result
Injection Vivofer [Iron Sucrose Complex Eq. to Elemental Iron 100mg/5ml] **Mfg. Date**: 05-2021 **Exp. Date**: 05-2023 **Reg** # 084189	VR 101	M/s Hamaz Pharmaceuticals, 13Km, Lutfabad, Bosan Road, Multan.	01-77004137/ DTL dated: 14-09-2021	**Result of test/ analysis with specifications applied:** USP 2020 **COMPOSITION:** Each 5ml ampoule contains: Iron Sucrose Complex USP Eq. to Elemental Iron……100mg **DESCRIPTION**: Reddish brown colored solution filled in amber glass ampoule, packed in PVC tray of 5 units in a labelled outer carton. Stated Volume: 5ml **VOLUME:** Limit: ……...NLT nominal volume 5ml Determined: 5ml **pH:**

				Limit: …….. 10.5-11.1 **Determined: 10.0** **(Does not comply with specifications)** **STERILITY:** the product is Sterile. **IDENTIFICATION: I**ron as sucrose is identified **ASSAY IRON:** Stated: 100mg/5ml Determined: 118.012mg/5ml **Percentage 118.012%** Limit: 95-105% **Does not comply** **Sucrose:** Limit: ……..260-340mg/ml Determined: **363.08**mg/ml (**Does not comply with specs)** **RESULT**: The sample is **SUB**-**STANDARD** on the basis of pH & **Assay Test**.

iii. Central Pharmacy (Main Medicine Store), Sheikh Zayed Hospital Rahim Yar Khan provided invoice/warranty No. 1352 dated 07.05.2021 issued by M/S Hamaz Pharmaceuticals, Pvt Ltd., Bosan Road Multan.
iv. Warrantor portion of the drug sample was sent to M/s Hamaz Pharmaceuticals Multan.
v. A copy of DTL report was sent to M/s Hamaz Pharmaceuticals Multan with directions to explain their position and provide requisite information in this regard. In response Firm requested re-testing of the sample. Provincial Quality Control Board turned down the request for re-testing of sample in its 241st meeting dated 31.03.2022.

Previous proceedings regarding retesting request:

241st meeting dated 31-03-2022

The Board in its 241st meeting dated 31-03-2022 decided to turn down the retesting request and directed DI to submit complete investigation 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/DRAP Act 2012 and Rules framed there under by the way of: --

a. **Manufacture for sale/sale of Substandard drugs**
b. **Issuance of false warranty**

3 Show cause notice issued to the accused

4 Personal hearing notice issued to the accused

Summary:

Manufacturing Date: 5-2021

Expiry Date: 5-2023

Sampling Date: 18-5-2021

Sent to DTL (Form 6): 18-05-2021

Date of receipt in DTL: 19-05-2021

DTL Report Date: 14-09-2021

Time extension granted: 233rd meeting dated 17-08-2021

1ST DI Communication with firm on dated: 29-09-2021

Date of Retesting Request of Firm: 06-10-2021

Fate of Retesting Request: turn down (241-M dated 31-03-2022)

Investigation Report Dated: 04-03-2023

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 **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Mr. Rafaqat Ali, Secretary DQCB, Rahim Yar Khan and Mr. Ilyas Provincial Inspector of drugs Sheikh Zayed Hospital Rahim Yar Khan was present along with original case record. No one among the nominated accused person was present. However, Mr. Usman representative on behalf of M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan Pakistan appeared before the Board and submitted written request for adjournment.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case on the request of the firm and provide another opportunity of hearing to the firm in the best interest of justice. Moreover, the drug inspector is directed to retain an appropriate portion for Court purposes and dispose-off the remaining stock having Expiry date of 05-2023 (if not recovered and seized on Form-3 & Form-5) from Expired Drug Disposal Committee (EDDC) of health facilities already constituted vide PSHD notification No. SO (HP) 2-9(2)/ 2021 dated 14-February, 2022 and PQCB order dated 06-05-2023 on guidelines regarding fate of case properties and report to the office of Secretary PQCB within 7 days.

7. Personal hearing notice issued to the accused

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 23

PQCB/R-741/2021

Sheikh Zayed Hospital, Rahim Yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Hamaz Pharmaceuticals Pvt Ltd., 13Km Bosan Road, Multan** through its Managing Director Amir Khan. 2. Amir Khan — Managing Director 3. Rana Muhammad Ashraf — Production Incharge 4. Muhammad Ashraf Arain — Quality Control Incharge/Warrantor Of M/s Hamaz Pharmaceuticals, 13Km Bosan Road, Multan**.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sheikh Zayed Hospital, Rahim Yar Khan reported that:-

i. He, on 22-06-2021, inspected the premises of M/s Central Pharmacy (Main Medicine Store), Sheikh Zayed Medical College/Hospital Rahim Yar Khan, took sample of drug on Form 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 454/DI-SZH-RYK dated 22.06.2021.
ii. The 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.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Injection Vivofer [Iron Sucrose Complex Eq. to Elemental Iron 100mg/5ml] **Mfg. Date**: 05-2021 **Exp. Date**: 05-2023 **Reg** # 084189	VR 101	M/s Hamaz Pharmaceuticals, 13Km, Lutfabad, Bosan Road, Multan.	01-77004693/ DTL dated: 14-09-2021	**Result of test/ analysis with specifications applied:** USP 2020 **COMPOSITION:** Each 5ml ampoule contains: Iron Sucrose Complex USP Eq. to Elemental Iron…….100mg **DESCRIPTION**: Reddish brown colored solution filled in amber glass ampoule, packed in PVC tray of 5 units in a labelled outer carton. Stated Volume: 5ml **VOLUME:** Limit: NLT nominal volume 5ml Determined: 5ml **pH:**

				Limit: 10.5-11.1 Determined: **10.1** **(Does not comply with specifications)** **STERILITY:** the product is Sterile. **IDENTIFICATION: I**ron as sucrose is identified **ASSAY IRON:** Stated: 100mg/5ml Determined: 113.72mg/5ml Percentage **113**.72% Limit: 95-105% **Does not comply with specs** **Sucrose:** Limit: 260-340mg/ml Determined: **360.485**mg/ml (**Does not comply with specs)** **RESULT**: The sample is **SUB**-**STANDARD** on the basis of **pH** & **Assay Test**.

iii. Central Pharmacy (Main Medicine Store), Sheikh Zayed Hospital Rahim Yar Khan provided invoice/warranty No. 1473 dated 27.05.2021 issued by M/S Hamaz Pharmaceuticals, Pvt Ltd., Bosan Road Multan.
iv. Warrantor portion of the drug sample was sent to M/s Hamaz Pharmaceuticals Multan.
v. A copy of DTL report was sent to M/s Hamaz Pharmaceuticals Multan with directions to explain their position and provide requisite information in this regard. In response Firm requested re-testing of the sample. Provincial Quality Control Board turned down the request for re-testing of sample in its 241st meeting dated 31.03.2022.

Previous proceedings regarding retesting request:

241st meeting dated 31-03-2022

The Board in its 241st meeting dated 31-03-2022 decided to turn down the retesting request and directed DI to submit complete investigation 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/DRAP Act 2012 and Rules framed there under by the way of: --

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

b. **Issuance of false warranty**

3 Show cause notice issued to the accused

4 Personal hearing notice issued to the accused

Summary:

Manufacturing Date: 5-2021

Expiry Date: 5-2023

Sampling Date: 22-6-2021

Sent to DTL (Form 6): 22-06-2021

Date of receipt in DTL: 22-06-2021

DTL Report Date: 14-09-2021

Time extension granted: 18th Committee meeting dated 13-09-2021

1ST DI Communication with firm on dated: 29-09-2021

Date of Retesting Request of Firm: 24-11-2021

Fate of Retesting Request: turn down (241-M dated 31-03-2022)

Investigation Report Dated: 04-03-2023

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 **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Mr. Rafaqat Ali, Secretary DQCB, Rahim Yar Khan and Mr. Ilyas Provincial Inspector of drugs Sheikh Zayed Hospital Rahim Yar Khan was present along with original case record. No one among the nominated accused person was present. However, Mr. Usman representative of M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan Pakistan appeared before the Board and submitted written request for adjournment.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case on the request of the firm and provide another opportunity of hearing to the firm in the best interest of justice. Moreover , the drug inspector is directed to retain an appropriate portion for Court purposes and dispose-off the remaining stock having Expiry date of 05-2023 (if not recovered and seized on Form-3 & Form-5) from Expired Drug Disposal Committee (EDDC) of health facilities already constituted vide PSHD notification No. SO (HP) 2-9(2)/ 2021 dated 14-February, 2022 and PQCB order dated 06-05-2023 on guidelines regarding fate of case properties and report to the office of Secretary PQCB within 7 days.

7. Personal hearing notice issued to the accused

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 24

PQCB/R-798/2021

Sheikh Zayed Hospital, Rahim Yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Hamaz Pharmaceuticals Pvt Ltd., 13Km Lutfabad, Bosan Road, Multan** through its Managing Director Amir Manzoor. 2. Amir Manzoor Managing Director 3. Muhammad Ashraf Production Incharge 4. Muhammad Ashraf Arain Quality Control Incharge/Warrantor Of M/s Hamaz Pharmaceuticals, 13Km Lutfabad**,** Bosan Road, Multan**.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sheikh Zayed Hospital, Rahim Yar Khan reported that:-

i. He, on 31-05-2021, inspected the premises of M/s Central Pharmacy (Main Medicine Store), Sheikh Zayed Medical College/Hospital Rahim Yar Khan, took sample of drug on Form 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. DI-SZH-RYK/407 dated 31.05.2021.
ii. The 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.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Injection Vivofer [Iron Sucrose Complex Eq. to Elemental Iron 100mg/5ml] **Mfg. Date**: 05-2021 **Exp. Date**: 05-2023	VR 102	M/s Hamaz Pharmaceutical 13Km, Lutfabad, Bosan Road, Multan.	01-77004361/ DTL dated: 14-09-2021	**Result of test/ analysis with specifications applied:** USP 2020 **COMPOSITION:** Each 5ml ampoule contains: Iron Sucrose Complex USP Eq. to Elemental Iron……100mg **DESCRIPTION**: Reddish brown colored solution filled in amber glass ampoule, packed in PVC tray of 5 units in a labelled outer carton. Stated Volume: 5ml **VOLUME:** Limit: NLT nominal volume 5ml Determined: 5ml

Reg # 084189				**pH:** Limit: 10.5-11.1 Determined: 11.1 **STERILITY:** the product is Sterile. **IDENTIFICATION**: Iron as Iron sucrose is identified **ASSAY IRON:** Stated: 100mg/5ml Determined: 114.2mg/5ml Percentage **114.2**% Limit**:** **95-105%** **Does not comply with specs** **Sucrose:** Limit: 260-340mg/ml Determined: **354.626**mg/ml (**Does not comply with specs)** **RESULT**: The sample is **SUB-STANDARD** on the basis of **Assay Test**.

iii. Central Pharmacy (Main Medicine Store), Sheikh Zayed Hospital Rahim Yar Khan provided invoice/warranty No. 1473 dated 27-05-2021 issued by M/S Hamaz Pharmaceuticals, Pvt Ltd., 13km Lutfabad Bosan Road Multan.
iv. Warrantor portion of the drug sample was sent to M/s Hamaz Pharmaceuticals 13km Lutfabad, Bosan Road Multan.
v. A copy of DTL report was sent to M/s Hamaz Pharmaceuticals 13km Lutfabad Bosan Road Multan with directions to explain their position and provide requisite information in this regard. In response Firm requested re-testing of the sample. Provincial Quality Control Board turned down the request for re-testing of sample in its 241st meeting dated 31.03.2022. The Board in its 259th Meeting dated 18-04-2023 unanimously decided to turn down the subject Review petition of the firm.

Previous proceedings regarding retesting request:

241st meeting dated 31-03-2022

The Board in its 241st meeting dated 31-03-2022 decided to turn down the retesting request and directed DI to submit complete investigation report for consideration by The Board.

259-M dated 18-04-2023

The Board in its 259th meeting dated 18-4-2023 decided to turn down the subject review petition and upheld the previous decision taken in 241-M and directed DI to submit complete investigation 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/DRAP Act 2012 and Rules framed there under by the way of: --

a. **Manufacture for sale/sale of Substandard drugs**
b. **Issuance of false warranty**

3 Show cause notice issued to the accused

4 Personal hearing notice issued to the accused

Summary:

Manufacturing Date: 5-2021

Expiry Date: 5-2023

Sampling Date: 31-5-2021

Sent to DTL (Form 6): 31-5-2021

Date of receipt in DTL: 03-06-2021

DTL Report Date: 14-09-2021

Time extension granted: 233 meeting dated 17-08-2021

1ST DI Communication with firm on dated: 29-09-2021

Date of Retesting Request of Firm: 06-10-2021

Fate of Retesting Request: turn down (241-M dated 31-03-2022) RP turn down in 259-M dated 18-4-2023

Investigation Report Dated: 08-06-2023

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 **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Mr. Rafaqat Ali, Secretary DQCB, Rahim Yar Khan and Mr. Ilyas Provincial Inspector of drugs Sheikh Zayed Hospital Rahim Yar Khan was present along with original case record. No one among the nominated accused person was present. However, Mr. Usman representative of M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan Pakistan appeared before the Board and submitted written request for adjournment.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case on the request of the firm and provide another opportunity of hearing to the firm in the best interest of justice.

Moreover, the drug inspector is directed to retain an appropriate portion for Court purposes and dispose-off the remaining stock having Expiry date of 05-2023 (if not recovered and seized on Form-3 & Form-5) from Expired Drug Disposal Committee (EDDC) of health facilities already constituted vide PSHD notification No. SO (HP) 2-9(2)/ 2021 dated 14-February, 2022 and PQCB order dated 06-05-2023 on guidelines regarding fate of case properties and report to the office of Secretary PQCB within 7 days.

7. Personal hearing notice issued to the accused

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 25

PQCB/R-815, 816,817,818,819,820,821,822/2022

Sheikh Zayed Hospital Rahim yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Hamaz Pharmaceuticals Pvt Ltd., 13Km Bosan Road, Multan** through its Managing Director Amir Manzoor. 2. Amir Manzoor Managing Director 3. Muhammad Ashraf S/o Muhammad Din Production Incharge 4. Muhammad Ashraf S/o Muhammad Ibrahim Quality Control Incharge/Warrantor Of M/s Hamaz Pharmaceuticals, 13Km Bosan Road, Multan**.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sheikh Zayed Hospital, Rahim Yar Khan reported that:-

i. He, on 27-03-2021, inspected the premises of M/s Central Pharmacy (Main Medicine Store), Sheikh Zayed Medical College/Hospital Rahim Yar Khan, took sample on Form 4 and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. DI-SZH-RYK/155, 156, 157, 158, 159, 160, 161, 162 dated 27-03-2022 for the purpose of test/analysis.
ii. The following drug sample, 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	DTL Test Report Result
1	INJECTION. CLOPREL [METOCLOPRAMIDE HYDROCHLORIDE: 10MG/2ML) **Mfg Date:** 02-2021 **Exp Date:** 02-2023 **Regn No:** 084186	CLI103	M/S HAMAZ PHARMACEUTICALS (PVT.) LTD., 13-KM, LUTFABAD, BOSAN ROAD, MULTAN-PAKISTAN.	01-77003568/DTL-BWP Dated 21 May 2021	**Specification Applied: USP 2020** **DESCRIPTION:** Colorless liquid in transparent gl undissolvable particulate matter seen with the naked ey **VOLUME** Limit: Not Less Than nominal volume Determined: --------- 2 ml **pH** Limit: ---------- 2.5-6.5 Determined: ---------- 5.3 **STERILITY:** The product is sterile. **IDENTIFICATION:** Metoclopramide HCl is identifie **ASSAY**: **Metoclopramide**

					Stated | **Determined** | **Percenta** 10mg/2ml | 9.84mg/2ml | 98.41% **RESULT**: The sample is declared **SUB-STANDARD**
2	INJECTION. CLOPREL [METOCLOPRAMIDE HYDROCHLORIDE: 10MG/2ML.) **Mfg Date:** 02-2021 **Exp Date:** 02-2023 **Regn No:** 084186	CLI104	M/S HAMAZ PHARMACEUTICALS (PVT.) LTD., 13-KM, LUTFABAD, BOSAN ROAD, MULTAN-PAKISTAN.	01-77003569/DTLBWP Dated 21 May 2021	**Specification Applied: USP 2020** **DESCRIPTION:** Colorless liquid in transparent gla dissolvable particulate matter seen with the naked eye. **VOLUME** Limit: Not Less Than nominal volume Determined: --------- 2 ml **pH** Limit: ---------- 2.5-6.5 Determined: ---------- 5.2 **STERILITY** The product is sterile. **IDENTIFICATION** Metoclopramide HCl is identifi **ASSAY** | **Stated** | **Determined** Metoclopramide HCl | 10mg/2ml | 9.7mg/2ml **RESULT**: The sample is declared SUB-**STANDARD**
3	INJECTION. CLOPREL [METOCLOPRAMIDE HYDROCHLORIDE: 10MG/2ML.) **Mfg Date:** 02-2021 **Exp Date:**	CLI105	M/S HAMAZ PHARMACEUTICALS (PVT.) LTD., 13-KM, LUTFABAD, BOSAN ROAD, MULTAN-PAKISTAN.	01-77003570/DTLBWP Dated 21 May 2021	**Specification Applied: USP 2020** **DESCRIPTION:** Colorless liquid in transparent glas dissolvable particulate matter seen with the naked eye. **VOLUME** Limit: Not Less Than nominal volume Determined: --------- 2.04 ml **pH** Limit: ---------- 2.5-6.5 Determined: ---------- 5.2 **STERILITY** The product is sterile. **IDENTIFICATION:** **Metoclopramide** HCl is identif

	02-2023 **Regn No:** 084186				<table><tr><th>ASSAY</th><th>Stated</th><th>Determined</th></tr><tr><td>Metoclopramide HCl</td><td>10mg/2ml</td><td>9.7mg/2ml</td></tr></table> **RESULT**: The sample is declared **SUB-STANDARD**
4	INJECTION. CLOPREL [METOCLOPRAMIDE HYDROCHLORIDE: 10MG/2ML.) **Mfg. Date:** 02-2021 **Exp Date:** 02-2023 **Regn No:** 084186	CLI106	M/S HAMAZ PHARMACEUTICALS (PVT.) LTD., 13-KM, LUTFABAD, BOSAN ROAD, MULTAN-PAKISTAN.	01-77003571/DTLBWP Dated 21 May 2021	**Specification Applied: USP 2020** **DESCRIPTION:** Colorless liquid in transparent gla dissolvable particulate matter seen with the naked eye. **VOLUME** Limit: Not Less Than nominal volume Determined: --------- 2.04 ml **pH** Limit: ---------- 2.5-6.5 Determined: ---------- 5.1 **STERILITY** The product is sterile. **IDENTIFICATION:** Metoclopramide HCl is identifi <table><tr><th>ASSAY</th><th>Stated</th><th>Determined</th></tr><tr><td>Metoclopramide HCl</td><td>10mg/2ml</td><td>9.8mg/2ml</td></tr></table> **RESULT**: The sample is declared **SUB-STANDARD**
5	INJECTION. CLOPREL [METOCLOPRAMIDE HYDROCHLORIDE: 10MG/2ML.) **Mfg Date:** 02-2021 **Exp Date:** 02-2023	CLI107	M/S HAMAZ PHARMACEUTICALS (PVT.) LTD., 13-KM, LUTFABAD, BOSAN ROAD, MULTAN-PAKISTAN.	01-77003572/DTLBWP Dated 21 May 2021	**Specification Applied: USP 2020** **DESCRIPTION:** Colorless liquid in transparent glas **dissolvable particulate matter seen with the naked e** **VOLUME** Limit: Not Less Than nominal volume Determined: --------- 2 ml **pH** Limit: ---------- 2.5-6.5 Determined: ---------- 5.2 **STERILITY** **The product is sterile.** **IDENTIFICATION** **Metoclopramide HCl is**

	Regn No: 084186				<table><tr><th>ASSAY</th><th>Stated</th><th>Determin</th></tr><tr><td>Metoclopramide HCl</td><td>10mg/2ml</td><td>9.63mg/2r</td></tr></table> **RESULT: The sample is declared <u>SUB-STANDARI</u>**
6	INJECTION. CLOPREL [METOCLOPRAMIDE HYDROCHLORIDE: 10MG/2ML.) **Mfg Date:** 02-2021 **Exp Date:** 02-2023 **Regn No:** 084186	CLI108	M/S HAMAZ PHARMACEUTICALS (PVT.) LTD., 13-KM, LUTFABAD, BOSAN ROAD, MULTAN-PAKISTAN.	01-77003573/DTLBWP Dated 21 May 2021	**Specification Applied: USP 2020** **<u>DESCRIPTION:</u>** Colorless liquid in transparent glas **dissolvable particulate matter seen with the naked e** **<u>VOLUME</u>** Limit: Not Less Than nominal volume Determined: --------- 2 ml **<u>pH</u>** Limit: ---------- 2.5-6.5 Determined: ---------- 5.1 **<u>STERILITY</u>: The product is sterile.** **<u>IDENTIFICATION</u>: Metoclopramide HCl is identif** <table><tr><th>ASSAY</th><th>Stated</th><th>Determin</th></tr><tr><td>Metoclopramide HCl</td><td>10mg/2ml</td><td>9.62mg/2r</td></tr></table> **RESULT: The sample is declared <u>SUB-STANDARI</u>**
7	INJECTION. CLOPREL [METOCLOPRAMIDE HYDROCHLORIDE: 10MG/2ML.) **Mfg Date:** 02-2021 **Exp Date:** 02-2023 **Regn No:** 084186	CLI109	M/S HAMAZ PHARMACEUTICALS (PVT.) LTD., 13-KM, LUTFABAD, BOSAN ROAD, MULTAN-PAKISTAN.	01-77003574/DTLBWP Dated 21 May 2021	**Specification Applied: USP 2020** **<u>DESCRIPTION:</u>** Colorless liquid in transparent glas dissolvable particulate matter seen with the naked eye. **<u>VOLUME</u>** Limit: Not Less Than nominal volume Determined: --------- 2 ml **<u>pH</u>** Limit: ---------- 2.5-6.5 Determined: ---------- 5.3 **<u>STERILITY</u>** The product is sterile. **<u>IDENTIFICATION</u>** Metoclopramide HCl is identif <table><tr><th>ASSAY</th><th>Stated</th><th>Determined</th></tr></table>

					Metoclopramide HCl | 10mg/2ml | 9.84mg/2ml **RESULT**: The sample is declared SUB-STANDARD
8	INJECTION. CLOPREL [METOCLOPRAMIDE HYDROCHLORIDE: 10MG/2ML.) **Mfg Date:** 02-2021 **Exp Date:** 02-2023 **Regn No:** 084186	CLI110	M/S HAMAZ PHARMACEUTICALS (PVT.) LTD., 13-KM, LUTFABAD, BOSAN ROAD, MULTAN-PAKISTAN.	01-77003575/DTLBWP Dated 21 May 2021	**Specification Applied: USP 2020** **DESCRIPTION:** Colorless liquid in transparent glas dissolvable particulate matter seen with the naked eye. **VOLUME:** Limit: Not Less Than nominal volume Determined: --------- 2 ml **pH** Limit: ---------- 2.5-6.5 Determined: ---------- 5.1 **STERILITY** The product is sterile. **IDENTIFICATION** Metoclopramide HCl is identifie **ASSAY** | **Stated** | **Determined** Metoclopramide HCl | 10mg/2ml | 9.85mg/2ml **RESULT**: The sample is declared SUB-STANDARD

iii. Central Pharmacy (Main Medicine Store), Sheikh Zayed Hospital Rahim Yar Khan provided invoice/warranty No. 1057 dated 17.03.2021 issued by M/S Hamaz Pharmaceuticals, Pvt Ltd., Bosan Road Multan.

iv. Warrantor portion of the subject batches of drug sample were sent to M/s Hamaz Pharmaceuticals Multan.

v. Copies of DTL reports were sent to M/s Hamaz Pharmaceuticals Multan with directions to explain their position and provide requisite information in this regard. In response Firm requested re-testing of the sample. Provincial Quality Control Board turned down the request for re-testing of sample in its 241st meeting dated 31.03.2022.

Previous Proceeding & Decision by the Board Regarding Retesting Request:

241st meeting dated 31.03.2022:

The board decided to turn down the subject retesting request of the firm and directed drug inspector to submit complete investigation report.

- In response to PQCB order dated 31-03-2022, firm submitted letter vide no. HP-SZHRYK/PQCB/0007 dated 28-04-2023 received in office of PQCB dated 02-05-2023. (after expiry 02-2023)
- PQCB wrote letter to DI Sheikh Zayed Hospital Rahim Yar Khan vide letter dated 20-07-2023 that the review petition against retesting order of PQCB cannot be entertained as sample has been expired and directed DI to submit investigation report.

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/DRAP Act 2012 and Rules framed there under by the way of: --

a. **Manufacture for sale/sale of Substandard drugs**
b. **Issuance of false warranty**

3 Show cause notice issued to the accused

Reply of show cause notice date 17-09-2023

Reference to the Show Cause Notice No, PQCB/R-815, 816, 817, 818,819, 820, 821, 822/202 1 dated 22.08.2023. Company considers the present show cause notice is continuation of the proceedings.

2 That company adheres strictly to the principles of current Good Manufacturing Practices (CGMP), resulting in high standards of production, quality, industrial safety, occupational health and environmental control. Raw materials, sourced from globally renowned manufacturers, are subjected to a demanding schedule of various testing procedures to produce quality products at the manufacturing facility approved through regular inspections by local regulatory authorities.

3. That we refute the reason of seizure because the Company has valid Drug Manufacturing License, GMP issued by DRAP, Islamabad and engaged in the manufacturing and storing of high-quality and efficacious pharmaceutical product under GMP compliance. Our past more than 20 years manufacturing history revealed that we have never been involved in contravention of any section subsection of Drug Act 1976, DRAP Act 2012 and rules framed there under.

4. Earlier, our retesting request was not considered by Honourable Board and our retesting request was turned down vide Order No. P-476, 477, 478, 479, 480, 481, 482, 483- 5/2021 dated 31.03.2022 without hearing of our point of view.

5. We have challenged the Order No. P-476, 477, 478, 479, 480, 481, 482, 483- 5/2021 vide Letter No. HP-SZHRYK/PQCB/0007 dated April 28, 2023 and requested honourable PQCB to give us a chance to explain our position.

6. That the Company seeks to challenge the findings of the Government Analyst Drug Testing Laboratory Bahawalpur rendered vide TRA 01-77003568/DTL to TRA 01-77003577/DTL dated 21-05-2021 (the "DTL Report') whereby Cloprel Injection 10mg/ml (Metoclopramide Hydrochloride 10mg/2ml) (the "Product") batch No. CLI103, CLI1 04, CLI105, CLII06. CLI107, CLI108, CLII09 & CLI1O have allegedly been declared as "Substandard" on the basis of Physical Test (Undissolvable particulate matter seen with the naked eye.)."A drug could not be declared as substandard when it meets the chemical specification":

7. It is once against submitted that the said reports are defected, faulty, flawed and deficient on the basis of following grounds:

a) The shape, colour and nature of the particulate matter has not been observed and reported by the

Govt. Analyst. Stating mere presence of matter without providing its identification and complete description (including chemical analysis) is of no legal value. The analyst had relied upon a physical test without performing required chemical test.

b) Drug Testing Laboratory (DTL), Lahore report No. TRA 01- 73007963/DTL dated 26-07-2021 (copy attached as Annexure 4) for the batch No. CLII10 of Cloprel Injection is contradictory to DTL

Bahawalpur Report No. TRA 01-77003577/DTL dated 21-05-2021. The same batch was found to be of quality standard but declared misbranded (only) by DTL, Lahore.

8. That the crucial question for legality of similar reports was evaluated in depth by Honorable Division Bench of Honorable Lahore High Court in case of Provincial Quality Control Board v/s. Irza Pharma reported as 1992 MLD 481. What is meant by Analyst when it is reported that the samples of the Drugs manufactured by the respondent conformed to the stated specifications chemically but did not conformed to the physical specifications of injections being adulterated with particles. The definitions of "Adulterated drug", Spurious and Substandard Drug as given in Section 3 of the Drug Act 1976 were examined. It was held that

A. That if the samples taken conform to the stated specifications chemically do not fall within the definition of the substandard drugs.

B. That the learned single Judge rightly held the term substandard drug with particles is not known to the Drugs Act; and that is true.

C. There was nothing on the record to show, as to what is the nature of the particles found the samples, and what are its consequences? (Whether Injurious to health).

D. That Analyst's. report in question, when considered within meaning of the definitions of "Adulterated drug", Spurious and Substandard Drug as given in Section 3 of the Drug Act 1976, the drugs tested and reported fell outside the category of definitions of Substandard Spurious and Adulterated drugs. The para 8 of the above Judgement is reproduced below

From the aforesaid definition, it is evident, that the Law Makers have taken note of the eventualities, implications and also the nature off the manufacturing of the drugs while making the law. Hence, the law and its intension, as envisaged by the Drugs Act is very sacred and clear. Unfortunately, in our country functionaries under the law misuse the same, which is nothing but malice in law. Can we allow course to perpetuate so as to leave room for rampant corruption? The obvíous answer is in the

negative. On the other hand, this Court under its Constitutional jurisdiction, as enjoined by the Constitution has to protect the observance of law as well as the bona fide exercise of the duties of the functionaries under the Statute. In this behalf, we are fortified in our view by the observations of the Supreme Court while commenting upon Article 2 of 1962 Constitution, now Article 4 of 1973 Constitution in the case reported as Malik Ghulam Jillani v/s The Federation of Pakistan PLD 1967 SC 373.

The relevant observations are added as hereunder: -

"Under the Constitution of Pakistan, a wholly different state of affairs prevails Power is expressly given by Article 98 to the Superior Court to probe into the exercise of public power by executive authorities, how high so ever, to determìne whether they have acted with lawful authority. The judicial power is reduced to a nullity if lavws are SO Worded or interpreted that the executive authorities may make what statutory rules they please thereunder and may use this freedom to make themselves the final judges of their own 'satisfaction' for imposing restrains on the enjoyment of the fundamental rights of citizens, Article 2 of the Constitution could be deprived of all its content through this process and the Courts would cease to be guardians of the nation's liberties."

9. That Government Analyst determined that the above samples were up to the Standard Quality as assay of drug was within the standard quality limit 90-110 %. However, he has declared this drug erroneously Sub-Standard on the basis of vague expression' It appears that Govt. Analyst, is unacquainted about the land mark historic judgment of Division Bench of Lahore High court in Intra-Court Appeals Nos. 127 and 128 of 1989, decided on 28th October, 1991 reported in 1992 MLD481 whereby such types of vague reports were declared as invalid and without lawful authority. The DB Judgment of Peshawar High court also held that drug could not be declared substandard on the basis of particle and fibers report without protocol was fatally defective. 1996 P Cr.L.J 1183 (Peshawar). Particulate matter in injections and parenteral infusions consists of extraneous mobile undissolved particles, other than gas bubbles, unintentionally present in the solutions. Similarly, products that produce air or gas bubbles when drawn into the sensor may also require microscopic particle count testing. There are basically two tests, light obscuration, which uses light blockage to determine the size and count of particulate matter in the solution, and microscopic assay, which is a measurement of un-dissolvable particles or substances present in the solution usually plastics, metals or dust. There are basically two tests, light obscuration, which uses light blockage to determine the size and count of particulate matter in the solution; and microscopic assay, which is a measurement of un- dissolvable particles or substances present in the solution usually plastics, metals or dust. Particles of varying sizes have been observed in inject-able drug products, such visible and sub visible. The particles of 1-50 Micron size are known as sub visible particles and particles of >50 micron is considered as visible particles. Visible particles are defined as those that can be detected under controlled conditions by the unaided human eye (i.e., without supplemental magnification). Identification of the composition of the particulate matter is the first step in characterizing particulate matter risk. Based on this information, particles can be further classified into one of three subcategories: extrinsic, intrinsic, and

a) Extrinsic particles are defined as those that are not part of the formulation, package, or process, but are foreign and unexpected. Examples of extrinsic particles include fibers (e.g., cellulous), clothing fragments, hair, rubber, metal, plastic, and paint.

b) Intrinsic particles are defined as those that arise fromn sources related to the formulation, packaging, or processes. Examples of intrinsic particle materials include glass, stainless steel, rubber from stoppers, and gasket material.

c) Inherent particles are defined as materials that are expected from the drug formulation, and thus represent generally accepted characteristic of the product. Examples of inherent matter Proteinaceous aggregates.

The clinical implications of extraneous particulate matter in injections are determined by many factors, including the size and number of particles, the composition of the material, the potential for microbiological contamination, the route of administration, the intended patient population, and the clinical condition of the patient. For example, an otherwise healthy individual receiving a subcutaneous or intramuscular injection containing sterile, inert particulates would likely experience no adverse effect or at worst would develop a small granulonma. On the other hand, a critically ill premature infant receiving a particle-laden infusion directly through an umbilical catheter might suffer considerable pathophysiologic sequelae.

10. That report of the Government analyst that simply states the result of the test but does not give the protocols at all is not conclusive evidence of the facts stated in it. The absence of the protocols of test in the report is a crystal-clear violation the law. The protocols are vital to determine whether test / analysis done properly and precisely for reaching their opinions. Gyanendra Nath Mittal v/s State AIR 1959 All, 634; S. Dutta and another v/s The State AIR 1959 Cal. 427 and Dharam Deo Gupta v. State AIR 1958 All. 865 fol. PLD 2003 Lah. 115, SBLR 2002 Trib. 83 & 1977 P Cr. LJ822 (The official statement or account which is the description of the experiment is the protocol of test). PLEASE Note federal legislation prevails when there is a conflict with provincial legislation.

11. That a Skilled Healthcare provider usually administers the injectable with the help of Disposable Syringes. The apprehension that patient's health will be at risk if the samples available in hospital have particle likely to be injurious to health is nothing but a tyranny based upon misrepresentation and misapplication. In reality, there is no chance of use of the drugs purchased by Governmnent Hospital and declared as substandard by Government Analyst.

12. That application of the Section 27(2) dealing with false warranty is malice in law as well as malice in fact because good and sufficient reason are available that warranty was given after release of medicines by Quality Control Department of the Company. The PQCB countersigning is the endorsement of Inspector on the levelling charge of Issuance of false warranty, which is always based upon misreading of Section 27(2) of the Drug Act 1976. The name of Muhammad Ashraf Araien-Incharge Quality Control is added in the list off accused and erroneously ascertained for the offences of Manufacturing for Sale / Sale of Substandard drug and issuance of false warranty because manufacturing and Quality Control Department are Distinct and Independent. The definition of manufacture under section 3 of the Drugs Act 1976 is reproduced here as reference

3(r) "manufacture", in relation to a drug, means all operations involved in the production of the drug. including processing, compounding, formulate, filling, packing, repacking, altering, ornamenting, finishing and labelling with a view to its storage, sale and distribution, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian and "to manufacture" shall be construed accordingly" \

the rule 16 (e) of Drugs (Licensing, Registering and Advertising) Rules, 1976. dealing with Conditions for the grant or renewal of license to manufacture drugs by way of formulation reproduced below

16(e) The Quality Control Department shall be independent of the manufacturing unit and its Incharge shall be whole time employee of the manufacturer shall possess a degree in pharmacy, or a degree in science with chemistry or a degree in medicine or pharmacology (for pharmacological testing) or a degree in microbiology (for microbiological testing) and has sufficient experience

in testing of drug

13. That the Discrimination done by Drugs Inspector & PQCB. The Company has been declared responsible in sheer violation of fundamental right guaranteed under constitution of Islamic Republic of Pakistan (articles 4 & 25). The article 10.A of constitution Islamic Republic of Pakistan gives fundamental Right to fair trial and due process. It is crystal clear that the equality and non-discrimination is vehemently emphasized & inbuilt within the Constitution of Pakistan. Article 25. The above P¿CB SCN is discriminatory, outside boundaries of fair trial, due process and the basic principles of Natural justice

14. We have a strict standard operating procedure is implemented in our factory for optical checking of vials and ampoules. The following supplied quantity was passed in both tests during the production and then testing on Liquid Particle Counter under USP monograph.

Batch no	Supplied quantity	DTL samples	Amount
CLI101	24180	230	
CLII02	32020	230	

CLII03	35500	230	Rs. 16582500/-
CLI104	31770	230	
CLII05	40550	230	
CLI106	34550	230	
CLI107	42970	230	
CLII08	39860	230	
CLI109	42760	230	
CLII10	10840	230	
	335000	2300	

15. It is further intimated that we have observed that analysis of existence of particle matter in drugs under BP Monograph is better than USP Monograph therefore we have got approval from DRAP to manufacture this drug under BP Monograph.

16. Without prejudice to the foregoing and despite the complete innocence of the Company and its officials, please note the following information as per your requirement:

2300

•Mr Amir Manzoor (director)

Mr. Muhammad Ashraf (Production In-charge)

Mr. Muhammad Ashraf Araien (Quality Control In-charge)

Accordingly, it is confirmed that the Company and its officials have not committed the offence u/s 23/27 of Drugs Act, 1976 (as amended) /DRAP Act 2012 and Rules (5) of the Punjab Drug Rules 2007.

In the light of above submission, it is requested that case may please be dropped by the PQCB as no contravention has been done under the Drug Act 1976 and Rules framed there under. Every citizen is entitled to be dealt in accordance t with law and due process as per requirement of 1973 constitution of Islamic Republic of Pakistan

Personal hearing notice issued to the accused

Summary:

Manufacturing Date: 02-2021

Expiry Date: 02-2023

Sampling Date: 27-03-2021

Sent to DTL (Form 6): 27-03-2021

Date of receipt in DTL: 27-03-2021

DTL Report Date: 21-05-2021

1ST DI Communication with firm on dated: 19-06-2021

Date of Retesting Request of Firm: 30-06-2021

Fate of Retesting Request: All 8 batches turn down 241-M dated 31-03-2022

Investigation Report Dated: 27-07-2023

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 **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Mr. Rafaqat Ali, Secretary DQCB, Rahim Yar Khan and Mr. Ilyas Provincial Inspector of drugs Sheikh Zayed Hospital Rahim Yar Khan was present along with original case record. No one among the nominated accused person was present. However, Mr. Usman representative of M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan Pakistan appeared before the Board and submitted written request for adjournment.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case on request of the firm and provide another opportunity of hearing to the firm in the best interest of justice. Moreover, the drug inspector is directed to retain an appropriate portion for Court purposes and dispose-off the remaining expired stock (if not recovered and seized on Form-3 & Form-5) from Expired Drug Disposal Committee (EDDC) of health facilities already constituted vide PSHD notification No. SO (HP) 2-9(2)/ 2021 dated 14-February, 2022 and PQCB order dated 06-05-2023 on guidelines regarding fate of case properties and report to the office of Secretary PQCB within 7 days positively.

7. Personal hearing notice issued to the accused

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 26

PQCB/R-476/2022

Sheikh Zayed Hospital, Rahim Yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore, Pakistan** through its Managing Director/warrantor Hamid Bukhtiar 2. Hamid Bukhtiar Managing Director/Warrantor 3. M. Hayat Hussain Production Incharge 4. Amar Mureed Quality Control Incharge of M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sheikh Zayed Hospital, Rahim Yar Khan reported that: -

i. He, on 24-11-2021 inspected the premises of M/s Central Pharmacy (Main surgical Store) Sheikh Zayed Medical College/Hospital, Rahim Yar Khan, took the subject sample on Form No. 4 for the purpose of test/analysis and sent to Drug testing Laboratory Bahawalpur vide memorandum no. 08/DI-SZH-RYK dated 24-11-2021.
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.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Gauze. Soft gauze [10cmx10cm 8 ply (Gauze swab)] **Mfg. Date**: 10-2021 **Exp. Date**: 10-2023 **Regn. No**: 050293	1013	M/s Karim Industries, 1/2Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.	01-86000341/DTL Dated: 19-01-2022	**Result of test/ analysis with specifications applied** BP 2020/BPC 1973 **DESCRIPTION:** absorbent cotton gauze consists of cotton fabric plain weave, bleached **t**o good white, clean and reasonably free from weaving defects, and other impurities. **Warp (BPC 1973):** Stated: avg 73/10cm (SD 1.33) Determined: 75/10cm **Weft (BPC 1973):** Stated: Avg 57/10cm (SD 1.33) Determined: 57.8/10cm

				<u>WEIGHT/UNIT AREA (BPC 1973):</u> Limit: Avg 15g/m² (SD 0.33) Determined:16.693 gm/m² **<u>SINKING TIME (BPC 1973):</u>** Limit: Not more than 10sec. Determined: 4.01 seconds **<u>ACIDITY/ALKALINITY (BPC 1973):</u>** **Limit**: Phenolphthalein = no pink color, Methyl Orange= Yellow color **Determined:** No pink color with Phenolphthalein and yellow color with Methyl Orange. **<u>STERILITY</u>: (BP 2020): product is non-sterile** **(Does not comply with specifications)** **RESULT:** The sample is declared **<u>SUB-STANDARD</u>** on the basis of sterility test.

iii. Central Pharmacy (Main surgical Store) Sheikh Zayed Medical College/Hospital, Rahim Yar Khan provided Invoice/warranty No. 1177 dated 03-11-2021 issued by M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan as proof of their purchase.

iv. Warrantor Portion was sent to M/s Karim Industries, ½ Km, Raiwind Lahore Road, Lahore, Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan and they were directed to provide requisite information in this regard. The firm challenged the DTL report and requested for retesting of drug sample in question from Appellate Laboratory/ NIH Islamabad. The Board in its 251st meeting dated 20-10-2022 decided to accept the appeal of withdrawal of the retesting request of the firm.

Previous proceedings regarding retesting request:

<u>251st meeting dated 20-10-2022</u>

The Board in its 251st meeting dated 20-10-2022 decided to accept the appeal of withdrawal of retesting request and directed DI to submit complete investigation 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/DRAP Act 2012 and Rules framed there under by the way of: --

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

b. **Issuance of false warranty**

3 Show cause notice issued to the accused

4 Personal hearing notice issued to the accused

Summary:

Manufacturing Date: 10-2021

Expiry Date: 10-2023

Sampling Date: 24-11-2021

Sent to DTL (Form 6): 24-11-2021

Date of receipt in DTL: 24-11-2021

DTL Report Date: 19-01-2022

1ST DI Communication with firm on dated: 18-03-2022

Date of Retesting Request of Firm: 06-04-2022

Fate of Retesting Request: accept withdrawal appeal of the firm (251-M dated 20-10-2022)

Investigation Report Dated: 22-07-2023

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 **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Mr. Rafaqat Ali, Secretary DQCB, Rahim Yar Khan and Mr. Ilyas Provincial Inspector of drugs Sheikh Zayed Hospital Rahim Yar Khan was present along with original case record. No one among the nominated accused person of M/s Karim Industries, 1/2Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan appeared before the Board. Secretary PQCB apprised the Board that the firm has submitted written request for adjournment vide Ref. No. Ki-24439 dated 30-01-2024.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case on request of the firm and provide another opportunity of hearing to the firm in the best interest of justice.

7. Personal hearing notice issued to the accused

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 27

PQCB/R-753/2021

Sheikh Zayed Hospital, Rahim Yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore, Pakistan** through its Managing Director/warrantor Hamid Bukhtiar**.** 2. Hamid Bukhtiar — Managing Director/Warrantor 3. M. Hayat Hussain — Production Manager 4. Amar Mureed — Quality Control Manager of M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sheikh Zayed Hospital, Rahim Yar Khan reported that: -

i. He, on 17-03-2021 inspected the premises of M/s Central Pharmacy (Main surgical Store) Sheikh Zayed Medical College/Hospital, Rahim Yar Khan and took subject sample on Form No. 4 for the purpose of test/analysis and sent to Drug testing Laboratory Bahawalpur vide memorandum no. 132/DI-SZH-RYK dated 17-03-2021.
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.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Gauze. Soft gauze [10cmx10cm 8 ply (Gauze swab)] **Mfg. Date**: 02-2021 **Exp. Date**: 02-2023 **Regn. No**: 050293	1009	M/s Karim Industries, 1/2Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.	01-77003510/DTL Dated: 20-06-2021	**Result of test/ analysis with specifications applied** BP 2020/BPC 1973 **DESCRIPTION:** cloth of plain weave bleached to good white, clean and reasonably free from weaving defects, cotton, leaf and shell. **Warp (BPC 1973):** Stated: avg 73/10cm (SD 1.33) Determined: 74.2/10cm **Weft (BPC 1973):** Stated: Avg 57/10cm (SD 1.33) Determined: 54/10cm **WEIGHT/UNIT AREA (BPC 1973):**

				Limit: Avg 15g/m² (SD 0.33) Determined: 22.39 gm/m² **Does not comply with specs** **SINKING TIME (BPC 1973):** Limit: Not more than 10sec. Determined: **4** seconds **ACIDITY/ALKALINITY (BPC 1973):** **Limit**: Phenolphthalein = no pink color, **Methyl Orange**= Yellow color **Determined: Pink color appeared on addition of Phenolphthalein. (Alkaline in nature**) **(Does not comply with specifications)** **STERILTY (BP 2020):** product is sterile **RESULT:** The sample is declared **SUB-STANDARD** on the basis of weight/m^2 and Acidity/Alkalinity test.

i. Central Pharmacy (Main surgical Store) Sheikh Zayed Medical College/Hospital, Rahim Yar Khan provided Invoice/warranty No. 846 dated 08-03-2021 issued by M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan as proof of their purchase.
ii. Warrantor Portion was sent to M/s Karim Industries, ½ Km, Raiwind Lahore Road, Lahore, Pakistan.
iii. A copy of Test/ Analysis report was sent to M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan and they were directed to provide requisite information in this regard. The firm challenged the DTL report and requested for retesting of drug sample in question from Appellate Laboratory/ NIH Islamabad.
iv. In response, the said request of the firm was considered by the PQCB under Section 22(5) of the Drugs Act 1976 (amended) in its 235th meeting dated 30-11-2021. The Board, after discussion, unanimously decided to *Allow* the said request for retesting of subject drug sample. Accordingly, the sample of drug in question was sent to the Appellate Laboratory/ NIH Islamabad. The Appellate Laboratory/ NIH Islamabad also declared drug sample in question as Substandard**.** The detail is as follow: -

Name of drug	**Batch no.**	**Name of manufacturer**	**NIH Test Report No. & Date**	**NIH Test Report Results**
Soft Gauze (10cmx10cm) 8ply	1009	M/s Karim Industries,1/2 Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.	No. 0293-P/2021 dated 08-02-2022	**DESCRIPTION:** Multi-folded cotton cloth of plain weaves bleached to good white, clean and reasonably free from weaving defects, cotton leaf and shell packed in printed paper and polythene packing. **WEIGHT/UNIT AREA:** **Determined:** Average 18.6gm/m^2

				Limit: 14.67-15.33 gm/m^2 **Does not Comply with BPC-73.** **ACIDITY OR ALKALINITY:** **Determined**: solution showed pink color Solution showed yellow color. **Limit**: solution does not show pink color. Solution shows yellow color. **Does not comply with BPC-73** **CONCLUSION:** The sample is of **Substandard** quality on the basis of tests performed.

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/DRAP Act 2012 and Rules framed there under by the way of: --

a. **Manufacture for sale/sale of Substandard drugs**
b. **Issuance of false warranty**

3 Show cause notice issued to the accused

4 Personal hearing notice issued to the accused

Summary:

Manufacturing Date: 2-2021

Expiry Date: 2-2023

Sampling Date: 17-3-2021

Sent to DTL (Form 6): 17-03-2021

Date of receipt in DTL: 24-11-2021

DTL Report Date: 20-06-2021

1ST DI Communication with firm on dated: 01-07-2021

Date of Retesting Request of Firm: 07-07-2021

Fate of Retesting Request: allow (235-M dated 30-11-2021)

Sample received in NIH: 09-12-2021

NIH report date: 08-02-2022 (62days)

Investigation Report Dated: 20-03-2023

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 **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Mr. Rafaqat Ali, Secretary DQCB, Rahim Yar Khan and Mr. Ilyas Provincial Inspector of drugs Sheikh Zayed Hospital Rahim Yar Khan was present along with original case record. No one among the nominated accused person of M/s Karim Industries, 1/2Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan appeared before the Board. Firm submitted written request for adjournment vide Ref. No. Ki-24435 dated 29-01-2024.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case on the request of the firm and provide another opportunity of hearing to the firm in the best interest of

7. Personal hearing notice issued to the accused

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 28

PQCB/R-551/2022

Lahore General Hospital, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore, Pakistan** through its CEO/warrantor Hamid Bukhtiar**,** 2. Hamid Bukhtiar CEO/ Warrantor 3. M. Hayat Hussain Production Manager 4. Amar Mureed Quality Control Manager of M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Lahore General Hospital, District Lahore reported that: -

i. She, on 16-09-2022 inspected the Main Medicine Store of Lahore General Hospital, District Lahore, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Lahore vide memorandum no 140227 dated 16-09-2022.
ii. Following product sample, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below: -

Name of product	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Bandages. MEDI LAP SPONGES [OPEN WOVEN BANDAGES CLOTH 30cm* 30cm (4ply) with X-RAY DETECTABLE THREAD, STERILE] **Mfg. Date**: Aug-2022 **Exp. Date**: Aug-2027	016	M/s Karim Industries, 1/2Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.	01-183001375/DTL Dated: 19-11-2022	**Result of test/ analysis with specifications applied** BP 2022 **DESCRIPTION:** Lap sponge of open wove white cotton cloth, folded into rectangles or squares, in such a manner that no cut edges are exposed, and stitched round the open sides. The X-ray detectable strip of blue colour is securely sewn into one corner of the pad. Claimed size=30cm x 30cm x 4ply **WARPS:** Limit: 135-163/10cm Determined: 155/10cm **WEFTS:** Limit: 84-96/10cm

Regn. No. MDMR-000067				Determined: 93/10cm **<u>WEIGHT PER UNIT AREA:</u>** Limit: NLT 33g/m² Determined: 55.30g/m² **<u>LENGTH</u>:** Limit: 30cm (NLT 5%) Determined: 31.2cm **<u>WIDTH</u>:** Limit: 30cm (NLT 5%) Determined: 30.4 cm **<u>STERILTY TEST</u>: The sample is non-sterile** **(DOES NOT COMPLY)** **RESULT:** The above sample is **<u>SUB-STANDARD</u>** on the basis of **STERILITY TEST** performed as per BP.

iii. The store keeper Main Medicine store, Lahore General Hospital, District Lahore, provided invoice/warranty No. 1244 dated 12-09-2022 issued by M/S Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.

v. **The Drug Inspector, Lahore General Hospital, District Lahore took the subject drug sample on Form-3 dated 22-12-2022 with directions of not to dispose of stock**.

vi. A copy of test/analysis report was sent to M/S Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

<u>Previous Proceedings of the Board:</u> (Regarding Retesting Request)

<u>20th Committee Meeting of the Board held on 17-05-2023</u>

2. The subject request for retesting of the drug sample was placed before the Committee Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **20th meeting** held on **17-05-2023** under the Convenorship of Director General, Drugs Control. The Secretary PQCB apprised that Drug Testing Laboratory report conveyed by the Provincial inspector of Drugs to manufacturer vide letter No. DI /693/LGH dated 03-12-2022 Manufacturer requested for retesting vide letter No. Ki/22-1366 Dated:10-12-2022

3. The office of the Secretary Provincial Quality Control Board asked the firm to adduce evidence in

controversion of Govt. Analyst Test Report vide letter No. PQCB/P-123-2/2023 dated 05-04-2023 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 firm provided relevant data.

4. The firm vide letter no. Ref no. Ki/23-1432 Dated 11.02.2023 requested to **withdraw** their re-testing request. The Committee after due deliberation and discussion unanimously decided to accept the firm's request for **withdrawa**l of the retesting requests of the subject drug samples 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 Committee.

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

a. **Manufacture for sale/sale of Substandard Therapeutic goods**

(Drug/Medical device)

b. **Issuance of false warranty**

6. Show-cause notice(s) issued to accused person(s) dated 29-08-2023

Firm replied to the show cause notice vide letter no. Ref No. Ki/23-1714 dated 15-09-2023

Reference to your Letter No. P¿CB/R-551/2022 dated 29-08-2023 concerning Medi Lap Sponges 30cm x 30cm bearing Batch No. 016, which DTL report declared of substandard quality under report No. TRA 01-183001375/DTL Dated 19-11-2022, citing the reason of non-sterility.

*We wish to inform you that we have conducted a thorough examination of the retained samples of above said batch through our Technical Experts at our testing lab. The results of our analysis indicate that the products meet of **standard quality as per requirements**, including the sterility test.*

*Further, as we received the sample portion from concern Hospital which **physical condition of packing was not in good form**. Ultimately, the result of that sample sterility does not comply as our experts examine because it is **already leaked** and could not comply the standard quality of **leakage test**.*

*Because sometimes due to **mishandling & transportation the issue of leakage** can be occurs as a single pin hole in blister packaging can disturb its sterility.*

*It is also submitted that all parameters regarding testing of our sample of Medi Lap Sponges are complies except Sterility Test which we understand it's **happened due to leakage of said samples** .*

*We have **already replaced the stock** of Medi Lap Sponges 30em x 30cm with fresh batches which declared of standard quality. Further we request you to **please allow us to get the stock re-sterilized from PARAS (Gama Radiation)**. So that the conformity of Sterility Test may comply in accordance and **give direction to the concern Hospital for consume the stock**.*

*In this regard, we are **ready to bear all the expenses**.*

*In view of the submissions made above, it is humbly prayed that **the case maybe dropped** in best interest of justice.*

7. Personal hearing notice(s) issued to accused person(s) dated 22-01-2024

Previous Proceedings & Decision by The Board:

275th Special meeting held on 31-01-2024

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Mr. Hassan Saeed Secretary DQCB Lahore and Ms Sadia Rana Drug Inspector Lahore General Hospital were present along with original case record. No-one appeared before the Board on behalf of M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore, Pakistan. Secretary PQCB apprised the Board that the firm has submitted written request for adjournment vide reference no. Ki-24437 dated 29-01-2024.

9. The Board after due deliberation and discussion unanimously decided to **adjourn** the case on the request of the firm and provide another opportunity of hearing to the firm in the best interest of justice

10. Personal hearing notice(s) issued to accused person(s) dated 20-02-2024

11. Case is placed before the Board for decision.

Summary:

Manufacturing Date: July-2022

Expiry Date: July-2025

Sampling Date (Form 4): 16-09-2022

Sent to DTL (Form 6): 16-09-2022

Date of receipt in DTL: 16-09-2022

DTL Report Date (Form 7): 19-11-2022

Time Extension: Granted on 13-12-2022 (254-M)

1ST DI Communication with firm on dated: 03-12-2022

Retesting Request of Firm: Yes (10-12-2022)

Fate of Retesting Request: Firm withdrew its retest request vide letter dated 11-02-2023 and firm's retesting withdrawal accepted in 20th Committee Meeting dated 17-05-2023

Investigation Report Dated: 18-04-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 29

PQCB/R-302/2022

Sheikh Zayed Hospital, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore, Pakistan** through its CEO/warrantor Hamid Bukhtiar**.** 2. Hamid Bukhtiar CEO/Warrantor 3. M. Hayat Hussain Production Manager 4. Amar Mureed Quality Control Manager of M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sheikh Zayed Hospital, Lahore reported that: -

i. She, on 09-09-2022 inspected the central medical store, Sheikh Zayed Hospital, Lahore, took subject product sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Lahore vide memorandum no 140440 dated 16-09-2022.
ii. Following product sample, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below: -

Name of product	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Bandages. MEDILAP Sponges [open woven bandages cloth 30cm*30cm 4ply with X-RAY DETECTABLE THREAD, STERILE] **Mfg. Date**: 09-2022 **Exp. Date**: 08-2027	017	M/s Karim Industries, 1/2Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.	01-177002893/DTL Dated: 17-11-2022	**Result of test/ analysis with specifications applied** BP **DESCRIPTION:** Lap sponges of open wove cotton cloth which is white, odorless with continuous longitudinal threads, no weaving defects and symmetrical cutting at the edges with blue X-ray detectable thread, claimed to be sterile. Claimed size=30cmx30cmx4ply **Warps:** Limit: 135-163/10cm Determined: 140.4/10cm **Wefts:**

Regn. No. MDMR-000067				Limit 84-96/10cm Determined: 89.3/10cm **<u>WEIGHT per unit area:</u>** Limit: NLT 33g/m² Determined: 52.22g/m² **<u>LENGTH</u>:** Limit: 30cm (NLT 5%) Determined: 30cm (0.3m) **<u>WIDTH</u>:** Limit: 30cm (NLT 5%) Determined: 30cm (0.3m) **<u>STERILTY TEST</u>: The sample is non-sterile** **(Does not comply)** **RESULT:** The sample is declared **<u>SUB-STANDARD</u>** on the basis of sterility test performed as per BP.

iii. Store keeper Main Medicine store, Sheikh Zayed Hospital, Lahore, provided invoice/warranty No. 1252 dated 09-09-2022 issued by M/S Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan as a proof of its purchase.
iv. Warrantor portion of drug sample was sent to M/S Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.
v. A copy of test/analysis report was sent to M/S Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of DRAP Act 2012 and Medical device Rules framed there under by the way of: --

i. **Manufacture for sale/sale of Substandard Therapeutic goods (Drug/Medical device)**
ii. **Issuance of false warranty**

3 Show cause notice issued to the accused dated 03-05-2023

4 Personal hearing notice issued to the accused 22-01-2024

Summary:

Manufacturing Date: 9-2022

Expiry Date: 8-2027

Sampling Date: 09-09-2022

Sent to DTL (Form 6): 16-09-2022

Date of receipt in DTL: 19-09-2022

DTL Report Date: 17-11-2022

1ST DI Communication with firm on dated: 07-12-2022

Date of Retesting Request of Firm: No

Investigation Report Dated: 28-03-2023

- **Note**

Raiding DI Department notification date: 21-06-2022

Raiding DI Gazette Notification date: 28-09-2022

Sampling date: 09-09-2022

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

5 Case was placed by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Mr. Hassan Saeed, Secretary DQCB, Lahore was present. No one among the nominated accused person of M/s Karim Industries, 1/2Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan was present. Firm submitted written request for adjournment vide Ref. Ki-24436 dated 29-01-2024.The Board after due deliberation and discussion unanimously decided to **left over** due to time constraints.

6. Personal hearing notice issued to the accused

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 30

No. PQCB/R-836/2019

Benazir Bhutto Hospital, Rawalpindi

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S Zafa Pharmaceuticals Laboratories (Pvt.) Ltd. L-1/B, Block-22, Federal "B" Industrial Area, Karachi-Pakistan,** through its Managing Director Jawad Amin Khan. 2. Jawad Amin Khan Managing Director 3. Noshaba Shaheen Production Manager 4. Shadman Athar Quality Control Manager 5. Shehzad Ahmed Khan Warrantor Of M/S Zafa Pharmaceuticals Laboratories (Pvt.) Ltd. L-1/B, Block-22, Federal "B" Industrial Area, Karachi-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Benazir Bhutto Hospital, Rawalpindi reported that:

i. The then Drug Inspector, on 18-04-2019 inspected the premises of Injections Section, Main Medicine Store, Benazir Bhutto Hospital, Rawalpindi took sample of subject drug on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide memo number 0000033857 dated 18-04-2019.

ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Rawalpindi as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Injection Zamoclav 600mg [Amoxicillin Sodium eq. to Amoxicillin 500mg, potassium Clavulenate eq. to Clavulanic Acid 100mg] **Mfg Date:** 03-2019 **Exp Date:** 03-20 **Reg number:**	48	M/S Zafa Pharmaceuticals Laboratories (Pvt.) Ltd. L-1/B, Block-22, Federal "B" Industrial Area, Karachi-Pakistan	01-19001463/ DTL dated: 22 Jun 2019	**Result of test/ analysis with specifications applied:** BP 2019 **PHYSICAL DESCRIPTION:** White to off white powder contained in colourless, ALU sealed glass vial having affixed label with brown color plastic flip off cap and grey rubber stopper packed in outer labelled carton. On reconstitution it forms visibly clear yellow coloured solution. **pH:** **Result: 8.84** **Limit: 8-10** **STERILITY TEST:** **Result: Sterile**

037383				**IDENTIFICATION:** Amoxicillin Sodium and Potassium clavulanate identified. **ASSAY OF AMOXICILLIN:** Stated: 500mg/vial Determined: 434.634mg/vial Percentage: 86.93% (DOES NOT COMPLY) Limit: 90-107.5% **ASSAY OF CLAVULANIC ACID:** Stated: 100mg/vial Determined: 81.713mg/vial Percentage: 81.71% (DOES NOT COMPLY) Limit: 90-107.5% **RESULT: The above sample is "Substandard" on the basis of the Assay test performed**

ii. Storekeeper, Main Medicine Store, Benazir Bhutto Hospital, Rawalpindi provided warranty/invoice No. 235905 dated 16-04-2019 issued by M/S Zafa Pharmaceuticals Laboratories (Pvt.) Ltd. L-1/B, Block-22, Federal "B" Industrial Area, Karachi.
iii. Warrantor Portion was sent to Zafa Pharmaceuticals Laboratories (Pvt.) Ltd. L-1/B, Block-22, Federal "B" Industrial Area, Karachi.
iv. A copy of test report from DTL was sent to Zafa Pharmaceuticals Laboratories (Pvt.) Ltd. L-1/B, Block-22, Federal "B" Industrial Area, Karachi with direction to explain their position and provide requisite information in this regard.

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

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 15-06-2023

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 27-06-2023 stating that:

Please refer to your Letter No. PQCB/R-836/2019 dated 15-06-2023 received on 26-06-2023 on the subject cited above; we have to bring to your knowledge that

1. The Letter No. 1855-58/Med. Store/Rwp dated 08-07-2019 was received on 10-07-2019,

along with the test report Of DTI Rawalpindi bearing No. TRA 01-19001463 dated 22-06-2019, from the Drugs Inspector, Benazir Bhutto Hospital, Rawalpindi. The DTL Report declared the sample as Substandard on the basis of assay of Amoxicillin and Clavulanic Acid.

The response of Letter No. 1855-58/Med. Store/Rwp was sent to Office of the Inspector of Drugs, Benazir Bhutto Hospital, Rawalpindi on 18-07-2019 that

(i) This product is highly sensitive to the temperature, moisture and light and it should be stored at 15t to 25t as stated on the carton ofthe Zamoclave 600mg Injection (both API can loss their potency due to the effect of heat and light). At the time of drawing the sample, temperature record (Storage Condition) of Medicine Store was not mentioned.

(ii) The sample is not sub-standard because analytical results of our keeping samples of Zamoclave 600 mg Injection, Batch No. 48, found within limits as defined in specification of Zamoclave 600 mg Injection.

Therefore, we without prejudice intend to send the sample to Federal Drug Laboratory Islamabad for retesting of the drug under Section 22(5) of the Drugs Act 1976.

2. The request for re-testing Of Substandard Injection Zamoclave 600 mg, Batch # 48,

(Mfg. Date: 03-2019, Exp. Date: 10-2020) was sent in July 2019 but no action was taking in this regard till August 2020 while the expiry date of product was October 2020. A Letter No. PQCB/574-6/2019 dated 1108-2020 received on 20-08-2020 from the Secretary, Provincial Quality Control Board, Punjab, Lahore for the submission of evidence in controversion of Govt. Analyst's Report (TRA No. 01-19001463/DTL).

In compliance to the letter No. PQCB/574-6/2019, to justifying the position following evidences was submitted to the Secretary, PQCB Punjab, Lahore on 27-08-2020 which will be available in PQCB

Record. In-process data of the product performed at the time of manufacturing. ii. Assay Test performed with test report at the time of manufacturing. iii. Assay Test performed on the keeping Sample.

3. Another similar Letter No. PQCB/574-6/2019 dated 17-09-2020 received on 02-10-2020 from the Secretary, Provincial Quality Control Board, Punjab, Lahore for the submission of evidence in controversion Of Govt. Analyst's Report (TRA No. 01-19001463/DTL).

In response of Letter No. PQCB/574-6/2019 dated 17-09-2020 received on 02-10-2020, above evidences were re-submitted to the Secretary, PQCB Punjab, Lahore on 08-10-2020.

In continuation of Letter No. 1855-58/Med. Store/Rwp dated 08-07-2019, a Letter No. 142-45/ Med. Store/ BBH/Rwp. dated March 18, 2023 received on April 03, 2023 from the Provincial Inspector of Drug, Benazir Bhutto Hospital, Rawalpindi regarding Substandard Injection Zamoclave 600 mg, Batch # 48, (Mfg. Date: 03-2019, Exp. Date: 10-2020).

The response of Letter No. 142-45/ Med. store/ BBH/Rwp. dated 18-03-2023 received on was submitted on 05-04-2023 along with copy of previous correspondence with provincial Inspector of Drugs and Secretary PQCB Punjab.

S. Another Letter NO. 223-26/ Med. Store/ BBH/Rwp, Dated 12-04 2023 received from the Provincial Inspector of Drugs , Benazir Bhutto Hospital, Rawalpindi state with reference to the Provincial Quality Control Board Letter No. PQCB/P-574-6/2019 dated 21-12-2022 that "The drug sample was scrutinized and observed that request was not entertained due to covid-19

pandemic. Now the sample has been expired".

The response of Letter No. 223-26/ Med. Store/ BBH/Rwp. Dated 12-04 2023 was sent to the Provincial Inspector of Drugs , Benazir Bhutto Hospital, Rawalpindi on 13-04-2023 and informed/asked that

(i) The Covid-19 was sprayed in the country in 2020 while the request for retesting of Zamoclave 600mg Injection, Batch No. 48, under Section 22(5) of the Drug Act 1976 was sent to the Inspector of Drugs, Benazir Bhutto Hospital, and Rawalpindi on 18-07-2019.

(ii) During Covid-19 all the pharmaceutical industry in Pakistan was working. Therefore we are unable to understand that why our sample of Zamoclave 600 mg Injection, Batch No. 48, was not sent to Federal Drug Laboratory Islamabad for retesting?

6. The name and CNIC Number of Managing Director, Production Manager, Quality Control Manager and Warrantor are given below ;

Managing Director (Non-technical): Mr. Jawad Amin Khan, CNIC No.42301-1514359-5

Production Manager: Ms. Noshaba Shaheen, CNIC No.42000-0507010-8

Quality Control Manager: Mr. Syed Shadman Athar, CNIC No. 42501-6638470-9 > Warrantor: Mr. Shahzad Ahmed Khan, CNIC No. 42201-1017296-9

7. Following documents are enclosed as per your requirement.

(i) Copy of Drug Manufacturing License. (ii) Copy of Registration Letter.

Keeping in view of the above facts, you are requested to kindly close the case of Zamoclave 600 mg Injection, Batch No. 48 which was expired in October 2020.

Personnel hearing notice(s) issued to accused person(s) vide dated 22-01-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 03-2019

Expiry Date: 03-2020

Sampling Date: 18-04-2019

Sent to DTL (Form 6): 18-04-2019

Date of receipt in DTL: 23-04-2019

DTL Report Date: 22-06-2019

Time Extension: N/A

1ST DI Communication with firm on dated: 10-07-2019

Date of Retesting Request of Firm: 18-07-2019

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the

Fate of Retesting Request: - turn down

Investigation Report Dated: 20-04-2023

Drugs Act 1976 in its **275th meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (operations) Primary & Secondary Healthcare department /Vice chairperson, PQCB. Jawad Ahsan, Secretary DQCB, Rawalpindi joined meeting via zoom link and Ms. Saira Bano Inspector of drugs, Benazir Bhutto Hospital, Rawalpindi was present along with original case record. No one on behalf of Zafa Pharmaceuticals Laboratories (Pvt.) Ltd. L-1/B, Block-22, Federal "B" Industrial Area, Karachi-Pakistan appeared before the board. The Firm has requested for the adjournment.

6. The Board after due deliberation and discussion unanimously decided to **Adjourn** the case in the best interest of justice and further decided to provide the firm another chance of hearing.

PROCEEDING & DECISION BY THE BOARD:

Case No. 31

PQCB/R-549/2022

Government Kot Khawaja Saeed Hospital Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s ICI Pakistan Ltd. Pharmaceuticals, 32/2A, Phase III, Industrial Estate Hattar-Pakistan** through its Vice President/ Director, Aamer Mahmud Malik 2. Aamer Mahmud Malik Vice President/ Director 3. Shahid Mukhtar Production Manager 4. Zafar Abbas Quality Control Incharge/ Warrantor of M/s ICI Pakistan Ltd. Pharmaceuticals, 32/2A, Phase III, Industrial Estate Hattar-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Government Kot Khawaja Saeed Hospital Lahore reported that: -

i. Her predecessor, on 11-04-2022, inspected the premises of Main Medicines Store of Government Kot Khawaja Saeed Hospital Lahore, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 123459 dated 11-04-2022.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Capsule. Tramed [Tramadol Hydrochloride …. 50mg] **Mfg Date** Feb 2022 **Expiry Date** Jan 2025	2B261	M/s ICI Pakistan Ltd. Pharmaceuticals, 32/2A, Phase III, Industrial Estate Hattar-Pakistan.	01-177000788/DTL dated 08-06-2022	**Analysis with specifications applied: BP 2021** **PHYSICAL DESCRIPTION:** White powder enclosed in hard gelatin capsule shell having yellow cap and body in "alu-alu" packing of ten units. **DISINTEGRATION:** All 6 units disintegrated within specified time. **IDENTIFICATION OF TRAMADOL HCL:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (TRAMADOL HCl IDENTIFIED) **ASSAY OF TRAMADOL HCl:**

Regn No. 024421				Stated: 50 mg /cap Determined: 49.82 mg/cap Percentage: 99.64% Limit: 95.0%–105.0% of the stated amount **UNIFORMITY OF WEIGHT: Fails to comply the criteria for uniformity of weight/weight variation as detailed below: -** Tolerance Limit: Not more than 2 of the individual masses deviate from the average weight by more than ± 10% and none deviates by more than twice that percentage (i.e., ± 20%) Average weight: 184 mg Determined: 02 out of 20 units deviate from average mass by more than ± 10% and 01 out of these 02 units deviate from the average mass by more than ± 20%. **(DOES NOT COMPLY)** **RESULT:** The above sample is **SUB-STANDARD,** on the basis of UNIFORMITY OF WEIGHT/ WEIGHT VARIATION performed as per BP.	

iii. The storekeeper of the Main Medicines Store of Government Kot Khawaja Saeed Hospital Lahore provided warranty bearing No. DC#MH-0011 dated 09-04-2022 issued by M/s Mediline HealthCare H#18, ST# 1, Imperial Garden, Paragon City, Barki Road, Lahore as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent to M/s Mediline HealthCare H#18, ST# 1, Imperial Garden, Paragon City, Barki Road, Lahore who in-turn provided invoice/warranty no. 60625300 dated 31-03-2022 issued by M/s ICI Pakistan Ltd. Pharmaceuticals, 32/2A, Phase III, Industrial Estate Hattar-Pakistan.

v. A copy of test/analysis report was sent to M/s ICI Pakistan Ltd. Pharmaceuticals, 32/2A, Phase III, Industrial Estate Hattar-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to the request of M/s ICI Pakistan Ltd. Pharmaceuticals, 32/2A, Phase III, Industrial Estate Hattar-Pakistan, the retesting request of the subject drug sample was considered in **252nd Meeting of the Board held on 01-11-2022** and the subject drug sample was sent to NIH, Islamabad, from where the sample was declared **Sub-standard** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result
Capsule. Tramed 50mg	2B261	M/s ICI Pakistan Ltd. Pharmaceuticals, 32/2A, Phase III, Industrial Estate Hattar-Pakistan.	0287-P/2022 dated 13-02-2023	**Analysis with specifications applied:** BP 2017 **WEIGHT VARIATION:** **Determined:** Four units out of 20 deviated from the 10% limit and none unit out of 20 deviated from the 20% limits. **Limit:** Not more than two of the units masses deviate from the 10% of average mass and none deviates by 20% of the average mass. **Does not comply with BP-2017** **CONCLUSION:** The sample is of **Sub-Standard** quality on the basis of test performed.

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

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

3. Show-cause notice(s) issued to accused person(s) dated 16-08-2023

Firm replied to the show cause notice vide letter dated 06-09-2023

1. *Please refer to the captioned subject and your show cause not¿ce No. POCB/R-594/2022 dated 16-08-2023 (the SCN") received on 30-08-2023 as well as the intimation letter dated 01-09-2023 issued by the Inspector of Drugs wherein Lucky Core Industries Limited (formerly ICI Pakistan Limited) (“LCI") has been directed to explain its position vis-à-vis allegations of manufacturing drug namely, Capsule Tramed 50 mg (Tramadol), Batch No. 2B261 (the "Product") allegedly declared 'substandard' by the Appellate Laboratory, National Institute of Health, Islamabad (“NTH") as well as the Drug Testing Laboratory (“DTL") on the basis of weight variation'.*
2. *It is brought to your kind attention that the allegations contained in the SCN under reply are entirely baseless, incorrect, untrue and unsubstantiated for having been based upon the shaky, non-conclusive, unsupported and tainted DTL and NIH Test Reports. As a matter of fact, LCI holds the distinction of being one of the leading pharmaceutical companies of the country and has been engaged in the manufacture, marketing, distribution and supply of the highest quality pharmaceutical products for the benefit of the public en mass. The extent of the good will and superior quality of LCI's products may be grasped from the factual reality that over the decades, LCI has upheld and maintained its commitment of manufacturing pharmaceutical products with strict adherence to international standards of quality, safety and efficacy as well as the current Good Manufacturing Practices (cGMP) and **there has never been any complaint** against LCI from any quarter whatsoever.*
3. *Essentially, after test and analysis of the samples of the Product by the Appellate Laboratory, the NIH Test Report bearing No. 0287-P/2022 dated 13-02-2023 is the purported 'conclusive proof’ under the provisions of the Drugs Act, 1976 (the “Drugs Act") and the Drug Regulatory Authority*

of Pakistan Act, 2012 ("DRAP Act"), Since, the NIH Report is doubtful, defective and inadmissible as evidence/proof of the alleged violation on part of the LCI, the SCNs is liable to be withdrawn on this score alone. In essence, the SCNs is premised upon ***inadmissible/defective test reports*** *and accordingly is marred by fundamental deficiencies and glaring infirmities. As such, the credibility, accuracy and veracity of the NIH Report is highly doubtful and questionable.*

4. *Without prejudice to the aforementioned stance of LCI, in response to the ill-founded, baseless and unwarranted SCNs under reply, it is submitted as under:*

i. *By way of introduction, it may be noted that Section 3 (z) of the Drugs Act prescribes the "specifications" for the purpose of test and analysis of drugs. Pursuant to the aforementioned provision of law "specifications" when applied to a drug mean:*

"i) such specifications as may be prescribed; or (ii) <u>when the specifications are not prescribed, the specifications as contained in the most recent edition</u> of any of the following publications, namely:

(5) the British Pharmacopoeia....

ii. First and foremost, it is essential to highlight that the NIH Report after test and analysis of the Product as per BP 2017 specifications' declares the same as "substandard" on the basis of the test performed. It is categorically pointed out that the Government Analyst failed to perform the test and analysis of the ***Product in question in accordance with the latest Pharmacopeial specifications*** *in stark negation of Section 3 (z) of the Drugs Act read with the provisions of the Drugs (Specifications) Rules, 1978 which emphasis testing as per the latest specifications. Congruently, the NIH Report being the 'incriminating evidence' of the alleged violation of the law is unreliable, inadmissible and defective. Accordingly, no case of any alleged violation of the applicable laws can be made out against LCI due to the lack of confidence inspiring, cogent evidence or on the basis of any defective or inadmissible adverse test report.*

iii. *Secondly, after a bare perusal of the DTL and NIH in contradistinction and comparison it is evident that the findings of* ***both the reports are contradictory****. For instance, the* ***DTL Report*** *after test and analysis as per the latest B.P 2021 specifications details as under:*

<u>Tolerance Limit</u>: Not more than 2 of the individual masses deviate from the average weight by more than +10% and none deviates by more than twice that percentage (i.e., _+20 %)

<u>Determined:</u> 02 out of 20 units deviate from average mass by more than _+10% and 01 out of these 02 units deviate from the average mass by more than+20 % (DOES NOT COMPLY)

On the other hand, the ***NIH after employing the B.P 2017*** *specifications tests in the following manner:*

WEIGHT VARIATION:

<u>Determined:</u> Four units out of 20 deviated from the 10 % limit and none unit out of 20 deviated from the 20 % limits.

<u>Limit:</u> Not more than two of the units' masses deviate from the 10 % of average mass and none deviates by 20 %o of the average mass.

The record shows that ***there are conflicting NIH and DTL Test Reports*** *of the Government Analyst of the same drug and such circumstances do not rule out the probability of error on part of the Government Analyst.* ***Such unsatisfactory evidence/test reports are improper/inadmissible*** *and could not, prima facie, lead to establishing any liability against LCI and no reliance can be placed upon the same.*

iv. *The afore-detailed stance of LCI is fully supported by cogent evidence. Mainly, the excellent quality and efficacy of the products manufactured by LCI is evidenced by the fact that the* ***same batch of the Product was also delivered to DHQ Hospital Gujranwala****. A sample of the Product in question was sent to the Government Analyst* ***Drug Testing Laboratory, Faisalabad which declared the Product to be of standard quality****.*

v. *Even otherwise, it cannot be denied that* ***weight variation is a physical test*** *parameter which is applied to ensure that all units in a batch are within a tolerance of their average weight giving intra and inter batch uniformity data. Weight variation narrates the consistency/uniformity of drug content/dose in each unit.* ***Consistency/uniformity of drug content****/dose is always determined through a test called 'Uniformity of Dosage Unit (P%. Eur. Method 2.9.40, British Pharmacpeia)', which is defined as the degree of uniformity in the amount of the active substance among dosage units. Primarily, Uniformity of Dosage Unit is demonstrated by either of two recommended methods, considering percentage content of active substance w.r.t. to average weight of dosage unit. The methods used for the aforesaid purposes are; (a) Uniformity of Content (determined by assay of the individual contents of active substance(s) of a number of dosage units) and (b) Weight variation or Uniformity of weight (by using Assay results of representative composite sample and estimating assay of individual unit). Accordingly, it is imperative to highlight that the drug product in question cannot be declared as substandard based on 'Weight Variation (or Uniformiy of weight)' which is only used for the* ***purpose of adjusting weight variation within a batch*** *during manufacturing and is* ***not the criterion for final batch release****. Essentially, weight variation is considered as an inprocess parameter used to control product manufacturing within operating range and to control process yield but is not on its own conclusive to declare a product substandard.*

vi. *Moreover, the test parameter i.e.* ***'Uniformity of Dosage Unit', has not been performed by DTL Lahore or NIH****, which is the one of main criteria for determining compliance with specifications.*

vii. *Lastly, it is essential to note that after receiving intimation that the Product was declared substandard, an* ***extensive investigation was conducted by LCI.*** *The results of all the tests conducted upon the retention sample of the Product after thorough in-house testing were found well within the prescribed limits in terms of the standard latest specifications. In this regard, it is pertinent to mention here that the Reports completely ignore/over-look the relation/lineage of weight variation with 'assay' and parameters which directly affect recovery and bioavailability of drugs i.e., assay and dissolution are also fully compliant with the specifications. For instance,* ***the assay value cited in the DTL Report is 99.64 % (= 49 .82 % mg/capsule)*** *which is almost equal to the label claim of 50 mg/capsule of the Product. Further, the dissolution test of the Product performed by LC's OC lab has found the Product fully compliant. Hence, on the basis of uniformity of drug recovery in the afforested tests, the alleged failure /non-compliance of the product is a practical impossibility. It is a matter of fact, that the Government Analysts of DTL and NIH have not performed test for ascertaining the 'dissolution' of the Product and surprisingly even* ***no method of analysis has been sought/inquired from LCI*** *for the complete analysis of the Product in question.*

viii. *Accordingly, it is to be noted on the basis of the above explanation, that LCI and its officials have not contravened the provisions of the Drug laws and the rules made thereunder.*

5. Albeit, despite the absolute and complete innocence of LCI and its officials, please note the following information and documents appended with this response, as per your requirement:

Aamer Mahmud Malik, Chief Operating Officer

Zafar Abbas, Quality Control Manager

6. Further, without prejudice to the fact that ***LCI vehemently denies the allegations contained in the SCN under reply****, LCI as part of its business practice to ensure continuance supply/availability of the Product has carried out complete replacement of the stocks of the product in*

question in wider interest of the general public.

*7. In view of the foregoing, your good office is most respectfully requested to **withdraw the captioned show cause notice** pertaining to Capsule Tramed 50 mg (Tramadol), Batch No. 2B261 on account of the **evident flaws, defects, and infirmities in the DTL and NIH Reports**. As such, no proceedings against LCI or its officials can be initiated on the basis of inadmissible and unreliable drug testing reports and proceeding further in this regard is futile.*

7. Personal hearing notice(s) issued to accused person(s) dated 22-01-2024

Previous Proceedings & Decision by the Board:

275th (Special) Meeting dated 31-01-2024

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Mr. Hassan Saeed Secretary DQCB Lahore and Ms. Nida Saleem Drug Inspector Govt. Kot Khawaja Saeed Teaching Hospital, Lahore was present along-with original case record. No-one appeared before the Board on behalf of **M/s ICI Pakistan Ltd. Pharmaceuticals, 32/2A, Phase III, Industrial Estate Hattar-Pakistan.** Secretary PQCB apprised the Board that the firm has submitted written request for adjournment

9. The Board after due deliberation and discussion unanimously decided to **adjourn** the case on the request of the firm and provide another opportunity of hearing to the firm in the best interest of justice.

10. Personal hearing notice(s) issued to accused person(s) dated 20-02-2024

11. Case is placed before the Board for decision.

Summary:

Manufacturing Date: Feb-2022

Expiry Date: Jan-2025

Sampling Date (Form 4): 11-04-2022

Sent to DTL (Form 6): 11-04-2022

Date of receipt in DTL: 15-04-2022

DTL Report Date (Form 7): 08-06-2022

Time Extension: Not Time Barred (Reporting Days: 55 Days)

1ST DI Communication with firm on dated: 15-06-2022

Retesting Request of Firm: Yes (24-06-2022)

Fate of Retesting Request: Allowed in 252-M dated 01-11-2022

Sample Sent to NIH: 07-11-2022

NIH Test Report: 13-02-2023 (Substandard) **[NIH Reporting Days: 92]**

Investigation Report Dated: 09-05-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 32

PQCB/R-585/2021

(B.V. Hospital Bahawalpur)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan** through its Chief Executive Officer Kashif Hussain. 2. Kashif Hussain — Chief Executive Officer 3. Syed Naveed Abbas — Production Incharge 4. Naeem — Quality Control Manager 5. Shakeel Bashir — Warrantor **of M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Central Pharmacy B.V Hospital, Bahawalpur reported that: -

i. She, on 07-05-2021, inspected the premises of Central Pharmacy, B.V Hospital, Bahawalpur and took subject drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo. No.193/DI/BVH, dated. 07-05-2021.
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.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**	**DTL Test Report Result**
Injection. Olam [Midazolam 1mg/ml] **Mfg Date:** March-2021 **Exp Date:** March-2023 **Registration No.**	OL 11	M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan	01-77004084/DTL Dated. 03-07-2021	**Analysis with specifications applied: USP 2020.** **Composition:** Each ml contains: Midazolam…….1mg **Description:** Colorless liquid in sealed transparent glass ampoule. (Stated volume: 5ml). 03 ampoules out of 10 contain visible particulate matter. **(Does not comply with the parenteral specifications).** **Volume:**

093476				

Limit	NLT Nominal volume
Determined	5.1ml

pH:

Limit	2.5-3.7
Determined	3.0

Sterility:

The product is sterile.

Identification:

Midazolam is identified.

Assay:

Midazolam

Stated	1mg/ml
Determined	0.9697mg/ml
Percentage	96.97%
Limit	90.0-110.0%

Result:

The sample is declared **Substandard** on the basis of **Physical Test**.

iii. Store Keeper of Central Pharmacy, B.V Hospital, Bahawalpur provided Invoice/warranty No 552, dated 20-04-2021 issued by M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan and they were asked to provide the requisite information in this regard. In response the firm challenged the Drug Testing Laboratory report and the office of Provincial Quality Control Board place the said retesting request in the 243rd Meeting of Retesting dated 12-05-2022 and Board after unanimously decided to turn down the said retesting request.

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. **Manufacture for sale /Sale of Substandard drug**
    b. **Issuance of false warranty**

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

Reply of Show Cause Notice:

It is written with reference to your letter No: PQCB/R-585/2021 dated 15/11/2022 received on 21-11-2022 regarding our above said product.(Copy attached)

In your said order, we were most astonishingly informed that the honorable PQCB Punjab Lahore has **Turn Down** our legitimate and with in time request for Re-testing of our above said product which was declared substandard by the honorable Govt Analyst Of Drug Testing Laboratory BWP on the basis of visible particulate matter vide Report NO: TRA NO: 01-77004084/DTL BWP dated 03-07-2021, despite clearing/complying with all other Pharmacopeial Parameters including Assay (copy attached).

It is further submitted that honorable PQCB Punjab Lahore vide letter No PQCB/P-622-7/2021 dated 12-8-2021 asked to adduce evidence in contyroversion of Govt Analyst Report vide letter No: BVH/LVN/DTL/BP/011 dated 27-07-2021 and provided all relevant raw data, QC analysis Reports and complete BMR.

To avoid the time limitations and having complete faith on the quality of our manufactured products. We requested for Re-testing of our above said product, having under section 22 subsections 4 & 5 of drug act 1976. To our letter No: P-622-7/2021 dated 12-08-2021.

Further, it is mentioned that sample of same production and above said same batch No forwarded from Ganga Ram Hospital Lahore has been declared of standard quality by Govt Analyst Lahore vide test report No: 01- 156001132/DTL dated 11-06-2021 which is strong evidence that our product is of standard quality, having faith in our product and as a gesture of professionalism, we not only issue recall of the product but also offer the above mention institute to replacement without cost.

You are hereby most humbly requested to reconsider/review your valued show cause notice vide letter No. PQCB/R-585/2021 dated 15-11-2022 with decision dated 12-05-2022.

4. Personal hearing notice(s) issued to the accused persons(s)

Summary:

Manufacturing Date: 03.2021

Expiry Date: 03.2023

Sampling Date (Form 4): 07.05.2021

Sent to DTL (Form 6): 07.05.2021

Date of receipt in DTL: 07.05.2021

DTL Report Date (Form 7): 03.07.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 18.07.2021

Date of Retesting Request of Firm: 27.07.2021

Fate of Retesting Request: Turn Down in 243rd meeting dated 12.05.2022

Investigation Report Dated: 05.10.2022

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 33

No. PQCB/R-844/2021

Benazir Bhutto Hospital, Rawalpindi

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S Caraway Pharmaceuticals, Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan** through its Managing Director Umer Farooq. 2. Umer Farooq Managing Director 3. Muhammad Javaid Production Manager 4. Murad Ali Quality Control Manager 5. Dr. Syed Tauqeer Ali Shah Warrantor Of M/S Caraway Pharmaceuticals, Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Benazir Bhutto Hospital, Rawalpindi reported that:-

i. She, on 16-02-2021 inspected the premises of Main Medicine Store, Benazir Bhutto Hospital, Rawalpindi, took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo No. 0000085206 Dated 16-02-2021.

ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Rawalpindi as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Cream Fusiway 15g [Fusidic Acid 20mg/g] **Mfg. Date**: 02-2021 **Exp. Date**: 01-2023 **Reg** # 050021	371	M/S Caraway Pharmaceuticals, Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan	01-74000926/ DTL dated: 19 Apr 2021	**Result of test/ analysis with specifications applied:** BP 2021 **PHYSICAL DESCRIPTION:** White colored, semi solid cream, filled in labelled, collapsible sealed aluminium tube, having white screw cap, further packed in outer labelled carton. **pH** Limit: 4.0-6.0 **Observed: 6.73 at 24.5C (DOES NOT COMPLY)** **ASSAY** Stated: 20mg/g

				Determined: 19.417mg/g Percentage 97.08% Limit: 95-105% **RESULT:** **The above sample is Sub-Standard on the basis of pH test performed.**

iii. The Store Keeper, Benazir Bhutto Hospital, Rawalpindi provided warranty/invoice No. 45124 dated 11-02-2021 issued by M/S Caraway Pharmaceuticals, Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, Islamabad.
iv. Warrantor Portion was sent to M/S Caraway Pharmaceuticals, Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, Islamabad.
v. A copy of Test/ Analysis reports was sent to M/S Caraway Pharmaceuticals, Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, Islamabad. In response, the firm challenged the report and requested for re-testing of the sample from Appellate Laboratory. The re-testing request was turned down by the Board in its 237th meeting dated 30-12-2021.

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 01-01-2024.

Personnel hearing notice(s) issued to accused person(s) vide dated 22-01-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 02-2021

Expiry Date: 01-2023

Sampling Date: 16-02-2021

Sent to DTL (Form 6): 16-02-2021

Date of receipt in DTL: 18-02-2021

DTL Report Date: 19-04-2021

Time Extension: N/A

1ST DI Communication with firm on dated: 04-05-2021

Date of Retesting Request of Firm: 07-05-2021

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act

Fate of Retesting Request: - Turn down in 237th meeting dated 30-12-2021

Investigation Report Dated: 16-08-2023

1976 in its **275th meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (operations) Primary & Secondary Healthcare department /Vice chairperson, PQCB. Jawad Ahsan, Secretary DQCB, Rawalpindi joined meeting via zoom link and Ms. Saira Bano Inspector of drugs, Benazir Bhutto Hospital, Rawalpindi was present along with original case record. No one on behalf of M/s Caraway Pharmaceuticals, Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, and Islamabad-Pakistan appeared before the Board and Firm has requested for the adjournment.

6. The Board after due deliberation and discussion unanimously decided to **Adjourn** the case in the best interest of justice and further decided to provide the firm another chance of hearing.

PROCEEDING & DECISION BY THE BOARD:

Case No. 34

PQCB/R-487/2021

Allied Hospital, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Caraway Pharmaceuticals, Plot 12, St N-3, National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan** through its Managing Director, Umar Farooq Khan 2. Umar Farooq Khan — Managing Director 3. Dr. Syed Tauqeer Ali Shah — Production In-Charge/ Warrantor 4. Murad Ali — Quality Control Incharge of M/s Caraway Pharmaceuticals, Plot 12, St N-3, National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Allied Hospital, District Faisalabad reported that: -

i. Her predecessor, on 26-02-2021, inspected the premises of Central Pharmacy, Allied Hospital, Faisalabad, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide memorandum no. 86138 dated 26-02-2021.
ii. The following drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Faisalabad**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Injection Cara-Lac [Each 1ml ampoule contains: Ketorolac Tromethamine USP … 30mg] **Mfg. Date:** Jan 2021 **Expiry Date:** Dec 2022	21A009	M/S Caraway Pharmaceuticals Plot 12, St N-3, National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan.	01-68007524/DTL dated 28-04-2021	**Analysis with specifications applied: USP 2020** **DESCRIPTION:** Colorless solution filled in transparent glass ampoule. **IDENTIFICATION:** Ketorolac Tromethamine is identified. **ASSAY:** Stated: 30 mg/ml Determined: 30.744 mg/ml Percentage: 102.48% (Complies) Limit: 90 – 110% (USP 2020) **pH:**

Regn. No. 054997				Stated: 6.9 – 7.9 (USP 2020) Determined: 6.93 (Complies) **EXTRACTABLE VOLUME:** **Stated:** Not less than nominal volume (USP 2020) **Determine:** 1.0 ml (Average of 10 ampoules) (Complies) **STERILITY:** Stated: Must be Sterile (USP 2020) Determined: Sterile (Complies) **VISIBLE PARTICULATES IN INJECTIONS:** **Stated:** According to USP 2020 (Visible particulates in injections <790>), "Inspected units must be free of visible particulates when examined without magnification against a black background and against a white background using illumination at a minimum intensity between 2000 and 3750 lux". **Determined: In case of given sample, visible particles are observed in 04 out of 20 ampoules. (Does Not Comply)** **RESULT:** Given sample is **Sub-Standard** with regards to Visible Particulates in Injections.

iii. Chief Pharmacy Technician, Allied Hospital Faisalabad provided invoice/warranty bearing No. 230 dated 06-02-2021 issued by M/s Ibrahim Enterprises, P-126, St. #5, Wakeelan Chiniot Bazar, Faisalabad as a proof of its purchase.

iv. M/s Ibrahim Enterprises, P-126, St. #5, Wakeelan Chiniot Bazar, Faisalabad was directed to explain their position, in response to which they provided invoice/warranty bearing No. IE 43355 dated 05-02-2021 issued by Caraway Pharmaceuticals, Plot 12, St N-3, National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan as a proof of its purchase.

v. Warrantor portion of drug sample was sent to M/s Ibrahim Enterprises, P-126, St. #5, Wakeelan Chiniot Bazar, Faisalabad.

vi. A copy of test/analysis report was sent to M/S Caraway Pharmaceuticals, Plot 12, St N-3, National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

Previous Proceedings & Decision by The Board: (Regarding Retesting Request)

PQCB 239th meeting held on 24-02-2022

2. The subject request for retesting of the drug sample was placed before the Provincial Quality Control

Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **239th** meeting held on **24-02-2022** under the chairmanship of Secretary Health Primary & Secondary Healthcare Department, Punjab in the presence of Board members as mentioned above. Muhammad Jawad, Production Manager of M/S Caraway Pharmaceuticals appeared before the Provincial Quality Control Board. Secretary PQCB apprised the Board that Drug Testing Laboratory report conveyed by Provincial Inspector of Drugs to manufacturer vide letter no. DI/AHF(PQCB)08/21 Dated **01-06-2021 received by the firm dated 14-06-2021**. Manufacturer requested for retesting vide letter no. 174/CP/ISB dated **21-06-2021**.

3. Secretary PQCB apprised the Board that the firm was asked to adduce evidence in controversion of Government Analyst Test Report 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 /secondary Standard vide letter No. PQCB/ P-413-6/2021 dated 14-07-2021. The Board observed that subject drug was declared substandard on the basis of physical description i-e., presence of visible particulate matter in the parenteral preparation. The significance of the physical test of parenteral preparations in the Compendia and possible hazards on the consumption of such preparation that were failed to comply the test were discussed at length and observed that, according to the chapter of General Monograph of **British Pharmacopoeia (BP 2018)** under the heading of "**Parenteral Preparations**" it is stated that

i. ***Solutions for infusion, examined under suitable conditions of visibility, are clear and practically free from particles.***
ii. *The labeling instructions for injections, infusions and concentrated solutions for injections states that* ***"these should not be used if visible particles are present"***

According to USP 42 in Physical Test Chapter under <790> Visible Particulate in Injections it is stated that manufacturer should test the batch for visible particles twice:

Visual inspection of all units during manufacturing:

"100% inspection during the manufacturing process, this procedure is sufficient to demonstrate that the batch is essentially free of visible particulates. A complete program for the control and monitoring of particulate matter remains an essential prerequisite.

Inspected units must be free of visible particulates when examined without magnification (except for optical correction as may be required to establish normal vision) against a black background and against a white background. Illumination at the inspection point is maintained at a minimum intensity between 2000 and 3750 lux. This can be achieved through the use of two 13-W or 15-W fluorescent lamps (e.g., Fl 3/T5 or F15/T8). The use of a high-frequency ballast to reduce flicker from the fluorescent lamps is recommended. Alternative light sources (e.g., incandescent, LED) that provide illumination at the point of inspection within the specified minimum intensity range are acceptable. Higher illumination intensity is recommended for examination of colored solutions or product in containers other than clear glass.

Before performing the inspection, remove any adherent labels from the container, and wash and dry the outside. The unit under inspection should be gently swirled and/or inverted, ensuring that no air bubbles are produced, and inspected for approximately 5 s against each of the backgrounds. The presence of any particles should be recorded"

i. *Sampling at batch release (after 100% manufacturing inspection):*
ii. *"General Inspection Level II, single sampling plans for normal inspection with an AQL of 0.65% (ISO-2859-1)"*

4. The Board scrutinized the DTL report and matter of failure of the subject drug was discussed at length. The Board observed that the drug sample failed to comply the test for particulate matter and was declared substandard on the bases of visual inspection where **04 out of 20 ampoules containing un-dissolvable visible particulate matter.** The visible un dissolved particles were observed in samples by the naked eye. The visible particulate matter is greater enough in size to pass through small arteries and veins which circulate the blood throughout the body including vital organs like heart and may cause a fatal disease i.e., myocardial infarction (MI) or it may block some

arteries supplying blood to the brain which may cause another life-threatening disease i.e., CVA and hemiplegia (paralysis). According to the guidelines of American Society of Parenteral and Enteral Nutrition, particles of 5 to 20 µm and larger are capable of obstructing blood flow through the pulmonary capillaries, which may lead to complications such as pulmonary embolism and death of the patient. If the visible particle is immunogenic *i.e.,* endotoxin or pathogenic by product of dead bacteria *etc.* it can cause life threatening consequences like septicemia, anaphylactic shock etc.

5. The Board was of the considered opinion that it is quite possible that some of the ampoules may contain particles while others do not. As the Government Analyst report reflects that in some of ampoules particulate matter is present while in others it is not. The Board was of the considered view that firm has not carried out the proper monitoring and neglected the strict checks of physical inspection of the injectable preparations which was mandatory requirement during the process of manufacturing as well as before the release of finished product. This clearly indicated the negligence and irresponsible attitude of the firm in manufacturing of life saving drugs. Moreover, after revamping, the Drug Testing Laboratories of the Punjab are testing the drug samples according to the Pharmacopeial International Standard of the test / analysis and all these laboratories are ISO Certified and are in process of WHO accreditation.

6. Keeping in view the serious consequences and facts of the case, the Board was of the considered opinion that presence of visible particulate matter should be considered as clear evidence and there left no need of further analysis. Furthermore, it is prerequisite for Injectable preparations that each and every unit of injectable must be free from particulate matter and should be checked before marketing. Even a single unit of injectable having such particulate matter(s) administered to a single patient may result in potential hazard and therefore render a safety risk. Considering the above facts in view, the Board after due deliberation unanimously decided to **turn down** the subject request for retesting of the sample. The Board further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board

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

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

b. **Issuance of false warranty**

8. Show-cause notice(s) issued to accused person(s) dated 19-08-2022

9. Personal hearing notice(s) issued to accused person(s) dated 22-01-2024

Previous Proceedings & Decision by The Board:

275th Special meeting held on 31-01-2024

10. Case was considered by the Provincial Quality Control Board, under section, 11 of the Drugs Act 1976 in its **275th-S meeting** held on **31-01-2024** under the Chairmanship of Vice-Chairperson. Ms. Rubina Akhtar, Secretary DQCB, District Faisalabad attended the meeting online via zoom link and Ms. Iqra Fayyaz, Drug Inspector Allied Hospital, District Faisalabad was present along with the original case record. No one among the nominated accused person appeared before the Board on the behalf of M/s Caraway Pharmaceuticals Plot 12, St. N-3, National Industrial Zone, Rawat, Islamabad-Pakistan. Secretary PQCB apprised the Board that personal hearing notice(s) was duly served to the accused persons of the firm but the representative of the firm submitted written request of adjournment on the behalf of the nominated accused persons. The Board after due deliberation and discussion unanimously decided to **adjourn the case** on the request of the firm. Moreover , the drug inspector is directed to retain an appropriate portion for Court purposes and dispose-off the remaining stock having Expiry date of December-2022 (if not recovered and seized on Form-3 & Form-5) from Expired Drug Disposal Committee (EDDC) of health facilities already constituted vide PSHD notification No. SO (HP) 2-9(2)/ 2021 dated 14-February, 2022 and PQCB order

dated 06-05-2023 on guidelines regarding fate of case properties and report to the office of Secretary PQCB within 7 days positively

11. Personal hearing notice(s) issued to accused person(s) dated 20-02-2024

12. Case is placed before the Board for decision.

Summary:

Manufacturing Date: Jan-2021

Expiry Date: Dec-2022

Sampling Date (Form 4): 26-02-2021

Sent to DTL (Form 6): 26-02-2021

Date of receipt in DTL: 03-03-2021

DTL Report Date (Form 7): 28-04-2021

Time Extension: Not Time Barred (Reporting Days: 58 Days)

1ST DI Communication with firm on dated: 01-06-2021

Retesting Request of Firm: Yes (21-06-2021)

Fate of Retesting Request: Turn Down in 239-M dated 24-02-2022

Firm's Review Petition on Retesting Turn Down: Yes (31-08-2022)

Fate of Review Request: Firm's review petition no. 253/CP/ISB dated 29-08-2022 **is** not addressed as sample expired when reviews started addressing.

Investigation Report Dated: 07-05-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 35

PQCB R-772/2021

DHQ Hospital, District Faisalabad

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Caraway Pharmaceuticals, Plot 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan** through its Managing Director, Umer Farooq 2. Umer Farooq — Managing Director 3. Muhammad Javaid — Production Manager 4. Murad Ali — Quality Control Manager 5. Dr. Syed Tauqeer Ali Shah — Warrantor of **M/s Caraway Pharmaceuticals Plot 12, St. N-3, National Industrial Zone, Rawat, Islamabad-Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, DHQ Hospital, District Faisalabad reported that:-

i. The then drug inspector, on 24-03-2021, inspected the premises of Main Medicine Store of DHQ Hospital, District Faisalabad, took three 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, Faisalabad vide memo number 87719 dated 24-03-2021.
ii. The subject drug sample, after test/analysis, was declared **Substandard & Adulterated** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:
iii. Pharmacy Technician of Main Medicine Store of DHQ Hospital, District Faisalabad, provided invoice/ warranty no. 249 dated 15-03-2021 issued by M/s Ibrahim Enterprises, P-126, St. No. 05, Wakeelan Chiniot Bazar, Faisalabad as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/s Ibrahim Enterprises, P-126, St. No. 05, Wakeelan Chiniot Bazar, Faisalabad who provided invoice/ warranty no. IE 45644 dated 11-03-2021 issued by M/s Caraway Pharmaceuticals Plot 12, St. N-3, National Industrial Zone, Rawat, Islamabad-Pakistan as a proof of its purchase.

v. A copy of test report of the drug sample was sent to M/S Caraway Pharmaceuticals Plot 12, St. N-3, National Industrial Zone, Rawat, Islamabad-Pakistan with directions to provide the requisite information and to explain their position in this regard. In response, firm requested for re-test/ analysis of their drug sample from Appellate Laboratory, National Institute of Health Sciences, Islamabad.

vi. Pursuant to their request, the Provincial Quality Control Board in its 247th meeting held on 21-07-2022, after due deliberation and discussion, unanimously decide to turn down the firm's request for retesting of the subject sample.

Name of drug	Batch No.	Name of Manufacturer	DTL Report No. & Date	DTL Test Report Results

Injection Cara-Lac (Each 1ml ampoule contains: Ketorolac Tromethamine USP....30mg) **Mfg. Date** Feb-2021 **Expiry Date:** Jan-2023 **Reg No.** 054997	21B001	M/S Caraway Pharmaceuticals Plot 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad.	01-68007846/DTL Dated 30-04-2021	**Analysis with specifications applied:** USP 2020 **DESCRIPTION:** Pale yellow colored solution filled in transparent printed glass ampoule. **NOTE:** Manufacturer describes description of contents of filled ampoule as **"Clear, colorless solution filled in USP type I printed glass ampoule"** but in case given sample **"Pale yellow colored solution is filled in transparent printed glass ampoule"** which does not comply with manufacturer's description of contents of filled ampoules. **Moreover, a glass particle visible to the naked eye is found in a sealed glass ampoule. (Does Not Comply)** **IDENTIFICATION**: Ketorolac Tromethamine is identified. **ASSAY** Stated: 30 mg / ml Determined: 31.069 mg / ml Percentage: 103.56 % (Complies) Limit: 90 - 110% (USP 2020) **pH** Stated: 6.9-7.9 (USP 2020) Determined: 7.03 (Complies) **EXTRACTABLE VOLUME** Stated: Not less than nominal Volume (USP 2020) Determined: 1.0 ml (Average of 10 ampoules) (Complies) **STERILITY** Stated: Must be Sterile (USP 2020) Determined: Sterile (Complies) **RESULT: Given sample is**

				Adulterated and Sub-Standard with regards to tests performed.

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

a. **Manufacture for sale/Sale of Substandard & Adulterated drug**
b. **Issuance of false warranty**

PREVIOUS PROCEEDINGS OF THE CASE:

SUBJECT- REVIEW PETITION AGAINST THE IMPUGNED ORDER P-414-04/2021 dated 05-04-2023 REGARDING OMISSION OF THE VERDIC OF "ADULTERATED DRUG " FROM THE FAISALABAD DTL REPORT NO. 01-68007846DTL dated 30-04-2021 Related to INJ. CARA-LAC X 1ml, BATCH # 21B001 Mfg. By MS CARAWAY PHARMACEUTICALS ISLAMABAD

BRIEF FACTS OF THE CASE

Respectfully Submitted Brief facts of the case are as under; -

1. That after due process of purchase procedure, we supplied to DHQ Hospital, Faisalabad Injection CARA-LAC (Each 1ml ampoule containing: Ketorolac Tromethamine USP 30mg), Batch # 21B001 to the following Government Hospitals.
    a. DHQ Hospital Faisalabad ----------8000+20 packs
    b. Aziz Bhatti Shaheed Hospital Gujrat- ----------6000+20 packs
    c. Benazir Bhutto Shaheed Hospital Rawalpindi. ----12000+20 packs
2. That On 25-03-2021 the Drug Inspector DHQ Hospital Faisalabad took the sample of same and sent to Drug Testing Laboratory Faisalabad for the purpose of test/analysis.
3. The Government Analyst reported the Drug sample as allegedly **"substandard &adulterated"** vide TRA NO. 01-68007846/DTL dated 30-04-2021 and the remarks of Government Analyst stated therein are as under **“manufacturer describes description of filled ampoule as clear colorless solution filled in USP Type 1 printed ampoule " but in the given ampoule "pale yellow colored solution is filled in transparent printed glass ampoule" which does not comply with manufacturer's deseription of contents of filled ampoule. Moreover, a glass particle visible to naked eye is found in a sealed glass ampoule** (does not comply).
4. That due to typographical error in the specs. of description of filled ampoule, the word **"clear solution"** was inserted instead of **"clear to pale yellow solution".** Later on we conveyed the clarification to the Drug Inspector including DTL along with proof of Reference Regulatory Authorities of UK & USA such as MHRA & FDA vide our letter no. 230/CP/ISB dated 13-04-ISO9001 2015 Certified 2021, refuted the findings of the Government Analyst DTL, Faisalabad and requested for retesting of the Product from the NIH as provided under Section 224) of the Drugs Act 1976 & Rules framed there under.
5. That other tests such as identification test, Assay test, PH test, Extractable volume and sterility tests are within the specifications, rendering it completely fit for patients use without any fear of risk as being under use in Aziz Bhatti Shaheed Hospital Gujrat & Benazir Bhutto Shaheed Hospital Rawalpindi.
6. That thereafter, the retesting request made by the company under section 22(5) of the Drug Act 1976, was considered by the Honorable Board in its 247th meeting held on 21-07-2022 wherein submissions were made and documentary evidence was presented which clearly necessitated the retesting of the sample of the Product from the NIH. But the request of retest was declined without any justifiable basis and without any attention paid to the cogent submissions presented by the company nor the same is reflected from the Impugned Order.
7. That thereafter, we left no way except to institute a Review Petition bearing no. 265/CP/ISB dated 07-

10-2022 against the impugned order no. PQCB/P-414-04/2021 dated 21-07-2022. which is **lying in the BOARD un-attended**.

8. That another substandard report from DTL Faisalabad, on re-testing, was declared as of standard quality by the NIH Islamabad. Moreover, the sample of same batch no. from BNSH Rawalpindi was also declared as of standard quality.
9. That also the Honorable Board was presented reports by DTL Rawalpindi and NIH wherein the Product belonging to the same Batch obtained by Drug Inspector, Benazir Hospital Rawalpindi and Drug Inspector and Aziz Bhatti Shaheed Teaching Hospital, Gujarat at two different instances were declared as samples of 'standard quality, **which provide sufficient evidence in support of retesting**. However, absolutely no heed was paid to the same and this Honorable Board in complete disregard of the evidence submitted by the firm, has proceeded to pass the Impugned Order wherein the retesting request has been declined without any justifiable basis.
10. That it is reflected from the standard reports of DTL Rawalpindi and NIH Islamabad of the same batch that the ambiguity regarding the color of the liquid of filled ampoule is clarified and has no impact on the result of failed report under question i.e. TRA NO. 01-68007846/DTL dated 30-04-2021. The matter of glass particle is in fact an accompanied material of packing material i.e. USP Type-I glass ampoule having no deleterious and deteriorative impact on the quality of drug. However, being not detected during optical inspection is a human error as the color of ampoule and glass particle is same.
11. That it is also reflected from the alleged test report that only one ampoule contains a glass particle visible to naked eye which cannot render the whole batch as non-conforming. The injection Cara-lac is filled in USP Type-1 glass ampoules under the stated conditions and sealed thematically by melting the thin top layer with a flame.
    a. **<u>The nature of glass particle is same as of ampoule i.e. USP Type-1</u>**, which is intrinsic and an accompanied material of glass ampoule and cannot be considered as a foreign particle.
    b. **<u>There is no any deleterious or deteriorative impact on the quality of the Product</u>**. All tests are clear including sterility test which substantiates and corroborates the fact that the Product is, for all intents and purposes, is safe and efficacious for use on patients as proved that the same batch is under use in two Government teaching Hospitals at Gujarat and Rawalpindi without any adverse report.
    c. **<u>The size of glass particle is as much as that it cannot be sucked into syringe</u>**, hence no chance of its entering into the human body.

Drug Act 1976, Under Section 3 (a) "adulterated Drug" means a drug....

I	Which consist in whole or in part of any filthy, putrid or decomposed substance or which contains any foreign matter, vermin, worm, rodent or insect; or	NA.
II	Which has been manufactured, packed, or held under unsanitary conditions whereby it may have been contaminated with dirt, filth, or any other foreign matter or whereby it may have been rendered injurious to health; or	NA
III	The container of which releases any poisonous or deleterious substance which may render the contents injurious to health; or	NA
IV	Which bears or contains as an ingredient a substance other than the prescribed substance; or	NA
V	With which any substance has been mixed or packed so as to reduce its quality or strength or for which any substance has been substituted wholly or in part.	NA

12. From the above submissions it is crystal clear that none of the definition of "adulterated drug" is applicable on the alleged DTL report # 01-68007846/DTL dated 30-04-2021 and as such **<u>the act of Government Analyst by declaring the drug as "adulterated" is illegal, uncalled for and unjustifiable which need to be rectified/omitted</u>**.
13. That the firm is a well-respected pharmaceutical company with an illustrious history of provision of the highest quality pharmaceutical products to the general public, but the consequences of verdict of "adulterated drug" are very serious, leading to deleterious effect on its reputation.

14. Moreover, it is reiterated that firm has not contravened provisions of Drug Laws.

PRAYER:

i. It is requested to kindly accept the instant request and set aside the verdict of **"adulterated drug"** imposed illegally and without justifiable basis by Government Analyst in DTL Report 01-68007846 dated 30-04-2021.
ii. It is also requested that an opportunity of personal hearing may please be given so as to assist further at time of arguments.

2. Personal hearing notice(s) issued to accused person(s) dated 29-03-2023

PQCB 258th meeting held on 05-04-2023

3. Issue was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Murad Ali (Quality Control Manager) along with Tariq Mehmood Khan (Counsel) of M/s Caraway Pharmaceutical Industries Limited appeared before the Board. Firm's representatives requested the Board for omission of word "adulterated" from the DTL Report No. 01-68007846/DTL dated 30-04-2021 stating that the definition of Adulterated under Section 3 (a) of The Drugs Act 1976 shows that the term "Adulterated" cannot be applied to the observation of a glass particle in the above mentioned DTL report and the declaration of the same is unjustifiable & hence, needs rectification.

4. The Board after careful perusal of the case record and scrutiny of the DTL report observed that the subject drug sample Injection Cara-Lac 1ml (Ketorolac), Batch No. 21B001 has been declared both, Substandard & Adulterated from the Drugs Testing Laboratory Faisalabad based on injection's description and presence of a glass particle visible to naked eye in a sealed glass ampoule respectively. Regarding firm's request of omission of the verdict of adulterated from the DTL report, the Board unanimously decided that **firm's request is hereby not accepted**, Moreover, the Board was of the opinion that the firm should submit arguments regarding adulteration reported in DTL report and merits of the case while defending the subject case when provided opportunity of hearing at the time of decision of the case. The Board decided that direction issued to the Drug Inspector to expedite investigation in the subject case and submit complete investigation report at the earliest.

Firm submitted review petition on the above mentioned orders vide letter no. 311/CP/ISB dated 30-05-2023

1. That by way of the instant petition, the Petitioner seeks to challenge the Impugned Order

PQCB/P414-04/2021 dated 05-04-2023, Issued on 08-05-2023 (the "Impugned Order") received on 22-05-2023 passed by this Learned Board whereby the request to omit the verdict of "Adulterated Drug from dtl report no. 01-68007846/dtl dated 30-04-2021 related to inj. Cara-lac (Each Iml ampoule containing: Ketorolac Tromethamine USP... 30mg), batch # 21B001, has been declined without any speaking orders and justifiable basis.

2. That the facts necessitating the institution of the instant Review Petition are that in order to refute the verdict of "adulterated drug" from the report of Drug Testing Laboratory, Faisalabad vide TRA No. 01-68007846/DTL dated 30-04-2021, the firm proceeded to request to rectify the alleged DTL report but on 05-04-2023 the PQCB, Punjab has not accepted our request to omit the verdict of "adulterated drug" from the report of Drug Testing Laboratory, Faisalabad (the "DTL Report") declared the same as allegedly Substandard and adulterated.
3. That bare perusal of the Impugned Order reveals that the same falls short of the

mandatory requirement stipulated under Section 24-A of the General Clauses Act, 1897 where under it is incumbent upon public functionaries to pass a well-reasoned order. A perusal of the Impugned

Order reveals that neither any attention has been paid to the cogent submissions presented by the Petitioner nor the same is reflected from the Impugned Order. Rather the request to rectify the DTL report has only been declined on the basis of the baseless and false findings of the Government Analyst/ DTL, Faisalabad, which by any means, cannot be allowed to be made the basis for determining the quality of the Product.

4. That there are numerous reports of DTL's of all Punjab, claiming to be substandard only on account of presence of particles but not declared as adulterated. But here in the instant case, the petitioner is of the view to facie discriminatory approach of the government functionaries.
5. That the Government Analyst described the result as under; « Manufacturer describes description of filled ampoule as "**clear colorless solution filled in USP Type 1 printed ampoule but in the given ampoule "pale yellow colored solution is filled in transparent printed glass ampoule"** which does not comply with manufacturer's description of contents of filled ampoule. Moreover, a glass particle visible to naked eye is found in a sealed glass ampoule (does not comply).
6. That due to typo-graphical error in the description of filled ampoule the word clear solution" was inserted instead of "clear to pale yellow solution". Later on we conveyed the clarification to the Drug Inspector including DTL along with proof of Reference Regulatory Authorities of UK & USA such as MHRA & FDA vide our letter no. 230/CP/ISB dated 13-04-2021, refuted the findings of the Government Analyst DTL, Faisalabad and requested for re-testing of the Product from the NIH as provided under Section 22(4) of the Drugs Act 1976 & Rules framed there under.
7. That all other tests such as identification test, Assay test, PH test, Extractable volume and sterility tests are within the specifications, rendering it completely fit for patients use without any fear of risk as the same being under use in Aziz Bhatti Shaheed Hospital Gujrat & Benazir Bhutto Shaheed Hospital Rawalpindi.

That thereafter, the retesting request made by the company under section 22(5) of the Drug Act 1976, was considered by the Honorable Board in its 247th meeting held on 21-07-2022 wherein submissions were made and documentary evidence was presented which clearly necessitated the retesting of the sample of the Product from the NIH. But the request of retest was declined without any justifiable basis and without any attention paid to the cogent submissions presented by the company nor the same is reflected from the Impugned Order

8. That thereafter, we left no way except to institute a Review Petition bearing no. 265/CP/ISB dated 07-10-2022 against the impugned order no. PQCB/P-414-04/2021 dated 21-07-2022., which is lying in the BOARD un-attended.
9. That another substandard report from DTL Faisalabad, on re-testing, was declared as of standard quality by the NIH Islamabad. Moreover, the sample of same batch no. from BNSH Rawalpindi was also declared as of standard quality.
10. That also the Honorable Board was presented reports issued by DTL Rawalpindi and NIH wherein the Product belonging to the same Batch obtained by Drug Inspector, Benazir Hospital Rawalpindi and Drug Inspector and Aziz Bhatti Shaheed Teaching Hospital, Gujarat at two different instances were declared as samples of 'standard quality, which provide sufficient evidence in support of retesting. However, absolutely no attention was paid to the same and this Honorable Board in complete disregard of the evidence submitted by the firm, has proceeded to pass the Impugned Order wherein the retesting request has been declined without any justifiable basis.
11. That it is reflected from the standard reports of DTL Rawalpindi and NIH Islamabad of

the hat the ambiguity regarding the color of the liquid of filled ampoule is clarified and impact on the result of failed report under question i.e. TRA NO. 01-68007846/DTL dated 30-04-2021. The matter of glass particle is in fact an accompanied material of glass ampoule i.e.USP Type-1, having no deleterious and deteriorative impact on the quality of drug. However, being not detected during optical inspection is a human error as the color of ampoule and glass particle is same.

12. That it is also reflected from the alleged test report that only one ampoule contains a glass particle visible to naked eye which cannot render the whole batch as defective. The injection Cara-lac is filled in USP Type-I glass ampoules under the sterile conditions and sealed thematically by melting the thin top layer with a flame.
13. The nature of glass particle is same as of ampoule i.e. USP Type-1, which is an accompanied material of glass ampoule and cannot be considered as a foreign particle. There is no any deleterious or deteriorative impact on the quality of the Product. All other tests are clear including sterility test which substantiates and corroborates the fact that the Product is, for all intents and purposes, is safe and efficacious for use on patients as the same batch is under use in two Government teaching Hospitals at Gujarat and Rawalpindi without any adverse report.

Drug Act 1976, Under Section 3 (a) "adulterated Drug" means a drug....

I	Which consist in whole or in part of any filthy, putrid or decomposed substance or which contains any foreign matter, vermin, worm, rodent or insect; or	NA.
II	Which has been manufactured, packed, or held under unsanitary conditions whereby it may have been contaminated with dirt, filth, or any other foreign matter or whereby it may have been rendered injurious to health; or	NA
III	The container of which releases any poisonous or deleterious substance which may render the contents injurious to health; or	NA
IV	Which bears or contains as an ingredient a substance other than the prescribed substance; or	NA
V	With which any substance has been mixed or packed so as to reduce its quality or strength or for which any substance has been substituted wholly or in part.	NA

14. From the above submissions it is crystal clear that none of the definition of "adulterated drug" is applicable on the alleged DTL report # 01-68007846/DTL dated 30-04-2021 and as such **the act of Government Analyst by declaring the drug as "adulterated" is illegal, uncalled for and unjustifiable which need to be rectified/omitted**.

15. That the firm is a well-respected pharmaceutical company with an illustrious history of provision of the highest quality pharmaceutical products to the general public, but the consequences of verdict of "adulterated drug" are very serious, leading to deleterious effect on its reputation.

16. Thus, it is reiterated that firm has not contravened provisions of Drug Laws and the rules made thereunder and are committed to ensure strict compliance in respect of quality of its products.

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/review the Impugned Order No. PQCB/P-414-04/2021 dated 05-04-2023 whereby the request to rectify the alleged DTL report pertaining to the sample of the injection Cara-Lac

(Each lml ampoule containing: Ketorolac Tromethamine USP... 3Omg) Batch no. 21B001 has

been declined.

ii. It is also requested that an opportunity of personal hearing may please be given so as to assist further at the time of arguments.

5. Personal Hearing notice issued to the firm on 05-06-2023.

PQCB 262nd meeting held on 13-06-2023:

6. Issue regarding review request by the firm on the subject matter was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **262nd meeting** held on **13-06-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Murad Ali (Quality Control Manager) along with Raza Shahid (Consultant) of M/s Caraway Pharmaceutical Industries Limited appeared before the Board. Firm's representatives reiterated the arguments raised in their review request and presented no fresh grounds in favour of their case. Firm restated their request before the Board for omission of word "Adulterated" from the DTL report of the subject drug sample, declaring it to be unjustifiable.

7. The Board after careful perusal of the case record and firm's request for reviewing the decision taken in 258th meeting dated 05-04-2023 observed that the subject matter has already been discussed at length in 258th meeting. The Board was of the stern view that firm's request to omit the word "Adulterated" from the DTL Faisalabad Test Report No. 01-68007846/DTL dated 30-04-2021 is unacceptable. Hence, the Board, after due deliberation & detailed discussion unanimously decided to **turn down** the firm's review petition and **upheld the previous decision** taken in 258th meeting dated 05-04-2023. The Board further directed the firm to submit the reply of Show-cause notice (which is already issued). The Board further directed to place the regular case before the Board in the upcoming meeting.

PQCB 275th-S meeting held on **31-01-2024:**

8. Case was considered by the Provincial Quality Control Board, under section, 11 of the Drugs Act 1976 in its **275th-S meeting** held on **31-01-2024** under the Chairmanship of Vice-Chairperson. Miss. Rubina Akhtar Secretary DQCB District Faisalabad attended the meeting via zoom link and Mr. Ijaz Ahmed Drug Inspector DHQ Hospital, District Faisalabad was present along with record of the case. No one among the nominated accused person appeared before the Board on the behalf of **M/s Caraway Pharmaceuticals Plot 12, St. N-3, National Industrial Zone, Rawat, Islamabad-Pakistan**. Secretary PQCB apprised the Board that personal hearing notice(s) was duly served to the accused persons of the firm but the representative of the firm submitted written request of adjournment on the behalf of the nominated accused persons. The Board after due deliberation and discussion unanimously decided to **adjourn the case** on the request of the firm. The Board further decided to provide another/ final chance of personal hearing to the accused persons.

9. Personnel hearing notice issued vide dated 20-02-2024.

Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 02-2021

Expiry Date: 01-2023

Sampling Date (Form 4): 24-03-2021

Sent to DTL (Form 6): 24-03-2021

Date of receipt in DTL: 25-03-2021

DTL Report Date (Form 7): 30-04-2021

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 04-04-2022

Retesting Request of Firm: Yes 17-01-2023

Fate of Firm's Retesting Request: Turn Down in 247th Meeting dated 21-07-2022

Investigation Report Dated: 06-04-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 36

PQCB/R-752/2019

(DHQ Teaching Hospital Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad through** its Managing Director Umar Farooq. 2. Umar Farooq — Managing Director 3. Arifullah Khan — Production Incharge/Warrantor 4. Noor Faraz — Quality Control Incharge **of M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, DHQ Teaching Hospital, District Sahiwal reported that: -

i. He, on 30-05-2019, inspected the premises of Medicine Store DHQ Teaching Hospital, Sahiwal and took subject drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur.
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.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**	**DTL Test Report Result**
Injection. Tramaway [Tramadol HCl: 100mg/2ml]	9C206	M/S Caraway Pharmaceuticals, Plot No. 12, St.N-3, National Industrial Zone (RCCI), Rawat, Islamabad	01-25003902/DTL Dated. 31-07-2019	**Analysis with specifications applied: MS /BP 2018.** **Composition:** Each 2ml contains: Tramadol HCl……100mg **Description (MS):** Colorless solution, filled in transparent printed glass ampoule (stated volume: 2ml). **04 out of 20 ampoules containing undissolvable visible particulate matter (Does not comply with the parenteral specifications).** **Volume (MS):**

Limit	2.1±0.05ml
Determined	2.08ml

pH (MS):

Limit	4.5-8.5
Determined	6.15

Sterility (BP):

The product is sterile.

Identification (MS):

Tramadol HCl is identified

Assay (MS):

Tramadol HCl:

Stated	100mg/2ml
Determined	104.26mg/2ml
Percentage	104.26%
Limit	90-110%

Result:

The sample is declared **Substandard** on the basis of Physical Test.

iii. Store Keeper of Medicine Store DHQ Teaching Hospital, Sahiwal provided Invoice/warranty No CARA/DHQ/004, dated 28-04-2019 issued by M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad and they were asked to provide the requisite information in this regard. In Response the company challenge the Drug Testing Laboratory Report, Bahawalpur report, the request of retesting was placed in 230th meeting held on 20-02-2021 and the Board decided to turn down the said request of retesting. The firm also applied review petition which was upheld by the Board in its 249

th meeting dated 23.08.2022.

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. **Manufacture for sale/Sale of Substandard drug**
    b. **Issuance of false warranty**

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board, under section 11 of Drugs Act 1976 in its **247th meeting** held on **21-07-2022** under the Chairmanship of Vice Chairperson Additional Secretary, Drugs Control Primary & Secondary Healthcare Department, Punjab in the presence of Board members as mentioned above. Mr. Ahmed Awais Secretary DQCB District Sahiwal was present along with original record of the case. Representative of the Firm Murad Alli (Current Quality Control Manager), Muhammad Javaid (Curent Production Manager) along with counsel of the firm Rana Maqsood Afzal (Advocate) appeared before the Board on the behalf of M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad. Counsel person of the firm submitted before the Board the orders of Honorable Lahore High Court, in the which the court directed the Provincial Quality Control Board to hear the Review Petition of the firm against the orders of retesting requests.
5. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case** with directions to address the Court Directions.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **274th meeting** held on **21.12.2023** under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson Ahmad Awais, Secretary DQCB District Sahiwal attended the meeting online via Zoom and Umair Majeed, Drug Inspector DHQ Teaching Hospital Sahiwal was present along with original case record. No one among nominated accused, appeared before the Board on the behalf of M/s Caraway Pharmaceuticals, Plot No. 12, Stteet No. 3, National Industrial Zone, RCCI, Rawat, Islamabad however, the firm submitted written request for adjournment.

7. The Board after discussion decided to **adjourn** the case and to provide another opportunity to appear before the Board in the best interest of justice.

Summary:

Manufacturing Date: 03.2019

Expiry Date: 02.2021

Sampling Date (Form 4): 30.05.2019

Sent to DTL (Form 6): 30.05.2019

Date of receipt in DTL: 01.06.2019

DTL Report Date (Form 7): 31.07.2019

Time Extension: N/A

1ST DI Communication with firm on dated: 25.07.2020

Date of Retesting Request of Firm: 27.08.2020

Fate of Retesting Request: Turn Down (Review Petition upheld)

Investigation Report Dated: 02.06.2022

4. Personal hearing notice(s) issued to the accused persons(s)

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-665/2020

(DHQ Teaching Hospital Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 5. **M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad through** its Managing Director Umar Farooq. 6. Umar Farooq Managing Director 7. Arifullah Khan Production Incharge/Warrantor 8. Noor Faraz Quality Control Incharge **of M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, DHQ Teaching Hospital, District Sahiwal reported that: -

vi. He, on 06-11-2019, inspected the premises of Medicine Store DHQ Teaching Hospital, Sahiwal and took subject drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory **Bahawalpur**.

vii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch	Name of	DTL Report	DTL Test Report Result

<table>
<tr><th></th><th>No.</th><th>Manufacturer</th><th>TRA No. & Date</th><th></th></tr>
<tr><td>Injection. Tramaway [Tramadol HCl: 100mg/2ml]</td><td>9F357</td><td>M/S Caraway Pharmaceuticals, Plot No. 12, St.N-3, National Industrial Zone (RCCI), Rawat, Islamabad</td><td>01-25004650/DTL

Dated. 14-02-2020</td><td>
<u>Analysis with specifications applied:</u> MS /USP 2018.

<u>Composition:</u>

Each 2ml Ampoule contains:

Tramadol HCl (BP)……100mg

<u>Description (MS):</u>

Colorless solution, filled in sealed transparent glass ampoule (stated volume: 2ml).

03 out of 20 ampoules containing undissolvable visible particulate matter (Does not comply with the parenteral specifications).

<u>Volume (MS):</u>
<table>
<tr><td>Limit</td><td>Not less than nominal (2ml)</td></tr>
<tr><td>Determined</td><td>2.00ml</td></tr>
</table>
<u>pH (MS):</u>
<table>
<tr><td>Limit</td><td>4.5-8.5</td></tr>
<tr><td>Determined</td><td>6.513</td></tr>
</table>
<u>Sterility (BP):</u>

The product is sterile.

<u>Identification (MS):</u>

Tramadol HCl is identified

<u>Assay (MS):</u>

Tramadol HCl:
<table>
<tr><td>Stated</td><td>100mg/2ml</td></tr>
<tr><td>Determined</td><td>94.17mg/2ml</td></tr>
<tr><td>Percentage</td><td>94.17%</td></tr>
</table>
</td></tr>
</table>

				Limit	90-110%
				Result: The sample is declared **Substandard** on the basis of Physical Test.	

viii. Store Keeper of Medicine Store DHQ Teaching Hospital, Sahiwal provided Invoice/warranty No CARA/DHQ/005, dated 02-11-2019 issued by M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad as a proof of its purchase.

ix. Warrantor portion of drug sample was sent to M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad and they were asked to explain their position in this regard.

x. A copy of test/analysis report was sent to M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad and they were asked to provide the requisite information in this regard. In Response the company challenge the Drug Testing Laboratory Report, Bahawalpur report, the request of retesting was placed in 230th meeting held on 20-02-2021 and the Board decided to turn down the said request of retesting. The firm also applied review petition which was upheld by the Board in its 249th meeting dated 23.08.2022.

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

c. **Manufacture for sale/Sale of Substandard drug**
d. **Issuance of false warranty**

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board, under section 11 of Drugs Act 1976 in its **247th meeting** held on **21-07-2022** under the Chairmanship of Vice Chairperson Additional Secretary, Drugs Control Primary & Secondary Healthcare Department, Punjab in the presence of Board members as mentioned above. Mr. Ahmed Awais Secretary DQCB District Sahiwal was present along with original record of the case. Representative of the Firm Murad Alli (Current Quality Control Manager), Muhammad Javaid (Curent Production Manager) along with counsel of the firm Rana Maqsood Afzal (Advocate) appeared before the Board on the behalf of M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad. Counsel person of the firm submitted before the Board the orders of Honorable Lahore High Court, in the which the court directed the Provincial Quality Control Board to hear the Review Petition of the firm against the orders of retesting requests.
7. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case** with directions to address the Court Directions.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **274th meeting** held on **21.12.2023** under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson Ahmad Awais, Secretary DQCB District Sahiwal attended the meeting online via Zoom and Umair Majeed, Drug Inspector DHQ Teaching Hospital Sahiwal was present along with original case record. No one among nominated accused, appeared before the Board on the behalf of M/s Caraway Pharmaceuticals, Plot No. 12, Stteet No. 3, National Industrial Zone, RCCI, Rawat, Islamabad however, the firm submitted written request for

adjournment.

7. The Board after discussion decided to **adjourn** the case and to provide another opportunity to appear before the Board in the best interest of justice.

Summary:

Manufacturing Date: 06.2019

Expiry Date: 05.2021

Sampling Date (Form 4): 06.11.2019

Sent to DTL (Form 6): 06.11.2019

Date of receipt in DTL: 09.11.2019

DTL Report Date (Form 7): 14.02.2020

Time Extension: Granted in 218-M

1ST DI Communication with firm on dated: 28.07.2020

Date of Retesting Request of Firm: 27.08.2020

Fate of Retesting Request: Turn Down (Review Petition upheld)

Investigation Report Dated: 02.06.2022

4. Personal hearing notice(s) issued to the accused persons(s)

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 37

PQCB/R-296/2022

Sher Shah Town, Multan (CPEIC)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Reckitt Benckiser Pakistan Ltd, F-18, S.I.T.E. Karachi,** through its Manufacturing Director Syed Naveed Hussain 2. Syed Naveed Hussain — Manufacturing Director 3. Noman Sheikh — Production Incharge 4. Shoaib Akhter — Quality Control Incharge 5. Daniyal Khan — Warrantor of **M/S Reckitt Benckiser Pakistan Ltd, F-18, S.I.T.E. Karachi**.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Sher Shah Town, District Multan, reported that: -

i. The then Drug Inspector, on 03-02-2022 inspected Medicine Store of Choudhary Pervaiz Elahi Institute of Cardiology, Multan, and took 04 types of drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.
ii. Following drug sample, sent vide memo no. 117736, dated 03-02-2022, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:

Name of drug	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**
DISPRIN (ACETYL SALICYLIC ACID 300mg) TABLET **Mfg. date: 12-2021** **Exp. date: 11-2024** **Reg# 000152**	1226	M/S RECKITT BENCKISER PAKISTAN LTD. F-18, S.I.T.E., KARACHI – PAKISTAN.	01-94001938/DTL Dated 05-03-2022
Specification applied: MS **DESCRIPTION:** **Stated**: White to off white, circular, flat tablets with beveled edge. “DISPIRIN” & sword motif embossed on both faces packed in Aluminum blister of 10 units in a labeled outer hard carton. Each outer carton contains 60 blisters of 10 units each i.e 10*60= 600 Tablets.			

Determined: White to off white, circular tablets with broken edges & rough surface. “DISPIRIN” & sword motif embossed on both faces packed in Aluminum blister of 10 units in a labeled outer hard carton. Each outer carton contains 60 blisters of 10 units each i.e 10*60= 600 Tablets. **(DOES NOT COMPLY)**

Uniformity of Weight (WEIGHT VARIATION):

Average Weight: 461.42 mg

Limits: ± 5% (NMT 2 Tablets), None deviate from ± 10%

Results: 18 out of 20 tablets deviate from ±5 %

Out of Which 07 deviate from ± 10% **(DOES NOT COMPLY)**

Units	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Wt. (mg)	437.9	427.4	415.6	529.8	527.2	510.2	444.7	420.2	516.9	429.9	423.2	515.3	430.8	409.4	487.4	519.6	489.8	435.1	440.0	417.9
% Wt. Variation	-5.1	-7.4	-9.9	14.8	14.3	10.6	-3.6	-8.9	12.0	-6.8	-8.3	11.7	-6.6	-11.3	5.6	12.6	6.2	-5.7	-4.6	-9.4

Identification: Aspirin (Acetyl Salicylic Acid) Identified.

Assay:

Aspirin

Stated: 300 mg/ Tablet

Determined: 293.92 mg/Tablet

Percentage: 97.97 % **(COMPLY)**

Limit: 95-105%

Disintegration Test:

Time: NMT 30 Minutes. **(COMPLY)**

Result: The above sample is **Substandard** on the basis of test performed

iii. Storekeeper, Medicine Store of Choudhary Pervaiz Elahi Institute of Cardiology, Multan provided Invoice/Warranty No. 36354720 date 01-02-2022 issued by M/S Reckitt Benkiser Pakistan Ltd, F-18, S.I.T.E. Karachi as proof of its purchase.

iv. Warrantor Portion of subject drug sample was sent to M/S Reckitt Benckiser Pakistan Ltd, F-18, S.I.T.E. Karachi.

v. Copy of Test/ Analysis report was sent to M/S Reckitt Benckiser Pakistan Ltd, F-18, S.I.T.E.

Karachi, with direction to explain their position and provide 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 the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
DISPRIN (ACETYL SALICYLIC ACID 300mg) TABLET	1226	M/S RECKITT BENCKISER PAKISTAN LTD. F-18, S.I.T.E., KARACHI – PAKISTAN	0179-P/2022 dated: 16-08-2022	**Analysis with specifications applied: MS** **DESCRIPTION:** White, circular tablets having inscription "Disprin and sword motif embossed on both sides having rough surface and broken edges packed in aluminum blister packing. **(Does not comply with manufacturer specifications which states that "White to off white circular, flat tablets with beveled edge. DISPRIN and sword motif embossed on both faces")** **WEIGHT VARIATION:** **Determined:** None of the tablet deviated from the 5% limit. **Limit:** Not more than 2 of the individual weight deviates from the average weight by more than 5% and none by more than 10%. (Complies with Manufacturer's specifications) **Result:** The sample is of **Substandard** quality on the basis of tests performed.

viii. Copy of NIH report was sent to M/S Reckitt Benckiser Pakistan Ltd, F-18, S.I.T.E. Karachi.

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(as amended)/DRAP Act 2012 and Rules framed there under by the way of: -

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

   b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 28-11-2023.

Reply to Show Cause Notice:

This is with reference to your letter No. PQCB/R-296/2022 dated 28-11-2023, received on 11-12-2023, regarding the alleged declaration of the sample of drug TABLET DISPRIN 300mg Batch No. 1226 as substandard vide NIH Test Report No.0179-P/2022 dated 16-08-2022, withdrawn from the medicine store of Chaudhry Pervaiz Elahi Institute of Cardiology, Multan by the Provincial Inspector of Drugs, Sher Shah Town, District Multan.

That this is in continuation to our following correspondence, recording our reservations on the illegalities in the procedure for

sampling and testing of our product, highlighting discrepancies in the DTL Report, contesting for retest of the drug sample from NIH, and recording our observations in the NIH Test Report as being incoherent with the result adduced:

I. Letter No. QM-023/2022 dated 11-04-2022 in response to Letter No. 321/DC/SST dated 09-03-2022 issued by Drug Controller, Sher Shah Town, District Multan.

II. Letter No. QM-026/2022 dated 25-04-2022 in response to Letter No. 341/DC/SST dated 12-04-2022, issued by Drug Controller, Sher Shah Town, District Multan.

III. Letter No. QM-027/2022 dated 18-05-2022 submitted to your good office, in response to your Letter No. PQCB/P-288-3/2022 dated 25-04-2022, challenging the test results of DTL Multan Report TRA 01-94001938 dated 05-03 2022, and requesting for re-testing of the sample by NIH, in accordance with the right vested by s. 22 of the Drugs Act 1976.

IV. Letter No. QM-052/2022 dated 28-11-2022, in response to Letter No. 672/DC/SST dated 19-11-2022 issued by the Drug Controller, Sher Shah Town, District Multan, highlighting the discrepancies in the NIH Test Report No.0179-P/2022 dated 16-08-2022, with copy to your good office.

V. Letter No. QM-051/2022 dated 28-11-2022, notifying the discrepancies in the NIH Test Report No.0179-P/2022 dated 16-08-2022, with copy to your good office.

That we again present our concerns in this letter over the legality of procedure so followed and the ultimate NIH Test Report finding that wrongly declares our product as of "Sub-standard" quality:

1. That initially, we did not receive any sealed/ marked warrantor's/ manufacturer's portion of the withdrawn sample, as required under s. 19 (3) of the Drugs Act, 1976 after the withdrawal of the sample from the stated premises on 03-02-2022. That the warrantor portion was received after a period of around 77 days, on 14-04-2022 along with the Letter No. 341/DC/SST dated 12-04-2022, from the office of Drug Controller Multan, that constitutes blatant violation of law.

2. That being a GMP compliant and quality conscious manufacturer, it is our company policy and practice to release finish drug product stocks for sale/ distribution, after achieving satisfactory confirmation of their quality being as per the DRAP approved and prescribed specifications, testing parameters and standards. That Tablet Disprin 300mg Batch No. 1226 was manufactured and release for sale after conducting necessary test/ analysis, and achieving satisfactory results, as per prescribed specifications, testing parameters and standards. That we duly performed complete test/analysis on the retention sample of the same batch available with us on receipt of the first intimation vide Letter dated 09-03-2022, and found it to be of satisfactory quality and compliance as per the prescribed specifications, testing parameters and standards.

Certificate of Analysis of the retention sample tested dated 07/04/22 and Certificate of Analysis of the finish product at the time of batch release dated 11/12/2021 is attached.

3. That it must be highlighted that the DTL Multan Test Report declared the product sample as substandard on the basis of OOS weight variation and "broken edges" of the tablet instead of "beveled edge", whereas the NIH Test Report has found the weight variation to be within compliance limit, however, the only non-compliance observed is "rough and broken edges" of the tablet.

4. That it shall be taken into account that the subject drug Tablet Disprin 300mg is an uncoated tablet formulated by Direct Compression, which is soluble in water. Such that the core tablet does not contain any film coating that would keep the tablet edges perfectly smooth, thereby declaring the drug sample of a water-soluble core tablet as sub-standard on basis of rough or broken edges is irrational.

5. That it should also be put to record that the stated sample was withdrawn on 03-02-2022 but not tested till 05-03-2022 by DTL Multan and on 16-08-2022 by NIH, such that we do not know the condition in which the sample was kept during the respective time periods. That uncontrolled storage conditions may impact the integrity of the sample and compromise the test results.

6. That the NIH report that shall be held as conclusive test result has only found non-compliance in the physical appearance of the tablet, and that too being a core tablet is justifiable. That the COA of the finish product when released and the retention sample of the same batch shows the tablet dosage form to be in full compliance with all the physical and chemical specifications, which further supports the argument that the withdrawn sample had been subjected to unsatisfactory transportation and storage condition resulting in damage to the tablet edges.

The firm provided the names of their technical staff.

4. Personal Hearing notice(s) issued to accused person(s) dated 22-01-2024.

PREVIUOUS PROCEEDINGS BY THE BOARD:

PQCB's 275th special Meeting held on 31-01-2024

5. Case was considered by Provincial Quality Control Board under Section 11 of The Drugs Act, 1976 in its **275th Special meeting** dated **31-01-2024** under the Chairmanship of Special Secretary (Operations) Primary & Secondary Healthcare Department, Punjab.Ms. Iram Kokab Secretary DQCB Multan was present online via zoom link. No-one appeared before the Board on behalf of M/S Reckitt Benckiser Pakistan Ltd, F-18, S.I.T.E. Karachi. Secretary PQCB has apprised the Board that the firm has submitted written request for adjournment vide ref number QM-018/2024 dated 30-01-2024. The Board after due deliberation and discussion unanimously decided to adjourn the case on request of the firm. The Board further decided to provide another/final opportunity of personal hearing to the accused.

Personal Hearing notice(s) issued to accused person(s) dated 20-02-2024

Case is placed before the board for decision

Summary of the case:

- **Mfg. date:12-2021**
- **Exp. Date: 11-2024**
- **Sampling date (Form 4): 03-02-2022**
- **Sent to DTL (Form 6): 03-02-2022**
- **Date of receipt in DTL: 04-02-2022**
- **DTL Report Date (Form 7): 05-03-2022**
- **DI 1st intimation to firm: 09-03-2022**
- **Retesting request if any: Yes, allowed in 245th meeting, dated: 16-06-2022**
- **Fate of Retesting Request: NIH Substandard**
- **Investigation report Dated: 05-07-2023**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 38

PQCB/R-105/2022

Children Hospital, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore-Pakistan** through its Managing Director, Muhammad Ali 2. Muhammad Ali Managing Director 3. Khair-un-Nisa Production Incharge 4. Tajammal Hussain Quality Control Incharge/ Warrantor of M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore- Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Children Hospital, District Faisalabad reported that: -

i. She, on 05-03-2022, inspected the premises of Central Pharmacy of Children Hospital, District Faisalabad, took following drug sample on Form No. 04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Faisalabad vide memorandum no. 120574 dated 05-03-2022.
ii. The subject 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**	**DTL Test Report Result**
Gauze. Surge Gauzes [Sterile Surge gauze swab/ sponges BP 10cm X 10cm X 8PLY] **Mfg Date** Feb 2022 **Expiry Date**	GS0322	M/s Surgitex Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore-Pakistan.	01-68014351/DTL dated 07-05-2022	**Results of test/Analysis with specifications applied:** BPC 1973 **DESCRIPTION:** Coton cloth of plain weave, bleached to a good white, clean, and reasonably free from weaving defects, cotton leaf and shell folded into a square pad and it was odorless. **THREADS PER STATED LENGTH** **Warps:** **Stated:** 69-77 per 10cm {73 per 10cm standard deviation 1.33} (BPC 1973) **Determined:** 73.33 per 10cm (Complies) **Wefts:** **Stated:** 53-61 per 10cm {57 per 10cm standard deviation 1.33} (BPC 1973)

Jan 2025 **Regn No.** 030772				**Determined:** 57.58 per 10cm (Complies) **<u>WEIGHT PER UNIT AREA:</u>** Stated: Average 15gm/m^2 {Standard Deviation 0.33} (BPC 1973) Determined: 15.8537 g/ m^2 (Complies) **<u>FLUORESCENCE:</u>** Stated: Not more than a few isolated fibers show intense blue fluorescence when examined under UV 365nm (BPC 1973) Determined: No intense blue color, slight brownish violet fluorescence (Complies) **<u>ABSORBENCY:</u>** **<u>Sinking Time:</u>** Limit: NMT 10 seconds at 20-25C (BPC 1973) Determined: Average of 3 tests=2.33 seconds (Complies) **<u>ACIDITY/ALKALINITY:</u>** Stated: Should be Neutral in reaction with phenolphthalein solution and methyl orange solution. **Determined: Alkaline as it gives pink color with phenolphthalein (Does Not Comply)** **<u>RESULT:</u> Given sample is Sub-Standard with regards to Alkalinity test.**

iii. The Medical Superintendent of Children Hospital, District Faisalabad provided Invoice/Warranty No. 45/21-22 dated 15-02-2022 issued by M/s Irshad Ul Haq Enterprises 1st Floor, 16 Chenab Market Susan Road Madina Town Faisalabad as a proof of its purchase.
iv. Warrantor portion of drug sample was sent to M/s Irshad Ul Haq Enterprises 1st Floor, 16 Chenab Market Susan Road Madina Town Faisalabad who in-turn, provided Invoice/ Warranty bearing No. 1502-2022 dated 15-02-2022 issued by M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore- Pakistan.
v. A copy of test/analysis report was sent to M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore- Pakistan with directions to provide the requisite information and to explain their position in this regard

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

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

(Medical Devices)

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 05-06-2023

Firm replied to the show cause notice vide letter no. RR/1206/23 dated 12-06-2023 and submitted copies of documents including DML & Registration Certificate of product

4. Personal hearing notice(s) issued to accused person(s) dated 22-01-2024

Previous Proceedings & Decision by The Board:

275th Special meeting held on 31-01-2024

5. Case was placed in PQCB **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Ms. Rubina Akhtar Secretary DQCB Faisalabad was present along-with original case record. Among nominated accused_Tajammal Hussain (Quality Control Incharge/ Warrantor) of M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore- Pakistan was present. Case was **left-over** due to time constraints

6. Personal hearing notice(s) issued to accused person(s) dated 20-02-2024

7. Case is placed before the Board for decision.

Summary:

Manufacturing Date: Feb-2022

Expiry Date: Jan-2025

Sampling Date (Form 4): 05-03-2022

Sent to DTL (Form 6): 05-03-2022

Date of receipt in DTL: 10-03-2022

DTL Report Date (Form 7): 07-05-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 28-07-2022

Retesting Request of Firm: No

Investigation Report Dated: 12-04-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 39

PQCB/R-401/2022

The Children's Hospital, Lahore

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area Karachi-74900., Pakistan,** through its MD/CEO, Javed Ghulam Muhammad 2. Javed Ghulam Muhammad MD/CEO 3. Muhammad Shahzad Production Incharge 4. Mehmood Ahmed Quality Control Incharge 5. Amjad Pervez QA Incharge/Warrantor of **M/S Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area Karachi-74900., Pakistan.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, The Children's Hospital & The University of Child Health Sciences, Lahore reported that: -

i. He, on 24-06-2022, inspected the premises of Main Medicine Store, Central Pharmacy, Children's Hospital and The Institute of Child Health, Lahore and took 05 different types of drug samples on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Lahore.
ii. Following drug sample, sent vide memo no. 131197 dated 24-06-2022, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing laboratory **Lahore** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Tablet Musidin (Tizanidine HCl (USP) eq to Tizanidine 2mg/tab) **Mfg. date: 02-2022** **Exp. date: 01-2025** **Reg# 027218**	P07765	M/S Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area Karachi-74900., Pakistan.	TRA. 01-177001648/DTL Date: 01-09-2022
Specification applied: USP 2021 **PHYSICAL CHARACTERISTICS**:			

White Colored Round Tablet Engraved "M" And "D" Along with Line of Bisection on One Side and Other Side Plain in Blister Pack Of 10 Units.

IDENTIFICATION: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (TIZANIDINE IDENTIFIED).

ASSAY OF TIZANIDINE:

Stated: 2 mg/tab

Determined: 2.03mg/tab

Percentage: 101.65%

Limit: 90.0% - 110.0% of the labeled amount of tizanidine.

DISSOLUTION TEST:

Tolerance 80% (Q) OF THE LABELED AMOUNT OF TIZANIDINE (C9 H8 CIN5 S) IS DISSOLVED. **Does not comply with the USP Specifications**

For S1: Each unit is not less than Q + 5%.

For S2: Average of 12 units (S1 + S2) is equal to or greater than Q, and no unit is less than Q – 15%.

For S3: Average of 24 units (S1 + S2 + S3) is equal to or greater than Q, not more than 2 units are less than Q – 15%, and no unit is less than Q – 25%.

Level	Number	Acceptance Criteria						Average (%)	Remarks
S1	6	Each individual unit should NLT Q + 5% (80%)							**Does not Comply**
		UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6		
Determined (%)		70.85	68.96	78.22	67.96	65.39	**57.59**		
S2	6	Average of 12 units (S1+S2) is ≥Q & no unit is ¿Q-15%.						**S1 +S2 = 68.44**	**Does not Comply**
		UNIT 7	UNIT 8	UNIT 9	UNIT 10	UNIT 11	UNIT 12		
Determined (%)		97.70	**55.68**	77.92	**60.56**	**54.80**	65.59		

Tolerance: The sample fails to comply the release limit at S2 stage, as average of 12 units is less than Q (80%), and 04 out of 12 units are below Q-15% i.e. (65%). And 01 out of 12 units is below Q-25% i.e. (55)

RESULT: The above sample is **SUB-STANDARD**, on the basis of **DISSOLUTION TEST** performed as per USP Test-1.

iii. The Medical Director, Children's Hospital, Lahore, provided warranty/delivery challan No.

8182204181 dated 31-05-2022 issued by M/S Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area Karachi-74900., Pakistan, as a proof of purchase.

iv. Warrantor Portion was sent to M/S Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area Karachi-74900., Pakistan.

v. Copy of test/analysis report was sent to M/S Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area Karachi-74900., Pakistan, with directions to explain their position and provision of 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. The retesting request was placed in PQCB's 254th meeting. The Board after due deliberation unanimously decided to **Turn Down** the subject request for retesting of the sample on the basis of **time barred** Under Section 22 (4) of the Drugs Act, 1976 (as amended).

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(as amended)/DRAP Act 2012 and Rules framed there under by the way of: -

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

b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 16-10-2023.

Reply to Show Cause Notice:

With reference to your letter no. PQCB/R-401/2022 dated 16.10.2023 received at Martin Dow Limited ("Company") on 31.10.2023 based on the drug testing laboratory, Lahore's ("DTL") report no. TRA 01-177001648/DTL dated 01.09.2022 ("Testing Analysis Report") on our product "Musidin 2mg Tablets" batch No. P07765 ("Subject Drug") alleging that the Subject Drug is substandard as defined in the Drugs Act 1976 and show cause as why action should not be taken against the Company ("Show Cause Notice").

We thank you for offering us a chance to clarify the issue and submit this response as follows:

1. It is humbly submitted that the facts as put forward to the Board are not factually accurate/ complete. The correct rendition is given below:

i. That on the receipt of the Testing Analysis Report the Company was made aware that the Subject Drug was tested against USP Dissolution Test 1. Where after the Company duly informed the respected Inspector, the Subject Drug is in compliance with USP Dissolution Test 2 and duly submitted documents to offer an explanation for the same.

ii. That the Subject Drug explicitly states that the manufacturing specifications are in compliance with USP and it is understood that a drug needs to comply with any of the tests provided under the USP. The batch of the Subject Drug was manufactured in February 2022 and was in compliance with regulations as required by DRAP at the time.

iii. It is pertinent to note that the warrantor portion of the Subject Drug was not handed over to the Company. Consequently, the process as required by the Punjab Drug Rules 2007 was not followed. This point was raised in our earlier response as well, especially in writing through our response bearing reference number RA/MAR/2022/11/1643. Through the erstwhile response the Company also appraised the Board that the Inspector in contravention of the applicable laws, rules and regulations did not provide the Company with the warrantor's sample of the Subject Drug. Subsequent to which, the Company requested the Provincial Quality Control Board to re-test the Subject Drug against USP Dissolution Test 2.

The above factual situation shows that the Subject Drug was not substandard; as to be categorized as substandard it must not be in compliance with any of the Dissolution Tests for the Subject Drug provided in the USP. The DTL by not testing against Dissolution Test 2 has erred in its function and without testing the Subject Drug against

Dissolution Test 2, it cannot categorize the Subject Drug as substandard as that will be a patently false statement and abuse of procedure. By allowing the DTL's findings to stand will mean that all products which do not comply with their respective Dissolution Test 1s are substandard, even if they comply with Dissolution Test 2.

2. Consequently, where our request for retesting has been turned down by the august Board, the ends of justice will be best served by allowing the retesting of the relevant batch of the Subject Drug either by the NIH or the DTL against Dissolution Test 2. As otherwise a drug not being substandard will be held to be so which shall be an abuse of the substantive laws provided in the drug regime and the rights afforded to the Company.

3. It is also clear that no speaking order as to how the Subject Drug is substandard has been issued at any time, especially given where the DTL test analysis clearly did not bench mark the Subject Drug against Dissolution Test 2.

4. The Company having patient safety and health at the forefront of its business remains cognizant of its responsibilities and ensures that all quality requirements are maintained. To substantiate our position, the Company has duly submitted all required and supporting documents previously to justify our compliance with USP as per Dissolution Test 2.

5. The Company has duly complied with all requirements put forth by the Provincial Quality Control Board and has previously submitted all relevant documents for your review. However, for purposes of ease and compliance, we respectfully submit the documents.

6. In the light of above-mentioned situation, the Subject drug cannot be considered as substandard drug due to fact that it is in compliance with Dissolution Test 2 of USP and DTL did not test the relevant batch of the Subject Drug against its applicable test.

The above patently provides cause as why no adverse action should be taken against the Company.

This letter is without prejudice to any of the rights and remedies available to the Company under law and/or any arguments put forward in any litigation(s).

4. Personal Hearing notice(s) issued to accused person(s) dated 22-01-2024.

PREVIUOUS PROCEEDINGS BY THE BOARD:

PQCB's 275th special Meeting held on 31-01-2024

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th Special meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (Operations)/Vice chairperson, PQCB. Mr. Hassan Saeed Secretary DQCB District Lahore and Mr. Faraz Ashraf Drug Inspector Children's Hospital, Lahore was present. No-one was present on behalf of M/S Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area Karachi-74900., Pakistan. M/S Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area Karachi-74900., Pakistan submitted written request for adjournment vide ref no. RA/MAR/2024/01/422 dated 31-01-2024.
6. Cases were left-over due to time constraint.

Personal Hearing notice(s) issued to accused person(s) dated 20-02-2024

Case is placed before the board for decision

Summary of the case:

- **Mfg. date:02-2022**
- **Exp. Date: 01-2025**
- **Sampling date (Form 4): 24-06-2022**

- **Sent to DTL (Form 6): 24-06-2022**
- **Date of receipt in DTL: 27-06-2022**
- **DTL Report Date (Form 7): 01-09-2022**
- **DI 1st intimation to firm: 13-09-2022**
- **Retesting request if any: Yes, turned down in 254th meeting, dated: 13-12-2022**
- **Investigation report Dated: 21-02-2023**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 40

PQCB/R-565/2022

Mayo Hospital, Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s MTI Medical Pvt Ltd., 586-587, Sundar Industrial Estate, Lahore,** through its CEO, Muhammad Ajmal Iqbal 2. Muhammad Ajmal Iqbal — CEO 3. Muhammad Adrees Khan — Production Incharge/Manager 4. Komal Shamshad — QA Incharge/Manager 5. Muhammad Amir Razzaq — QC Incharge/Manager 6. Muhammad Raza Shafaat — Warrantor of **M/s MTI Medical Pvt Ltd., 586-587, Sundar Industrial Estate, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Mayo Hospital, Lahore reported that: -

i. He, on 26-08-2022, inspected the business premises of Main Medicine Store (S-1), Mayo Hospital, Lahore and took 02 different types of drug samples on Form No.04 and sent to Drug Testing Laboratory Lahore for the purpose of test/analysis.
ii. The subject drug sample, sent vide memorandum no. 138128 dated 26-08-2022, after test/analysis was declared as **Substandard and Misbranded** by Government Analyst Drug Testing Laboratory Lahore as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report TRA No. & Date**
Capsule Tosson [Tamsulosin HCl SR Pellets eq. to Tamsulosin Hcl…0.4mg/Cap] **Mfg. date: 04-2022** **Exp. date: 04-2024** **Reg # 081854**	487	M/s MTI Medical Pvt Ltd., 586-587, Sundar Industrial Estate, Lahore.	01-177002606/DTL, date: 17-11-2022
Specification applied: BP 2022 **DESCRIPTION**: White colored pellets enclosed in hard gelatin capsule shells having blue colored cap and transparent body pcked in blister packing of 10 units. **IDENTIFICATION:** The retention time of major peak in sample chromatogram corresponds to the retention time of the major peak in			

standard chromatogram (Tamsulosin HCl Identified).

ASSAY BY UNIFORMITY OF CONTENT OF TAMSULOSIN HCl:

Stated: **0.4mg/Capsule**

Determined: **0.288mg/capsule**

Percentage: **72.10%**

Limit: **95.0-105.0% of the stated amount**

(Does Not Comply)

	Unit 1	**Unit 2**	**Unit 3**	**Unit 4**	**Unit 5**	**Unit 6**	**Unit 7**	**Unit 8**	**Unit 9**	**Unit 10**	**Average**
Assay	67.13%	71.93%	78.94%	70.86%	72.14%	69.24%	68.09%	79.85%	77.39%	65.39%	72.10%

The sample fails to comply the content uniformity test, as none of the 10 units is complying the limit.

LABELLING:

In the composition part of the outer carton, it is stated "Each capsule contains: Tamsulosin HCl SR pellets equivalent to tamsulosin…0.4mg, however, on the front part of the outer carton laser printed: "Composition Tamsulosin SR pellets eq. to Tamsulosin HCl…0.4mg" is written.

RESULT: The above sample is **Sub-Standard**, on the basis of the **Assay by Uniformity of Content as per BP** and **Misbranded as per the Drugs Act, 1976, 3(s)(iv).**

iii. He also seized the stock of above mentioned product (Quantity=9920 Capsules=992Packs) on Form 3.
iv. Store Keeper, Main Medicine Store (S-1), Mayo Hospital, Lahore provided warranted Delivery Challan no. TSR-2140 dated 29-07-2022 issued by M/s MTI Medical Pvt Ltd., 586-587, Sundar Industrial Estate, Lahore, as a proof of purchase.
v. Warrantor portion was sent to M/s MTI Medical Pvt Ltd., 586-587, Sundar Industrial Estate, Lahore.
vi. A copy of test/analysis report was sent M/s MTI Medical Pvt Ltd., 586-587, Sundar Industrial Estate, Lahore to explain their position and provide requisite information in this regard.

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 and Rules framed there under by the way of :-

a. **Manufacture for sale/ Sale of Substandard and Misbranded Drug**
b. **Issuance of false warranty**

3. Showcause/personal hearing notice(s) issued to accused person(s)

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

With reference to Letter No. PQCB/R-565/2022 Dated Lahore the 08-01-2024, our product Tosson SR 0.4mg Capsule (Tamsulosin) was declared sub-standard and misbranded by

DTL Lahore. As manufacturers we, MTI Medical (Pvt.) Ltd. and our Pharmacovigilance Officers have taken the matter very seriously and professionally handled this product failure by recalling the complete batch and the Batch Recall Advertisement has been attached. (Annexure 1). We have replaced the already supplied stock of Tosson Capsules 0.4mg with the fresh stock of the same product batch no. 627. The replaced stock of Tosson 0.4mg SR Capsule Batch No. 627 has been declared of standard quality by the Drug Testing Laboratory Lahore. DTL Report has been attached along with this letter. (Annexure 2) Furthermore, it is to inform you that we have shifted the specifications of Tosson 0.4mg SR Capsule from BP Specifications to USP Specifications. We have already informed Drug Regulatory Authority of Pakistan about change in specifications. The label claim has been revised as per USP Specifications for Tosson 0.4mg SR Capsule. (Annexure 3) PSI of our firm has already been conducted on 25-10-2023 and we request you to kindly consider this case under the already conducted PSI. We will be thankful for your co-operation in this regard.

PREVIOUS PROCEEDING AND DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th Special meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (Operations)/Vice chairperson, PQCB. Mr. Hassan Saeed Secretary DQCB, Lahore and M. Altaf Drug Inspector Mayo Hospital Lahore were present along with original case record. Among the nominated accused persons Komal Shamshad Quality Assurance Manager and Muhammad Amir Razzaq Quality Control Manager of **M/s MTI Medical Pvt Ltd**., 586-587, Sundar Industrial Estate, Lahore was present. Cases was left-over due to time constraints.

Personal Hearing notice(s) issued to accused person(s) dated 20-02-2024.

Summary:

Manufacturing Date: 04-2022

Expiry Date: 04-2024

Sampling date (Form-4): 26-08-2022

Date of receipt in DTL: 26-08-2022

DTL Report date: 17-11-2022

Date of Retesting Request of Firm: No.

Investigation Report dated: 24-08-2023

PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 41

PQCB/R-827/2021

(Allama Iqbal Town, Lahore)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Ethical Laboratories (Pvt.) Ltd., 14-Km Thokar Niaz Baig, Multan Road, Lahore, Pakistan** through its Chief Executive Officer, Abdul Waheed Sheikh. 2. Abdul Waheed Sheikh — Chief Executive Officer 3. Abdul Sattar — Production Manager 4. Fahad Jalil — Quality Control Manager **of M/S Ethical Laboratories (Pvt.) Ltd., 14-Km Thokar Niaz Baig, Multan Road, Lahore, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Allama Iqbal Town, Lahore reported that: -

i. The then Provincial Inspector of Drugs, on 11.02.2021, inspected the business premises of M/S Ethical Laboratories (Pvt.) Ltd., situated at 14-Km Thokar Niaz Baig, Multan Road, Lahore, Pakistan and took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 85262 dated 14.02.2021.
ii. Following Drug samples after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Lahore, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tablet AZM (Acetazolamide :250mg) **Mfg Date:** 01.2021 **Expiry Date:** 01.2026 **Regn No.** 019159	AZT223	M/s Ethical Laboratories (Pvt.) Ltd., 14-Km Thokar Niaz Baig, Multan Road, Lahore, Pakistan	01-73007691/ DTL dated: 16.04.2021	**Specifications applied: USP2020** **Physical Characteristics:** White colored, round, biconvex tablet, plain from one s EL engraved and scored from other side, packed in an ALU/PVC blister of 1 x 10's u **Identification:** Acetazolamide is identified. **Assay:** Complies **Dissolution: Does not comply with the USP Specifications as detailed below:** **Tolerance Limit:** NLT 75% (Q) of the labeled amount of acetazolamide after 60 minutes. **For S1:** Each unit is not less than Q+5%. **For S2:** Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15%.

For S3: Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than
units are less than Q-15%, and no unit is less than Q-25%.

Dissolution of Acetazolamide									
Level	**Number Tested**	**Acceptance Criteria**						**Average (%)**	**Rema**
S1	6	Each individual unit should NLT Q+5% (80%)						**52.73**	**Does com**
Determined (%)		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
		44.66	**37.44**	53.93	59.49	**46.52**	74.32		

RESULT: The above sample is Sub-Standard, on the basis of Dissolution performed as per USP.

iii. A copy of test/analysis report was sent to M/S Ethical Laboratories (Pvt.) Ltd., 14-Km Thokar Niaz Baig, Multan Road, Lahore, Pakistan and they were asked to provide the requisite information in this regard. In response, the firm challenged the test/analysis reports of the drug samples and requested to re-test the above-mentioned drug samples from Appellate Laboratory, National Institute of Health, Islamabad.

iv. Pursuant to the request of M/s Ethical Laboratories (Pvt.) Ltd., 14-Km Thokar Niaz Baig, Multan Road, Lahore, Pakistan the retesting request of the subject drug samples was considered in the 247th Meeting of the Board held on 21.07.2022 and the subject drug samples were sent to NIH, Islamabad, from where the samples was declared **Sub-standard** as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Test Report No.**	**NIH Test Report Result**
Tablet AZM (Acetazolamide :250mg)	AZT223	M/s Ethical Laboratories (Pvt.) Ltd., 14-Km Thokar Niaz Baig, Multan Road, Lahore, Pakistan	0208-P/ 2022 dated 03.11.2022	**Analysis with specifications applied:** USP-39 **Dissolution Test:** Determined: All the six tablets deviated from the limit. Limit: Not Less than 75% (Q) of the labeled amount of $C_4H_6N_4O_3S_2$ (Acetazolamide) is dissolved in 60 minutes. **Does not Comply with USP-39** **Remarks:** Percentage release of drug among all six units tested at first level is found less than 80% (Q+5%) of the stated amount of acetazolamide. Moreover drug release in two units is found less than Q-25% at S1 level. Therefore, Dissolution test is stopped at first stage.

				Result: The sample is of Sub-Standard quality on the basis of test performed.

vii. A copy of test/analysis report of NIH was sent to M/S Ethical Laboratories (Pvt.) Ltd., 14-Km Thokar Niaz Baig, Multan Road, Lahore, Pakistan by the Provincial Inspector of Drugs.

2. Drug Inspector requested for grant of permission for prosecution against the 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: -
   a. **Manufacturing/ Stocking for sale of Substandard drug**
3. Show-cause/Personal Hearing notice(s) issued to accused person(s).

Reply of Show-Cause Notice:

Please refer to your letter No. PQCB/R-827/2021 dated 29-11-2023_wherein M/s Ethical Laboratories (Private) Limited (the **"Company"**) has been directed to once again explain its stance vis-à-vis the allegations of manufacturing AZM tablets Batch No. AZT223 (the **"Product"**) which has been supposedly declared as "sub-standard" by Drug Testing Laboratory, Lahore vide Report No. TRA 01-73007691/DTL (the **"DTL Report"**) dated 28-04-2021 and Appellate Laboratory report No. 0208-P/2022 dated 03-11-2022 (the **"NIH Report"**).

At the very-out the contents of the Reports and the allegations leveled against the Company in the letter under reply are vehemently denied. The Company is one of the leading pharmaceutical companies of the Country and has carried out its business strictly in accordance with the prevailing law.

Accordingly, the stance of the Company vis-a-vis the Reports is as under:

The sample of the Product was allegedly declared as substandard by DTL on the basis of dissolution test vide the Report;

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Tablet AZM (Acetazolamide :250mg) **Mfg Date:** 01.2021 **Expiry Date:** 01.2026 **Regn No.** 019159	AZT223	M/s Ethical Laboratories (Pvt.) Ltd., 14-Km Thokar Niaz Baig, Multan Road, Lahore, Pakistan	01-73007691/ DTL dated: 16.04.2021	**Specifications applied: USP2020** **Physical Characteristics:** White colored, round, biconvex tablet, plain from one side, EL engraved and scored from other side, packed in an ALU/PVC blister of 1 x 10's units. **Identification:** Acetazolamide is identified. **Assay:** Complies **Dissolution: Does not comply with the USP Specifications as detailed below:** **Tolerance Limit:** NLT 75% (Q) of the labeled amount of acetazolamide after 60 minutes. **For S1:** Each unit is not less than Q+5%. **For S2:** Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15%.

For S3: Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 units are less than Q-15%, and no unit is less than Q-25%.

Dissolution of Acetazolamide									
Level	**Number Tested**	**Acceptance Criteria**						**Average (%)**	**Remarks**
S1	6	Each individual unit should NLT Q+5% (80%)						**52.73**	**Does not comply**
Determined (%)		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
		44.66	**37.44**	53.93	59.49	**46.52**	74.32		

RESULT: The above sample is Sub-Standard, on the basis of Dissolution Test performed as per USP.

Since, the Company was not guilty of an offense in contravention of the applicable law the same verified its batch manufacturing record to conclude that the Product was of standard quality. Q.C lab released the sample of compression start complying to U.S.P dissolution test specifications with following results. For the ease of reference, the internal tests of the Product at the compression stage, finished product and retained samples are mentioned below:

Dissolution of Acetazolamide Tablets (Initial Stage of Compression Results)									
Level	**Number Tested**	**Acceptance Criteria**						**Average (%)**	**Remarks**
S1	6	Each individual unit should NLT Q+5% (80%)						98.45%	Complies
Determined (%)		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
		85.52%	96.64%	98.86%	108.77%	97.65%	103.71%		

(See **annex-1** for testing method and **annex-2** for batch testing record and related documents.)

Further, Q.C lab released the sample of finished pack complying to U.S.P dissolution test specifications with following results;

Dissolution of Acetazolamide Tablets (Finished Pack Result)

Level	Number Tested	Acceptance Criteria						Average (%)	Remarks
S1	6	Each individual unit should NLT Q+5% (80%)						87.2%	Complies
Determined (%)		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
		91.37%	79.86%	88.47%	85.34%	91.37%	88.86%		

(See annex-1 for testing method and annex-3 for batch testing record and related documents.)

After receipt of the letter under reply along of the DTL Report, the Company's QC department again performed the dissolution test on the retained samples of the said batch and observed the following results:

Dissolution of Acetazolamide Tablets

Level	Number Tested	Acceptance Criteria						Average (%)	Remarks
S1	6	Each individual unit should NLT Q+5% (80%)						97.74%	Complies
Determined (%)		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
		81.5%	80.06%	86.5%	101.75%	93.78%	100.82%		

(See annex-4 for test report and related documents.)

In this context, it is stressed that for testing purposes, a secondary reference standard by Sigma Aldrich was used as per USP reference calibration standards. (See annex-5 for related documents). After employing the USP 2020 testing method, the Product was subjected to testing as per the approved SOPs and all three times (Testing of tablets, testing of finished pack and retained samples) the Product passed the dissolution test (See **annex-2** for our SOP for dissolution test of AZM 250mg Tablets, **annex-3 and 4** for testing results). The dissolution test apparatus being used by us has been qualified as per USP criteria and PQ test results complied with USP. (See **annex-6** for PQ report and related documents).

Furthermore the sample was allegedly declared sub-standard by the National appellate laboratory, NIH Islamabad vide report no. 208 - P / 2022 dated 3rd November 2022 saying;

DETAILS OF RESULT OF TEST OR ANALYSIS (NIH REPORT)

(With Protocols of the test applied)

Nomenclature: Tablet AZM 250 mg

Batch No: AZT223

Date of manufacture: 01-2021

Date of expiry: 01-2026

Manufacturer: M/s Ethical Laboratories Pvt Ltd 14 km Multan Road Lahore Pakistan

DISSOLUTION TEST:

Determined:

All the six tablets deviated from the limit.

Limit:

Not less than 75% (Q) of the labeled amount of C4H6N4O3S2 is dissolved in 60 minutes.

Does not comply with USP 39.

Remarks: percentage release of the drug among all six units tested at first level is found to be less than 80% (Q + 5%) of the stated amount of acetazolamide. Moreover, drug release in two units is found less than Q-25% at S1 level. Therefore, the dissolution test is stopped at the first stage. Conclusion: sample is of sub-standard quality on the basis of test performed.

Reference; united states pharmacopoeia - 39.

Protocol for dissolution;

Dissolution medium: 0.01N Hydrochloric acid; 900ml

Dissolution parameters:

Apparatus 1: basket

Temperature: 37 $\pm$0.5^{o}C

Speed: 100 rpm

Time: 60 minutes

Wavelength: 265nm

Tolerance:

Not less than 75 %(Q) of the labeled amount of C4H6N403S2 is dissolved in 60 minutes.

Procedure:

Place 900ml dissolution medium in each of six vessels of the apparatus**.**

As = 2.815

Tablet	**Au=absorbance of the sample solution**	**Calculation by formula = Au/As x 100**	**Percentage**

1	1.784	1.784/2.815 x 100	63.37%
2	1.547	1.547/.2.815 x 100	54.95%
3	1.328	1.328/2.815 x 100	47.17%
4	1.397	1.397/2.815 x 100	49.62%
5	1.590	1.590/2.815 x 100	56.48%
6	1.583	1.583/2.815 x 100	56.23%

All the six tablets deviated from the limit

(Copy of NIH report enclosed. See annex-8)

In reference to NIH report context, the company does not agree with the results as major contraventions from USP were evident from the report proving that government analyst performed the analysis in totally the wrong way and produced falsified results. Keeping in view, all errors are discussed as follows;

Grounds Regarding Flaws in NIH Report

1. Analyst did not use the standard formula for calculation of dissolution results, which is given in USP as mentioned here under:

Samples: Standard solution and Sample solution

Determine the percentage of the labeled amount of acetazolamide ($C_4H_6N_4O_3S_2$) dissolved:

$(A_U/A_S) \times C_S \times D \times (V/L) \times 100$

A_U = absorbance of the Sample solution

As = absorbance of the Standard solution

Cs = concentration of the Standard solution (mm)

D = dilution factor of the Sample solution, if needed

V = volume of Medium, 900 mL

L = label claim (mg/Table

Tolerances: NLT 75% (Q) of the labeled amount of acetazolamide ($C_4H_6N_4O_3S_2$) is dissolved

Uniformity of Dosage Unit (905): Meet the requirements

Contrarily, NIH analyst used this formula:

Result= Au / As x 100

Au = absorbance of the sample solution

As = absorbance of the standard solution

As = 2.815

Analyst did not take the dilution factor of standard and sample solutions under consideration and skipped it for both solutions.

2. Analyst made Standard dilution in the wrong way. As per USP Chapter <857> ULTRAVIOLET-VISIBLE SPECTROSCOPY ULTRAVIOLET-VISIBLE SPECTROSCOPY, the standard solution was to be made keeping concentration of 10ug / ml or 0.01mg / ml but analyst made 0.05mg / ml which is 5 times or 500% higher that USP recommended concentration. Concentrated solutions results in a seemingly saturated signal and inaccurate absorbance readings. Also at high concentrations, molecules can interact with each other, causing a shift in their electronic energy levels. This can shift the absorption spectrum from the UV range to the visible range, making it difficult to analyze the specific peaks of interest. (Inner filter effect).

3. The standard solution concentration mentioned in the NIH Report is 0.05mg / ml while the sample concentration is 0.055mg / ml in such, there is a difference of 10% between both values. In addition, the analyst rounded off the third decimal to hide the difference. This difference is huge. USP recommends using the same concentration of standard and sample solutions.

1- Place 900ml in each of six vessels of the apparatus

2. Equilibrate it at $37^{o}C \pm 0.5\ ^{o}C$

3. Place one tablet in each vessel immediately operate at 100 rpm for 60 minutes

4 Determined the amount of ($C_4H_6N_4O_3S_2$) dissolved by employing UV absorption at the wavelength of maximum absorbance at about 265nm on filtered portions of the solution under test suitably diluted with medium in comparison with a standard solution having a known concentration of acetazolamide RS in the same medium

Sample Dilution: 250/900 x 10/50 = 0.05mg / ml

Standard Dilution: 50/50 x 5/100 = 0.05mg / ml

Result= Au / As x 100

Au = absorbance of the sample solution

As = absorbance of the standard solution

As = 2.815

4. Government analyst mentioned 100 as the potency of acetazolamide reference standard. But the potency of reference standard provided to the appellate lab by the company (vide letter no. NIH-ISB-DCTMD-SMPL-1-05 dated 18 August 2022) was 99.65%. Analyst falsely assumed the potency of reference standard as 100%, which is totally incorrect and contributed to falsified results.

Working/Reference Standard

Acetazolamide

Lot #22AC00144 Storage: Room Temp/Protect from light

Mfg. Date: 07-2022 Exp. Date: 06-2027

Potency: 99.65% As is basis 99.82% on Dried basis

Manufacturer: CTX LIFE SCIENCES (INDIA)

5. USP monograph of acetazolamide tablets, if followed in true letter and spirit, describes that the solutions made as per USP monograph will produce UV absorbance of 0.2 to 0.8. But in NIH report, absorbance of standard solution is mentioned as 2.815 which is 351% higher than USP's upper limit of 0.8 A.Us Thus, results are not acceptable.

(see annex-7 for latest USP monograph of product Acetazolamide 250mg Tablets, annex-8 for NiH report indicating the said error and annex-9 for USP General Chapter <857>.)

Accordingly, it appears that the Reports and the observations contained therein result from an error on part of the Government Analyst and the notice under reply are liable to be withdrawn. Without prejudice to the foregoing, the information demanded vide the letter under reply is as under:

a. Copy of DML & Product Registration letter **(annex-10)**

b. Names of accused persons as per DML **(annex-11)**

c. Detail of recalled stock **(annex-12)**

d. Drug registration letter **(annex-13)**

e. CNICs of technical staff **(annex-14)**

f. JDs and appointment letters of technical persons **(annex-15)**

g. Official WhatsApp number and email for official correspondence **(annex-16)**

In view of the foregoing explanation, your good office is most respectfully requested to consign the matter pertaining to AZM tablets Batch No. AZT223 to record in the interest of justice.

Summary:

Manufacturing Date: 01.2021

Expiry Date: 01.2026

Sampling Date (Form 4): 11.02.2021

Sent to DTL (Form 6): 14.02.2021

Date of receipt in DTL: 18.02.2021

DTL Report Date (Form 7): 16.04.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 07.10.2021

Date of Retesting Request of Firm: 20.10.2021

Fate of Retesting Request: Substandard by NIH (Dissolution Test)

Investigation Report Dated: 03.07.2023

Personal Hearing Notice issued to accused person (s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 42

PQCB/R-868/2019

Data Gunj Baksh Town, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Don Valley Pharmaceuticals (Pvt) Ltd. 31 km, Main Ferozepur Road, Lahore-54400 Pakistan** through its Chief Executive Officer, Dr. Shela Javed Akram 2. Dr. Shela Javed Akram — Chief Executive Officer 3. Muhammad Yamin — Production Incharge/ Warrantor 4. Darakhshan Kamran — Quality Control Incharge of M/s Don Valley Pharmaceuticals (Pvt) Ltd. 31 km, Main Ferozepur Road, Lahore-54400 Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, office of the Chief Drugs Controller Punjab, Lahore reported that:

i. He, on 28-05-2019, inspected the premises of Governor House Medical Center Lahore, took different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide Memo. No. 40491 dated 30-05-2019.
ii. Following Drug samples after test/analysis was declared as **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report No. & Date	DTL Test Report Result
Powder for Reconstitution. CEFIDON [Cefixime (as trihydrate) …. 100mg/ 5ml] **Mfg Date:** Apr-2019 **Exp Date:** Apr-2021	7956	M/s Don Valley Pharmaceuticals (Pvt) Ltd. 31 km, Main Ferozepur Road, Lahore-54400 Pakistan	01-143000256/DTL Dated. 29-Aug-2019	**Result of test/analysis with specifications applied:** USP 2018 **PHYSICAL DESCRIPTION:** OFF-WHITE TO CREAM POWDER FOR SUSPENSION IN AMBER GLASS BOTTLE WITH A SEALED SCREW CAP AND STOPPER. **LABELING: IT IS OBSERVED THAT:** 1. **THE SUSPENSION PREPARATION METHOD PRINTED ON OUTER CARTON AS WELL AS ON LABEL OF IMMEDIATE CONTAINER OF PRODUCT, BOTH IN ENGLISH AND URDU ARE DIFFERENT.** 2. **PREPARATION METHOD IN**

Regn No. 084922				**ENGLISH DESCRIBES PREPARATION WITH CALIBRATED CUP OF 20ML WHICH IS NOT PRESENT IN PACK, ONLY DISPENSING SPOON OF 5ML IS PRESENT. (MISBRANDED)** **IDENTIFICATION**: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (CEFIXIME TRIHYDRATE identified) **ASSAY OF CEFIXIME:** Stated: 100 mg /5mL Determined: **80.98 mg / 5mL** Percentage: **81.0% (NOT COMPLIES)** Limit: 90.0%–120.0% **RESULT:** The above sample is **SUBSTANDARD,** on the basis of ASSAY OF CEFIXIME as per USP & **MISBRANDED,** as per THE DRUGS ACT, 1976 3 [s(iv)].

iii. The Medical Superintendent of Governor House Medical Center Lahore submitted Invoice/warranty No. ZT-2019-60019 dated 28-05-2019 issued by M/s Zahid Traders, House No. 61 Shah Shams Qari, Golf Road GOR-I Lahore as a proof of its purchase.

iv. Warrantor portion of subject drug sample along with a copy of test/ analysis report were sent to M/s Zahid Traders, House No. 61 Shah Shams Qari, Golf Road GOR-I Lahore who in-turn provided Invoice/warranty No. 1905-12992 dated 28-05-2019 issued by M/s Don Valley Pharmaceuticals (Pvt) Ltd. 31 km, Main Ferozepur Road, Lahore-54400 Pakistan as a proof of its purchase.

v. A copy of test/ analysis report of the subject drug sample was sent to M/s Don Valley Pharmaceuticals (Pvt) Ltd. 31 km, Main Ferozepur Road, Lahore-54400 Pakistan and they were asked to provide requisite information in this regard.

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

    a. **Manufacture for sale/ Sale of Substandard & Misbranded drug**

    b. **Issuance of false warranty**

3. Show-cause/ personal hearing notice(s) issued to accused person(s) dated 20-02-2024

4. Case is placed before the Board for decision.

Summary:

Manufacturing Date: April 2019

Expiry Date: April 2021

Sampling Date (Form 4): 28-05-2019

Sent to DTL (Form 6): 30-05-2019

Date of receipt in DTL: 30-05-2019

DTL Report Date (Form 7): 29-08-2019

Time Extension: Granted on 17-09-2019 (210-M)

1ST DI Communication with firm on dated: 25-10-2019

Retesting Request of Firm: No

Investigation Report Dated: 22-07-2020

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 43

PQCB/R-308/2021

(Gojra)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan** through its Chief Executive Officer, Dr. Shehla Javed Akram 2. Dr. Shehla Javed Akram — Chief Executive Officer 3. Muhammad Yamin — Production Incharge/ Warrantor 4. Tariq Mehmood — Quality Control Incharge of M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Gojra, District Toba Tek Singh reported that: -

i. He, on 13-01-2021, inspected the business premises of M/S Dawn Medical Store The Bazari No. 47 Chowk Anarkali Gojra, District Toba Tek Singh and took samples of three different type of drugs on Form No. 04 for the purpose of test and analysis and sent them to Drug Testing Laboratory, Faisalabad.
ii. One out of these three drug samples, 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**	**DTL Test Report Results**
Suspension. Cefidon [Each reconstituted 5ml contains: Cefixime USP……100mg (as Cefixime Trihydrate)]	9577	M/S Don Valley Pharmaceuticals (Pvt) Limited, 31km, Main Ferozepur Road, Lahore-Pakistan	TRA No.01-68006937/DTL Dated: -15-03-2021	**Analysis with specifications applied: USP 2020.** **Description:** Off white granular powder gives fruity smell after reconstitution, contains in amber colored glass bottle sealed with aluminum screw cap, packed in outer hard carton along with spoon and measuring cup. **Identification:** Cefixime (trihydrate) identified. **Assay:** Stated: 100mg Cefixime/5ml

Determined	**80.15mg cefixime/5ml**
Percentage	**80.15%**
Limit	90-120% (USP-2020)

Does not comply.

PH:

Stated	2.5-4.5 (USP 2020)
Determined	3.44 (Complies)

Result: Given sample is **Substandard** with regards to Assay.

iii. M/S Dawn Medical Store The Bazari No. 47 Chowk Anarkali Gojra, District Toba Tek Singh provided invoice/ Warranty No. 50, Dated. 01-01-2021 issued by M/S Talha Medicine Company Toba Tek Singh who inturn provided invoice/warranty No. 2003-15277, Dated. 13-03-2020 issued by M/S Don Valley Pharmaceuticals (Pvt) Limited, 31km, Main Ferozepur Road, Lahore-Pakistan as a proof of its purchase.

iv. Warrantor portion and copy of test report was sent to M/S Talha Medicine Company Toba Tek Singh and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Don Valley Pharmaceuticals (Pvt) Limited, 31km, Main Ferozepur Road, Lahore-Pakistan and they were asked to provide the requisite information in this regard. In response the firm challenged the Drug Testing Laboratory Report Faisalabad. Provincial Quality Control Board placed the request of retesting in its 19th Meeting held on 21-10-2021 in which the Board decided to turn down the subject request of Retesting.

vi. The firm submitted Review Petition which was referred back on 24.03.2022.

vii. On the directions of Honorable Lahore High Court Lahore the PQCB heard the Review Petition and uphold the previous decision taken in 19th Committee meeting held on 21.10.2021.

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 notice(s) issued to accused person(s).

REPLY OF SHOW CAUSE NOTICE BY FIRM:

With reference to your letter no: PQCB/R-308/2021, dated 7 ^ 0 March, 2022 we M/S Don Valley Pharmaceuticals (Pvt.) Ltd wants to bring this into your kind consideration that our product Cefidon Suspension having batch no: 9577 got substandard by DTL report no: IRA No.01-68006937/DTL, dated: 15 ^ alpha March 2021 by the Drug Testing Laboratory Punjab. In pursuance of the above said report we want to explain our position.

1. In reference to your above-mentioned letter we would like to submit as under:

i. It is clarified that the Assay of our Product has been calculated at 94.75% which is within the prescribed limits of 90% to 120%. Moreover, maybe there is difference in the criteria which are used by the Government Analyst of the Drug Testing Laboratory Punjab for the evaluation of assay of our product OR the sample taken by drug inspector was not stored at said conditions of temperature and moisture as mentioned on box.

In order to prove our stance, we are enclosing herewith the following documents for your kind reference:

- Bulk, in-process and finished reports at the time of batch release

ii. Further, we have checked retained samples of our Product and have found them within limits in all aspects according to the prescribed pharmacopeia.

Copy of the test conducted by the company on its retained samples is enclosed herewith as a reference.

2. We have made the retesting request by our letter no CEFIDON/DV/024-2021, dated 4 ^ a May. 2021 which was turn down by PQCB order No. PQCB/P-288-03/2021, dated 21- 10 2021 against which review petition was also filed which is pending adjudication before this Honorable Board.
3. In view of the foregoing, it is submitted that the product complies with the requisite specifications and is of standard quality hence any the titled show cause notice and any consequent proceedings may kindly be withdrawn in the interest of justice. We will be highly oblige to you in this regard.

Summary:

Manufacturing Date: 03.2020

Expiry Date: 03.2022

Sampling Date (Form 4): 13.01.2021

Sent to DTL (Form 6): 15.01.2021

Date of receipt in DTL: 15.01.2021

DTL Report Date (Form 7): 15.03.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 14.04.2021

Date of Retesting Request of Firm: 30.04.2021

Fate of Retesting Request: Turn Down in 19th Committee Meeting dated 21.10.2021 (Time Barred). The firm submitted Review Petition which was referred back on 24.03.2022. On the directions of Honorable Lahore High Court Lahore the PQCB heard the Review

Petition and uphold the previous decision taken in 19th Committee meeting held on 21.10.2021.

Investigation Report Dated: 18.05.2021

4. Personal hearing notice(s) issued to the accused persons(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 44

No. PQCB/ R-547/2021

Tehsil Pindi Gheb, District Attock

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore,** through its Chief Executive Officer, Dr. Shehla Javed Akram. 2. Dr. Shehla Javed Akram Chief Executive Officer. 3. Muhammad Yamin Production In-Charge/Warrantor. 4. Tariq Mehmood Quality Control In-Charge Of **M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Pind Dadan Khan, District Jhelum reported that:-

i. He, on 23.10.2021, inspected the premises of M/S Fazal-e-Noor Medical Store, Near Nadra Office, Pind Dadan Khan and took sample of Capsule Opicap 20mg, Batch no. EH-21-016 vide on Form 4 for the purpose of test/analysis.
ii. The sample was forwarded to Drug Testing Laboratory Rawalpindi vide Memo number 00000109585 dated 24-10-2021 for test/analysis.
iii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Rawalpindi as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Capsule Opicap [Omeprazole (as enteric coated Pellets0: 20mg] **Mfg. Date**: 06-2021 **Exp. Date**: 06-2023	EH-21-016	M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore	01-74003025/ DTL dated: 24 Dec 2021	**Result of test/ analysis with specifications applied:** USP 2021 **PHYSICAL DESCRIPTION:** White to off-white-coloured pellets, filled in hard gelatin capsule shells of opaque yellow coloured cap and transparent light yellow coloured body, packed in ALU/ALU blister of 1*7's, further packed in labelled outer carton containing

Reg # 028001				2 blisters (14 capsules). **IDENTIFICATION:** Omeprazole identified. **ASSAY:** Stated: 20mg/capsule Determined: 10.258 mg/capsule Percentage 51.29% **(DOES NOT COMPLY)** Limit: 90-110% **RESULT:** **The above sample is SUB-STANDARD with respect to Assay test performed.**

iv. The proprietor of M/S Fazal-e-Noor Medical Store, near Nadra Office, Pind Dadan provided Invoice No. 185353 dated 13-08-2021 issued and signed by M/S Tariq Pharmacy, Muhammadia Chowk, Jhelum.

v. The Warrantor portion was sent to M/S Tariq Pharmacy, Muhammadia Chowk, Jhelum vide letter No. 02DI/PDK dated 04-01-2022. He was also asked to provide the requisite information.

vi. M/S Tariq Pharmacy, Muhammadia Chowk, Jhelum, provided Invoice/Warranty no.2108-19304 dated 06-08-2021 issued and signed by M/S Don Valley Pharmaceuticals Pvt. Ltd., Main Ferozepur Road, Lahore.

vii. M/S Don Valley Pharmaceuticals was asked to verify that Invoice Number 2108-19304 dated 06-08-2021 and the authority letter issued to M/S Tariq Pharmacy, Muhammadia Chowk, Jhelum and to explain their position.

viii. In response to the Regd. Official Letter No. 05Di/PDK dated 15-01-2022, the Firm replied vide Ref: No. OPICAP/DV/0165-2022 dated 21-01-2022, explained their position and challenged the DTL Report TRA No. 01-74003025/DTL dated 24-12-2021 and requested for Re-testing of sample from Appellate Laboratory at National Institute of Health, Islamabad. The Firm also provided the names of their Chief Executive Officer, Production In-charge and Quality Control In-charge

ix. The Re-testing request of the Firm was forwarded to Secretary, Provincial quality Control Board, Lahore vide Regd. Letter No. 13DI/PDK dated 25-01-2022.

x. Pursuant to the request of M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore, the retesting request of the subject drug sample was considered in the 244th meeting by the Board held on 31-05-2022, retesting request was **allowed** by the Board and the subject drug sample was sent to National Institute of Health, Islamabad, from where the sample was declared as **Sub-standard** as detailed below:

Name of drug	**Batch no.**	**Name of manufacturer**	**NIH Test Report**	**NIH Test Report Results**

			No. & Date	
Capsule Opicap (Omeprazole) 20mg	EH-21-016	M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore	No. 0156-P/2022 dated 20th July, 2022	**Result of test/ analysis with specifications applied:** USP-39 **Assay:** Stated: 20mg/capsule Found: 5.864 mg/capsule Percentage 29.32% **(DOES NOT COMPLY)** Limit: 90-110% **Does not Comply with USP-39** **RESULT:** The sample is of **Sub-standard** quality on the basis of test performed.

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated. 30/12/2022.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 22-02-2023 stating that:

1. We are in receipt of the Show Cause Notice No. PQCB/R-547/2021 dated 30-12-2022 where under you have directed M/S Don Valley Pharmaceuticals (Pvt.) Ltd. to show cause as to why any legal action may not be taken against the Company including but not limited to the initiation of prosecution before the Honorable Drug Court and cancellation of the Drug Manufacturing License and Drug Registration, for allegedly violating the provisions of the Drugs Act, 1976 and the DRAP Act, 2012 along with the rules

framed thereunder.

2. At the very outset it is to be noted that the Company is engaged in the manufacturing of high-quality and efficacious pharmaceutical products which are being manufactured at the state-of-the-art manufacturing site of the Company. Admittedly, no complaint with respect to the quality of the pharmaceutical products manufactured by the Company has been received from anywhere which not only affirms the excellent quality of the pharmaceutical products but also reflects the strict adherence of the Company with the Drug Laws and the rules made thereunder. It is in this background, that the Company seeks to refute the

Findings of the Government Analyst Drug Testing Laboratory Rawalpindi rendered vide TRA No.01-74003025/DTL dated 24-12-2021 (the"DTL Report") as-well as findings of Government Analyst NIH vide TRA No.0156-P/2022 dated 20-072022 whereby Capsule Opicap (Omeprazole 20mg) batch No. EH-21-016 has allegedly been declared as 'Substandard' on the basis of Assay.

3. You may please note that the testing method for the subject drug in question is as prescribed in United State Pharmacopoeia (The "USP"). Which included both dissolution test as well as assay test using HPLC method for assay testing. But, the Government analyst of both the Laboratories performed the single test using HPLC and skipped the Dissolution test, which is also an official test to determine the content uniformity of Active Pharmaceutical Ingredient (Omeprazole) prescribed in the USP, Hence Declaring a product substandard on the basis of incomplete testing is not justified.

4. Furthermore, it is important to submit that storage conditions for medicines must be ensured as per specified in the outer unit carton of the Product. For the drug in question ideal storage conditions were 25 to 30degree, storage in such condition ensures long term efficacy as well least degradation of the API in the Product. Upon perusing the Show Cause Notice, premises from where sample was taken is located somewhere in Tehsil Pind Dadan Khan District Jhelum also that the sample was taken during the alarming humid month of August. Hence, it is to believe that inappropriate storage conditions were the main cause for failure of Assay test.

(Copy of the Outer Unit Carton of the Product is enclosed as "Enclosure l")

5. Even otherwise, it is clear that the entire manner in which the sample of the Product has been obtained and tested is riddled with glaring infirmities and illegalities. The Government Analyst has clearly and visibly failed to adhere with the ordinary testing protocols employed totest a pharmaceutical product and as a result of the same has rendered erroneous findings vis-å-vis the quality of the Product. In view thereof, it shall be against the dictates of justice to penalize the Company and its officials on the basis of a flawed and faulty investigation.

6. Without prejudice to the foregoing and despite the complete innocence of the Company and its officials, please note the following information as per your requirement:

(Director) Dr. Shela Akram

(Production Incharge) Muhammad Yamin (Quality Control In-charge) Tariq Mehmood Copy of Drug Manufacturing Certificate.

7. Accordingly, it is confirmed that the Company and its officials have not violated the provisions of the drug laws and the rules made thereunder. In view of the foregoing, it is respectfully requested that the titled show cause notice and any subsequent proceedings may kindly be withdrawn in the interest of justice, equity and fair-play.

Personnel hearing notice(s) issued to accused person(s) vide dated 22-01-2024.

Case is placed before the Board.

Summary:

Manufacturing Date: 06-2021

Expiry Date: 06-2023

Sampling Date: 23-10-2021

Sent to DTL (Form 6): 24-10-2021

Date of receipt in DTL: 27-12-2021

DTL Report Date: 24-12-2021

Time Extension: N/A

1ST DI Communication with firm on dated: 15-01-2022

Date of Retesting Request of Firm: 20-01-2022

Fate of Retesting Request: - allowed in 244th meeting 31-05-2022

Investigation Report Dated: 20-08-2022

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275th meeting** held on **31-01-2024** under the chairmanship of Special Secretary, (operations) Primary & Secondary Healthcare department /Vice chairperson, PQCB. M. Ishfaq (Quality Control Manager) and Advocate Fatima Zahid on behalf of M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore appeared before the Board.

The case was leftover due to time constraints.

Case No. 45

PQCB/R-115/2022

Tehsil Phalia, District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan** through its Chief Executive Officer, Dr. Shehla Javed Akram 2. Dr. Shehla Javed Akram — Chief Executive Officer 3. Muhammad Yamin — Production Incharge 4. Tariq Mehmood — Quality Control Incharge 5. Muhammad Ishfaque — Warrantor of M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Phalia, District Mandi Bahauddin reported that: -

i. He, on 18-12-2021, inspected the business premises of M/s Farooqi Medical Store, Main Bazaar Qadirabad Tehsil Phalia, District Mandi Bahauddin, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Faisalabad vide memorandum no. 113676 dated 21-12-2021
ii. The sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Faisalabad**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report No. & Date**	**DTL Test Report Result**
Capsule. Opicap [Each capsule contains: Enteric-coated pellets of Omeprazole equivalent to Omeprazole …. 20mg] **Mfg Date:** June 2021 **Expiry Date:** June 2023 **Regn No.**	EH-21-016	M/S Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.	01-68013013/ DTL Dated 28-01-2022	**Analysis with specifications applied: USP 2021** **DESCRIPTION:** Off-white pellets encapsulated in yellow color transparent body and opaque yellow cap of hard gelatin capsules, contained in Alu-Alu blister of 7's packed in outer unit carton. **IDENTIFICATION:** Omeprazole identified. **ASSAY:** Stated: 20 mg/ Capsule Determined: 10.851 mg/ Capsule

028001				Percentage: **54.255% (Does Not Comply)** Limit: 90–110 % (USP 2021) **RESULT:** Given sample is **Sub-Standard**, with regards to Assay.

iii. M/s Farooqi Medical Store, Main Bazaar Qadirabad Tehsil Phalia, District Mandi Bahauddin provided invoice/ warranty bearing No. 21109 dated 18-09-2021 issued by M/s Mian Medicine Distributor, Civil Hospital Road Mandi Bahauddin.
iv. Warrantor portion of drug sample was sent to M/S Mian Medicine Distributor, Civil Hospital Road Mandi Bahauddin.
v. A copy of test/analysis report was sent to M/s Mian Medicine Distributor, Civil Hospital Road Mandi Bahauddin who in-turn provided invoice/warranty bearing no. 2108-19275 dated 04-08-2021 issued by M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan as a proof of its purchase.
vi. A copy of test/analysis report was sent to M/S Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample 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 Provincial Quality Control Board in its 244th meeting held on 31-05-2022 allowed to send the drug sample to NIH, Islamabad for retesting from where the sample was declared Substandard as detailed below**:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Test Report No.**	**NIH Test Report Result**
Capsules OPICAP 20mg	EH-21-016	M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.	0155-P/2022 dated 17-08-2022	**Analysis with specifications applied:** United States Pharmacopoeia-39 **ASSAY:** Stated: 20 mg/ capsule Determined: 7.234 mg/ capsule Limit: 90-110% Percentage: **36.17%** **Does not Comply with USP-39** **CONCLUSION:** The sample is of **Sub-Standard** quality on the basis of the tests performed.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 16-11-2022

Firm replied to the show cause notice vide letter dated 23-11-2022

1. We are in receipt of the Show Cause Notice No. POCB/R-115/2022 dated 16-11-2022 where under you have directed M/s Don Valley Pharmaceuticals (Pvt.) Ltd. (the Company") to show cause as to why any legal action may not be taken against the Company including but not limited to the initiation of prosecution before the Honorable Drug Court and cancellation of the Drug Manufacturing License and Drug Registration, for allegedly violating the provisions of the Drugs Act, I976 and the DRAP Act, 2012 along with the rules framed thereunder.

2. In response to the Show Cause Notice under reply, we would like to submit as hereunder:

i. *The Company is engaged in the manufacturing of high-quality and efficacious pharmaceutical products which are being manufactured at the state-of-the-art manufacturing site of the Company. Admittedly, no complaint with respect to the quality of the pharmaceutical products manufactured by the Company has been received from anywhere which not only affirms the excellent quality of the pharmaceutical products but also reflects the strict adherence of the Company with the Drug Laws and the rules made thereunder. In this backdrop,* ***the Company seeks to refute the erroneous and inaccurate findings of the Government Analyst Drug Testing Laboratory Lahore*** *rendered vide TRA No. 01-68013013/DTL dated 28-01-2022 (the "DTL Report") and the Government Analyst* ***National Institute of Health Islamabad*** *rendered vide Test Report No. 0155-P/2022 dated 17-08-2022 (the "NIH Report") whereby Capsule Opicap (Omeprazole 20mg) batch No. EH-21-016 (the "Product") has allegedly been declared as 'Substandard' on the basis of Assay.*

ii. *Please note that the testing method/criteria for the subject drug in question is prescribed in the United State Pharmacopoeia (USP) Monograph which mandates that* ***both the Dissolution test as-well the Assay test using HPLC method be performed on the drug. However, the same has not been done in the present case****.* ***The Government Analysts have only performed a single test using the HPLC method and have disregarded the Dissolution test****, which is also an official test to determine the content uniformity of the Active Pharmaceutical Ingredient (AP) under USP. In view thereof, since the* ***compete testing protocols have not been followed by the Government Analysts****, it is completely unjustified to declare the Product as substandard.*

iii. *Furthermore, it is submitted that it is mandatory to ensure the compliance of the storage conditions specified on the outer unit carton of the Product. As per the label claim of the Product,* ***it is essential to store it under 30°C and to protect the same from sunlight & moisture****. The foregoing conditions have been listed on the label claim to ensure long-term efficacy of the Product as-well as to prevent the degradation of the API. Since, the results of all tests conducted at the time of the release of the Product were in compliance with the parameters set under USP, it is evident that the alleged deviation observed in the DTL Report and the NIH Report has occurred only due to the inability of the third parties, including but not limited to the store keeper, to store and maintain the Product in accordance with the specified storage conditions.*

iv. *The aforementioned submission is further substantiated by the results of the tests conducted upon the retention samples of the Product which were kept in an appropriate storage environment. In view thereof,* ***it shall be against the dictates of Justice to penalize the Company and its officials on the basis of the negligence exhibited by third parties to store the Product in a proper manner****.*

v. *Without prejudice to the foregoing and despite the absolute innocence of the Company and its officials, please find the following information as per your requirement.*

Production In-charge (Muhammad Yamin)

Quality control In-charge (Tariq Mahmood)

vi. *Accordingly, it is reiterated that the entire manner in which the sample of the Product has been obtained and tested is riddled with glaring infirmities and illegalities.* ***The Government Analysts have clearly and visibly failed to adhere with the ordinary testing protocols*** *employed to test a pharmaceutical product and as a result of the same has rendered erroneous findings vis-à-vis the quality of the Product. In view thereof, it shall be against the dictates of justice to penalize the Company and its officials on the basis of a flawed and faulty investigation.*

vii. *In view of the foregoing, it is affirmed that the Company and its officials have not violated the provisions of the drug laws and the rules made thereunder. Therefore, it is respectfully requested that t****he titled show cause notice and any subsequent proceedings may kindly be withdrawn*** *in the interest of justice, equity and fair-play.*

4. Personal hearing notice(s) issued to accused person(s) dated 22-01-2024

Previous Proceedings & Decision by The Board:

275th Special meeting held on 31-01-2024

5. Case was placed in PQCB **275th Special meeting** held on **31-01-2024** under the chairmanship of Vice chairperson, PQCB. Ms. Uzma Mazhar Secretary DQCB Mandi Bahauddin was present along-with original case record. No one among nominated accused was present, However, Counsel of the firm Fatima Zahid (Advocate) was present on the behalf of M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan. Case was **left-over** due to time constraints.

6. Personal hearing notice(s) issued to accused person(s) dated 20-02-2024

7. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 06-2021

Expiry Date: 06-2023

Sampling Date (Form 4): 18-12-2021

Sent to DTL (Form 6): 21-12-2021

Date of receipt in DTL: 23-12-2021

DTL Report Date (Form 7): 28-01-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 10-02-2022

Retesting Request of Firm: Yes (16-02-2022)

Fate of Retesting Request: Allowed in 244th Meeting Dated 31-05-2022

Sample Received at NIH: 09-06-2022

NIH Report: 17-08-2022 (Substandard)

Investigation Report Dated: 29-09-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 46

PQCB/R-245/2022

Tehsil Sarai Alamgir, District Gujrat

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan** through its Chief Executive Officer, Dr. Shehla Javed Akram 2. Dr. Shehla Javed Akram — Chief Executive Officer 3. Muhammad Yamin — Production Incharge 4. Tariq Mehmood — Quality Control Incharge 5. Muhammad Ishfaq — Warrantor of **M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Sarai Alamgir, District Gujrat reported that: -

i. He, on 07-02-2022, inspected the business premises of M/s Ansar Medicose situated at Sadat Market Sarai Alamgir, Tehsil Sarai Alamgir, District Gujrat, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Faisalabad vide memorandum no. 118073 dated 08-02-2022
ii. The sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Faisalabad**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report No. & Date**	**DTL Test Report Result**
Capsule. Opicap [Each capsule contains: Enteric-coated pellets of Omeprazole equivalent to Omeprazole …. 20mg] **Mfg Date:** June 2021 **Expiry Date:** June 2023	EH-21-015	M/S Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.	01-68013870/ DTL Dated 25-03-2022	**Analysis with specifications applied: USP 2021** **DESCRIPTION:** Off-white pellets encapsulated in yellow color transparent body and opaque yellow cap of hard gelatin capsules, contained in Alu-Alu blister of 7's packed in outer unit carton. **IDENTIFICATION:** Omeprazole identified. **ASSAY:** Stated: 20 mg/ Capsule Determined: 9.791 mg/ Capsule

Regn No. 028001				Percentage: 48.955% **(Does Not Comply)** Limit: 90–110 % (USP 2021) **RESULT:** Given sample is **Sub-Standard**, with regards to Assay.

iii. M/s Ansar Medicose situated at Sadat Market Sarai Alamgir, Tehsil Sarai Alamgir, District Gujrat provided invoice/ warranty bearing No. 17384 dated 07-01-2022 issued by M/s Madani Medicose Main Bazar, Lalamusa.
iv. Warrantor portion of drug sample was sent to M/s Madani Medicose Main Bazar, Lalamusa.
v. M/s Madani Medicose Main Bazar, Lalamusa. provided invoice/warranty bearing no. 2107-19137 dated 13-07-2021 issued by M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan as a proof of its purchase.
vi. A copy of test/analysis report was sent to M/S Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample 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 Provincial Quality Control Board in its 247th meeting held on 21-07-2022 **allowed** to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Test Report No.**	**NIH Test Report Result**
Capsules OPICAP 20mg	EH-21-015	M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.	0213-P/2022 dated 05-09-2022	**Analysis with specifications applied:** United States Pharmacopoeia-39 **ASSAY:** Stated: 20 mg/ capsule Determined: 8.114 mg/ capsule Limit: 90-110% Percentage: **40.57%** **Does not Comply with USP-39** **CONCLUSION:** The sample is of **Sub-Standard** quality on the basis of the tests performed.

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 and Rules framed there under by the way of :-

a. **Manufacture for sale /sale of Substandard drug**
b. **Issuance of false warranty**

REPLY OF THE FIRM:

- This is in response to Show Cause Notice No. PQCB/R-245/2022 dated 18-11-2023 wherein your good-office has instructed M/s Don Valley Pharmaceuticals (Pvt.) Limited (the "Company") to show cause as to why any legal action including but not limited to the initiation of prosecution before the Honorable Drug Court along with cancellation/suspension of the Drug Manufacturing License and Drug Registration, may not be taken against the Company for allegedly contravening the provisions of the Drugs Act, 1976 and the DRAP Act, 2012.
- At the very outset, it is submitted that the Company is one of the leading national pharmaceutical companies in the country. It is a matter of fact that the Company has shown strict adherence with the Drug Laws and Good Manufacturing Practices. The aforementioned submission is substantiated by the fact that no complaint in relation to the quality of the pharmaceutical products manufactured by the Company has been received from any quarter whatsoever. In view thereof, the Company duly submits that the findings of the Government Analyst Drug Testing Laboratory Faisalabad rendered vide TRA No. 01-68013870 dated 25- 03-2022 (the "DTL Report") along with the findings of the Government Analyst National Institute of Health Islamabad vide TRA No. 0213- P/2022 dated 05-09-2022 (the "NIH Report") whereby its product, namely, Capsule Opicap [Contains Omeprazole 20mg] Batch No. EH- 21-015 (the "Product") has been allegedly declared as "substandard" are defective, erroneous and without any merit.
- It is a matter of fact that the Company has a comprehensive testing framework and all of its pharmaceutical products are subjected to a rigorous testing regime prior to their release in the market. Similarly, the Product was subjected to a stringent testing protocol as was only given clearance for release in the market once it was affirmed that the same was of standard quality. Even otherwise, a thorough investigation has been conducted on the retained samples as well as the in-process batches wherein no abnormality has been observed and it was confirmed that the Product is of standard quality,
- In view of the forgoing, it is thus submitted that the alleged deviation observed in the DTL Report as well as the NIH Report has solely occurred due to the inability of third parties to maintain/store the Product in specific storage conditions In this regard, it is essential to submit that as per the label claim of the Product the same has to be stored below 30 C and in a place away from sunlight and moisture. The foregoing submission is substantiated by the fact that the retention samples which were stored and maintained in a controlled environment by the quality control department of the Company have been tested and the results obtained in pursuance thereof have shown compliance with the requisite specifications whereas there is no record of the storage conditions of the premises of M/s Ansar Medcose situated at Sadar Market Sarai Alamgir, Tehsil Sarai Alamgir, District Gujrat. On account of the foregoing, it is essential to dispense with the requirements stipulated under Section 32(3) of the Drugs Act, 1976 so as to prevent the unlawful and illegal prosecution of the Company and its officials.
- Even otherwise, and without prejudice to the foregoing, it is submitted that the technical errors whilst testing the Product i.e., improper handling of the calibration apparatus as well as environmental variables at the testing facility may have potentially affected the Assay of the Product. Additionally, it may also be noted that there is a significant lapse between the time frame within which the Product was obtained by the Drug Inspector till it was tested by the NIH. In this regard, no investigation has been conducted to ascertain whether the Product was stored properly during the aforementioned time-period. As such, it is essential to determine the external factors which had led to the decrease of Omeprazole in the Product. This shall be in consonance with the principles of due process and administration of justice which bar the initiation of unlawful and arbitrary proceedings against the Company and its officials.
- Additionally, the DTL. Report and NIH Report, alike, fail to evidence other tests to be carried out on the Product to test its quality, including but not limited to weight variation test and content uniformity test. The weight variation is a satisfactory method for determining drug content uniformity of drug distribution. Uniformity of content studies are an essential step in the quality control of tablets or capsules as defined in all major pharmacopoeias. It ensures that all tablets are within a tolerance of their average weight giving intra and inter batch uniformity data. In view

thereof, the failure to carry out such tests meant that there was no way to corroborate the alleged findings of the assay test to ensure that the Product complies with the requisite standard and specifications,

- Notwithstanding the foregoing and despite the absolute and complete innocence of the Company and its officials in the subject matter, please find the following information/documents as per your requirement:
    - Name of CEO. (Dr.Shela Javed Akram
    - Name of Production In-charge. (Shabana Kashif)
- Insert Name of the Quality Control In-charge. (Tariq Mahmood)
- Accordingly, it is reiterated that the Product is of standard quality and the alleged non-compliance observed by the Government Analysts has not occurred due to any violation on behalf of the Company and its officials, additionally, the results of the tests reports are inconclusive.Therefore, it shall be a great travesty of justice to penalize the Company and its officials for the offences alleged in the titled Show Cause Notice since the variation observed is a result of the omissions and negligence of third parties.
- In view thereof, it is submitted that no case has been made out against the Company and its officials as they have not contravened the provisions of the Drug Laws and the rules framed thereunder. Accordingly, you are very kindly requested to withdraw the titled Show Cause Notice and all subsequent proceedings and consign the case to record.

PREVIOUS PROCEEDINGS OF THE CASES:

275th-S meeting held on 31-01-2024:

5. Case was considered by the Provincial Quality Control Board, under section, 11 of the Drugs Act 1976 in its **275th-S meeting** held on **31-01-2024** under the Chairmanship of Vice-Chairperson. Secretary Provincial Quality Control Board apprised the Board that Show Cause and Personal Hearing notice was duly served to accused persons. Miss. Mehwish Secretary DQCB District Gujrat attended the meeting via zoom link. Among the nominated accused persons Muhammad Ishfaq (Warrantor) was present of **M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan** along with counsel person of firm Fahma Zahid. The case was **left over** due to time constraints.

Summary:

Sampling date: 07-02-2022

DTL Report date: 25-03-2022

1st DI Communication with firm on dated: 06-05-2022

Date of Retesting Request of Firm: 16-05-2022.

Investigation Report dated: 09-12-2022

Manufacturing Date: 06-2021

Expiry Date: 06-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 47

PQCB/R-244/2022

(Chishtian)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan** through its Chief Executive Officer, Dr. Shehla Javed Akram 2. Dr. Shehla Javed Akram — Chief Executive Officer 3. Muhammad Yamin — Production Incharge 4. Tariq Mehmood — Quality Control Incharge 5. Muhammad Ishfaque — Warrantor of M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 21-02-2022, inspected the business premises of M/s Asif Medicose, Basti Ghulam Ali Near Pull Ashiq Muhammad, Tehsil Chishtian, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Bahawalpur vide memorandum no. 119251 dated 23-02-2022

ii. The sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report No. & Date	DTL Test Report Result
Capsule. Opicap [Each capsule contains: Enteric-coated pellets of Omeprazole equivalent to Omeprazole …. 20mg] **Mfg Date:** 08-2021 **Expiry Date:** 08-2023	EH-21-019	M/S Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.	01-86001098/ DTL Dated 25-04-2022	**Analysis with specifications applied: USP 2021** **COMPOSITION:** Each capsule contains: Enteric coated pellets of omeprazole equivalent to Omeprazole…….20mg **DESCRIPTION:** Off-white, round and spherical pellets in hard gelatin capule of transparent yellow body and opaque yellow cap in blister of seven enclosed in outer carton. **IDENTIFICATION:** Omeprazole identified.

Regn No. 028001				**ASSAY:** Stated: 20 mg/ Capsule Determined: 9.51 mg/ Capsule Percentage: **45.76**% **(Does Not Comply)** Limit: 90–110 % **RESULT:** Given sample is **Sub-Standard**, with regards to Assay.

iii. M/s Asif Medicose, Basti Ghulam Ali Near Pull Ashiq Muhammad, Tehsil Chishtian, provided invoice/ warranty No. 12139 dated 06-02-2022 issued by M/s Javed Sons, Pharma Plus College Road Chishtian.

iv. Warrantor portion of drug sample was sent to M/S Javed Sons, Pharma Plus College Road Chishtian.

v. A copy of test/analysis report was sent to M/s Javed Sons, Pharma Plus College Road Chishtian who in-turn provided invoice/warranty no. 2108-19517 dated 31-08-2021 issued by M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan as a proof of its purchase.

vi. A copy of test/analysis report was sent to M/S Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample 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 Provincial Quality Control Board in its 248th meeting held on 04-08-2022 **allowed** to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Test Report No.**	**NIH Test Report Result**
Capsules OPICAP 20mg	EH-21-019	M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.	0231-P/2022 dated 06-10-2022	**ASSAY:** Stated: 20 mg/ capsule Determined: 9.032mg/ capsule Limit: 90-110% Percentage: 45.16**%** **Does not Comply with USP-39** **CONCLUSION:** The sample is of **Sub-Standard** quality on the basis of the tests performed.

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. **Manufacture for sale/ Sale of Substandard drug**
   b. **Issuance of false warranty**

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

REPLY OF SHOW CAUSE NOTICE BY FIRM:

1. We are in receipt of the Show Cause Notice No. PQCB/R-244/2022 dated 06-01-2023 whereunder you have directed M / s Don Valley Pharmaceuticals (Pvt.) Ltd. (the "Company") to show cause as to why any legal action may not be taken against the Company including but not limited to the initiation of prosecution before the Honorable Drug Court and cancellation of the Drug Manufacturing License and Drug Registration, for allegedly violating the provisions of the Drugs Act, 1976 and the DRAP Act, 2012 along with the rules framed thereunder.

2. In response to the Show Cause Notice under reply, we would like to submit as hereunder:

i. The Company is engaged in the manufacturing of high-quality and efficacious pharmaceutical products which are being manufactured at the state-of-the-art manufacturing site of the Company. Admittedly, no complaint with respect to the quality of the pharmaceutical products manufactured by the Company has been received from anywhere which not only affirms the excellent quality of the pharmaceutical products but also reflects the strict adherence of the Company with the Drug Laws and the rules made thereunder. In this backdrop, the Company seeks to refute the erroneous and inaccurate findings of the Government Analyst Drug Testing Laboratory Bahawalpur rendered vide TRA No. 01-86001098/DTL dated 25-04-2022 (the "DTL Report") and the Government Analyst National Institute of Health Islamabad rendered vide Test Report No. 0231-P/2022 dated 06-10-2022 (the "NIH Report") whereby Capsule Opicap Batch No. EH-21-19 (the "Product") has allegedly been declared as 'Substandard' on the basis of Assay.

ii. It is submitted that it is mandatory to ensure the compliance of the storage conditions specified on the outer unit carton of the Product. As per the label claim of the Product, it is essential to store it under 30 C and to protect the same from sunlight & moisture. The foregoing conditions have been listed on the label claim to ensure long-term efficacy of the Product as-well as to prevent the degradation of the API. Since, the results of all tests conducted at the time of the release of the Product were in compliance with the parameters set under USP, it is evident that the alleged deviation observed in the DTL. Report and the NIH Report has occurred only due to the inability of the third parties, including but not limited to the store keeper, to store and maintain the Product in accordance with the specified storage conditions.

    [Copies of the label claim of the Product along with the Certificate of Analysis is enclosed herewith as "Enclosures I-II"]

iii. The aforementioned submission is further substantiated by the results of the tests conducted upon the retention samples of the. Product which were kept in an appropriate storage environment. In view thereof, it shall be against the dictates of justice to penalize the Company and its officials on the basis of the negligence exhibited by third parties to store the Product in a proper manner.

    [Copy of the results conducted on the retention samples is enclosed herewith as "Enclosure III"]

iv. Without prejudice to the foregoing and despite the absolute innocence of the Company and its officials, please find the following information as per your requirement:

    Production In-charge (Shabana kashif)

Quality control In-charge (Muhammad Tariq Mahmood)

v. Accordingly, it is reiterated that the entire manner in which the sample of the Product has been obtained and tested is riddled with glaring infirmities and illegalities. The Government Analysts have clearly and visibly failed to adhere with the ordinary testing protocols employed to test a pharmaceutical product and as a result of the same has rendered erroneous findings vis-à-vis the quality of the Product.

vi. In view thereof, it shall be against the dictates of justice to penalize the Company and its officials on the basis of a flawed and faulty investigation. In view of the foregoing, it is affirmed that the Company and its officials have not violated the provisions of the drug laws and the rules made thereunder. Therefore, it is respectfully requested that the titled show cause notice and any subsequent proceedings may kindly be withdrawn in the interest of justice, equity and fair- play.

Summary:

Manufacturing Date: 08.2021

Expiry Date: 08.2023

Sampling Date (Form 4): 21.02.2022

Sent to DTL (Form 6): 23.02.2022

Date of receipt in DTL: 25.02.2022

DTL Report Date (Form 7): 25.04.2022

Time Extension: N/A

1ST DI Communication with firm on dated: 13.05.2022

Date of Retesting Request of Firm: 24.05.2022

Fate of Retesting Request: Allowed in 248th meeting dated 04.08.2022 (NIH Substandard)

Investigation Report Dated: 10.12.2022

4. Personal hearing notice(s) issued to the accused persons(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 48

PQCB/R-295/2023

(Bahawalpur City)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan** through its Chief Executive Officer (CEO) Abdul Majeed Bajwa. 2. Abdul Majeed Bajwa — Chief Executive Officer (CEO) 3. Muhammad Anwar — Production Manager 4. Muhammad Ali — Quality Control Manager 5. Abdul Raheem — Warrantor of **M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Bahawalpur City reported that: -

i. He, on 16.05.2023, inspected the premises of Director Livestock situated at Habib Colony, Street No. 2 Bahawalpur and took different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 166972 dated 16.05.2023.
ii. Following Drug samples after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Bahawalpur, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Injection Loxicon, 50ml (Meloxicam: 10mg/ml) **Mfg Date:** 04.2023 **Expiry Date:** 04.2025 **Regn No.** 057187	LOX036	M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan	01-10097003565/ DTL dated: 17.06.2023	**Specifications applied: BP vet 2023** **Composition:** Each ml contains: Meloxicam: 10mg **Description:** Yellow color liquid in amber glass sealed vial. Stated volume: 50ml **Volume:** Complies **pH:** Limit: 7.5-9.1. Determined: **9.917 (Does not Comply)** **Sterility:** The product is sterile **Identification:** Meloxicam is identified. **Assay (USP):** Complies

				Result: The sample is declared **SUB-STANDARD** on the basis of pH TEST.

iii. The Director Livestock, Bahawalpur Division, Bahawalpur provided Invoice/warranty No 1377, Dated. 18.04.2023 issued by M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan and they were asked to provide the requisite information in this regard.

2. Drug Inspector requested for grant of permission for prosecution against the 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: -
    a. **Manufacture and selling of Substandard**
    b. **Issuance of false warranty**
3. Show-cause/Personal Hearing notice(s) issued to accused person(s).

Reply of Show-Cause Notice:

This is with reference to your Show Cause Notice No. PQCB/ R - 295/2023 Dated 16-02-2024, regarding Product Inj. Loxicon-INJ 50ml Each ml contains: Meloxicam 10mg/ml Batch No. Lox-036 manufactured b - Ms Vetcon Pharmaceuticals Pvt. Ltd., Plot No.7-10B, Small Industrial Estate, Bhimber, AJK Pakistan. Product was declared "substandard" on a pH test basis Vide TRA No.01-10097003565/DTL dated 17-06-2023.

We submit our explanation that according to the BP-Vet Specification, the pH limit is "between" 7.5 and 9.1, whereas the pH determined from our product is 9.917, which comes out to be a minor difference. This further explains that the DTL report's statements about the product's assay, sterility, and identification have been compiled with satisfactory. We assure you that we will adhere all necessary measures to prevent this type of error in the future and our Quality Control Department is diligently monitoring the situation.

Regarding the requisite information, please find the details below: -

Sr.#	**Name of Attached Documents**
01	Our reply of show "cause notice on company letter head.
02	PQCB Show Cause Notice
03	TRA/Form 7
04	Warranty Invoice
05	pH Meter Calibration Certificate

06	Drug Registration Certificate
07	Drug Manufacturing License
08	BMR (Complete Record, Include QC, QA, Product Test Report)
09	Relevant Pharmacopeia

Names of verified persons

a. Chief Executive: M. Anwar Bajwa

b. Production Incharge: Muhammad Ahsan

c. Quality Control Incharge: Dr. Muhammad Ali Bajwa

d. Warrantor: Abdul Rahim - Email:acct.vetconpharma@gmail.com/Whatsap Number: 0323-4511130

It is humbly requested, that since it is a borderline case with only minur difference and negligible in the desired pH test. Kindly issue us a WARNING letter so that Department of Livestock & Dairy Development Bahawalpur may be able to use this product. We shall take all necessary preventive measures to make sure that all procedures and results are in compliance.

Summary:

Manufacturing Date: 04.2023

Expiry Date: 04.2025

Sampling Date (Form 4): 16.05.2023

Sent to DTL (Form 6): 16.05.2023

Date of receipt in DTL: 17.05.2023

DTL Report Date (Form 7): 17.06.2023

Time Extension: N/A

1ST DI Communication with firm on dated: 13.07.2023

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated: 01.08.2023

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 49

No. PQCB/R-719,754,772/2020

Rawal Town, Rawalpindi

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad-Pakistan** through its Chief Executive Officer, Faheem Qureshi. 2. Faheem Qureshi Chief Executive Officer 3. Muhammad Hashim Baig Production Manager/Warrantor 4. Muhammad Safdar Fatmi Quality Control Manager Of M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Rawal Town, Rawalpindi reported that: -

i. The then Drug Inspector, on 27-07-2020, inspected the premises of M/S Kousar Medicose, Banni Chowk, Rawalpindi, took subject drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide memorandum no. 0000072371,0000072370 and 0000072369dated 27-07-2020.

ii. The said drug sample after test/analysis were 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**
Film coated Tablet Fabix [Febuxostat 40mg] **Mfg Date** 12-2019 **Expiry Date** 11-2021 **Regn. No.** 091587	19L235	M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad	01-72001437/DTL dated 27-09-2020	**Analysis with specifications applied: MS** **PHYSICAL DESCRIPTION:** White coloured, round shaped, biconvex tablet, plain from both sides packed in Alu-Alu blister of 1x10's tablets, further packed in labelled outer carton containing two blisters (20 tablets). Manufacturer specifications state that the colour of tablets should be "Yellow" while in actual that were of white colour. (Does not comply). **ASSAY: (MS)** Stated: 40mg/Tablet Determined: 37.262mg/Tablet

Percentage: 93.15%

Limit: 90%–110%

RESULT: The above sample is SUBSTANDARD, on the basis of physical characteristics observed.

Film coated Tablet Soivan

[Amlodipine (as Besylate) 5mg, Valsartan 80mg]

Mfg Date

03-2020

Expiry Date

02-2022

Regn. No.

091593

20C093

M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad

01-72001435/DTL

dated

27-09-2020

Analysis with specifications applied: USP2019

PHYSICAL DESCRIPTION: White to off white coloured, round shaped, biconvex tablet, and plain from both sides packed in Alu-Alu blister of 1x14's tablets, further packed in labelled outer carton.

IDENTIFICATION:

Amlodipine Besylate identified.

Valsartan identified.

ASSAY:

Name	Stated	Determined	Percentage	Limit
Amlodipine	5mg/tablet	5.324mg/tablet	106.48%	90-110%
Valsartan	80mg/tablet	82.867mg/tablet	103.58%	90-110%

DISSOLUTION:

Stage 1

Amlodipine:

Tablet No.	% Drug Release	Tablet No.	% Drug Release
1	14.73%	4	32.51%
2	39.56%	5	35.23%
3	39.78%	6	35.50%

Limit: NLT 80% (Q) of the labelled amount of amlodipine.

				Result: All the units release was less than 55% (Q-25) for amlodipine. So, fail to comply dissolution testing. **<u>Valsartan:</u>** **Tablet No.** / **% Drug Release** / **Tablet No.** / **% Drug Release** 1 / 24.94% / 4 / 44.69% 2 / 59.18% / 5 / 50.85% 3 / 57.36% / 6 / 55.08% **Limit:** NLT 80% (Q) of the labeled amount of Valsartan. **Result:** All the units release was less than 65% (Q-15) and three units release was less than 55% (Q-25) for valsartan. So, fail to comply dissolution testing. Note: Dissolution testing for sample was not proceeded to S2 and S3 as acceptance criteria for S3 does not meet during dissolution testing at S1. Limit for S3: From 24 units (6 at S1, 6 at S2 and 12 at S3) NMT 2 units are<Q-15 (65%) and no unit is <Q-25% (55%) **<u>RESULT: The above sample is SUBSTANDARD, on the basis of the Dissolution test performed.</u>**
FILM COATED TABLET FABIX (FEBUXOSTAT : 80 MG) **Mfg Date** 04-2019 **Expiry Date** 03-2021 **Regn. No.** 091592	19D077	M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad	01-72001436/DTL dated 27-09-2020	**Analysis with specifications applied: MS** **<u>PHYSICAL DESCRIPTION (MS):</u>** **White coloured, round shaped, biconvex tablet, plain from both sides packed in Alu-Alu blister of 1x10's tablets, further packed in labelled outer carton containing two blisters (20 tablets).** **Manufacturer specifications state that the colour of tablets should be "Yellow" while in actual that were of white colour. (DOES NOT COMPLY)** **<u>ASSAY: (MS)</u>** **Stated:** 80 mg /Tablet **Determined:** 74.483 mg /Tablet **Percentage:** 93.10% **Limit:** 90-110% **<u>RESULT</u>: <u>The above sample is Substandard, on the basis of Physical</u>**

				characteristics observed.

iii. M/S Kousar Medicose, Banni Chowk, Rawalpindi provided invoice/warranty bearing No. LP/KM/W-036/20 dated 07-07-2020 issued by M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad.
iv. Warrantor portion of drug sample was sent to M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, and Street No. S-5, National Industrial Zone, Rawat, Islamabad.
v. A copy of test/analysis report was sent to M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, and Street No. S-5, National Industrial Zone, Rawat, Islamabad with directions to explain their position and provide requisite information in this regard.
vi. The firm challenged the DTL report and requested re-testing of the sample from Appellate Laboratory, Islamabad. The Re-testing request of the Firm was forwarded to Provincial Quality Control Board.
vii. Pursuant to the request of the firm, the subject drug sample was sent to National Institute of Health, Islamabad, from where the sample was declared as **Sub-standard** as detailed below:

Name of drug	**Batch no.**	**Name of manufacturer**	**NIH Test Report No. & Date**	**NIH Test Report Results**
Fabix tablets 40mg	19L235	M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad	No.0238-P/2021 dated 7th July,2021	**Result of test/ analysis with specifications applied:** MS **Description:** **White, circular, biconvex film coated tablets having broken edges packed in blister packing further contained an outer carton. (Does not comply with official pharmacopoeia which states that "Physical and Chemic properties retained throughout the shelf life of the pharmaceutical product."** **Identification**: Febuxostat identified. **WT. Variation:** Complies with manufacturer specifications. **Disintegration Time**: Determined: 05minutes Limit: Not more than 30 minutes **Assay*:*** Stated: 40mg/Tab Found: 37.84mg/Tab Limit: 90-110% Percentage: 94.61% (Complies with manufacturer specifications.

<table>
<tr>
<td></td>
<td></td>
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<td></td>
<td><u>Result:</u>

The sample is of Sub-standard quality as defined in the Drug Act,1976 for the reason(s) given below:

<u>Description</u>:

White, circular, biconvex film coated tablets having broken edges packed in blister packing further contained an outer carton. (Does not comply with official pharmacopoeia which states that “Physical and Chemic properties retained throughout the shelf life of the pharmaceutical product.”

.</td>
</tr>
<tr>
<td>Soivan Tablets</td>
<td>20C093</td>
<td>M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad</td>
<td>No.0241-P/2021 dated 26th Aug,2021</td>
<td>Result of test/ analysis with specifications applied: USP-39

<u>Description:</u>

White, circular, biconvex film coated tablets packed in blister packing further contained in an outer carton.

<u>Identification</u>:

Amlodipine and Valsartan identified.

<table>
<tr><th><u>DISSOLUTION TEST:</u></th><th><u>DETERMINED</u></th><th><u>LIMIT</u></th></tr>
<tr><td>Amlodipine</td><td>11.81%</td><td>NLT 80% (Q) of the labelled amount is dissolved</td></tr>
<tr><td>Valsartan</td><td>44.148%</td><td>NLT 80% (Q) of the labelled amount is dissolved</td></tr>
</table>

Does not comply with USP-39

<u>Result:</u>

The sample is of Sub-standard quality as defined in the Drug Act,1976 for the reason(s) given below:

Result of Dissolution test does not comply with USP-39</td>
</tr>
<tr>
<td>Fabix Tablet 80 mg</td>
<td>19D077</td>
<td>M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad</td>
<td>No. 0217-P/2021 dated 17-06-2021</td>
<td>Result of test/ analysis with specifications applied: MS

<u>Description:</u>

White, circular, biconvex film coated tablets having broken edges packed in blister packing further contained an outer carton. (Does not Comply with official pharmacopoeia which states that “Physical and chemic properties retained throughout the shelf life of the pharmaceutical product.”)

<u>Identification</u>:

Febuxostat identified.

<u>Wt. Variation:</u> complies with manufacturer specifications.</td>
</tr>
</table>

Disintegration Time: complies with manufacturer specification.

ASSAY TEST:	STATED	DETERMINED	LIMIT	PERCENTAGE
Febuxostat	80mg/tab	76.784mg/Tab	90-110%	95.98%

Complies with manufacturer specification.

Result:

The sample is of Sub-standard quality as defined in the Drug Act,1976 for the reason(s) given below:

White, circular, biconvex film coated tablets having broken edges packed in blister packing further contained an outer carton. (Does not Comply with official pharmacopoeia which states that "Physical and chemic properties retained throughout the shelf life of the pharmaceutical product.")

viii. Copies of the NIH test report were forwarded to M/S Linta Pharmaceuticals (Pvt.) Ltd., Plot No.3, Street No. S-5, National Industrial Zone, Rawat, Islamabad.

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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated. 27-12-2023

Personnel hearing notice(s) issued to accused person(s) vide dated 20-02-2024

Case is placed before the Board.

Summary:

Sampling Date: 27-07-2020

Sent to DTL (Form 6): 27-07-2020

Date of receipt in DTL: 29-07-2020

~~**DTL Report Date**: 27-09-2020~~

Time Extension: N/A

1ST DI Communication with firm on dated: 20-10-2020

Date of Retesting Request of Firm: 12-11-2020

PROCEEDING & DECISION BY THE BOARD:

Fate of Retesting Request: -allowed in 230 meeting and 16th committee meeting

Investigation Report Dated: 05-09-2023