Primary & Secondary Healthcare Department
PROVINCIAL QUALITY CONTROL BOARD, PUNJAB.

261 Meeting of PQCB

Date: 25-05-2023

Time: 11:00 AM

Venue

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

TABLE OF CONTENTS

- **Case No. 10**
- R-292/2022 (Case Id: 0000085518)
- **Case No. 11**
- R-111/2022 (Case Id: 0000079601)
- **Case No. 12**
- R-05/2023 (Case Id: 0000099649)
- **Case No. 13**
- R-347/2022 (Case Id: 0000075149)
- **Case No. 14**
- R-443/2021 (Case Id: 0000086418)
- **Case No. 15**
- R-251/2022 (Case Id: 0000092661)
- **Case No. 16**
- R-233/2022 (Case Id: 0000085703)
- **Case No. 17**
- R-478/2021 (Case Id: 0000055836)

- **Item No 2**
- **ADJOURNED CASES OF PREVIOUS MEETING**
  - **Case No. 1**
  - R-471/2022 (Case Id: 0000097956)
  - **Case No. 2**
  - PQCB/R-309/2021 (Case Id: 0000058310)
  - **Case No. 3**
  - R-415/2022 (Case Id: 0000098209)
  - **Case No. 4**
  - R-525/2021 (Case Id: 0000068525)
  - **Case No. 5**
  - R-310/2022 (Case Id: 0000087516)
  - **Case No. 6**
  - R-367/2022 (Case Id: 0000071761)
  - **Case No. 7**
  - R-475/2022 (Case Id: 0000072444)
  - **Case No. 8**
  - R-438/2022 (Case Id: 0000098890)

- **Case No. 9**
- R-240/2022 (Case Id: 0000085912)
- **Case No. 10**
- R-496/2022 (Case Id: 0000097926)

- **Item No 3**
- **MISBRANDED**
  - **Case No. 1**
  - R-783,784/2019 (Case Id: 0000031457)
  - **Case No. 2**
  - R-303,304,305/2022 (Case Id: 0000083432)
  - **Case No. 3**
  - R-572/2018 (Case Id: 0000117805)
  - **Case No. 4**
  - R-689/2021 (Case Id: 0000052555)
  - **Case No. 5**
  - PQCB/R-273&275/2022 (Case Id: 0000083780)
  - **Case No. 6**
  - PQCB/R-98/2021 (Case Id: 0000059915)
  - **Case No. 7**
  - R-641/2021 (Case Id: 0000070119)
  - **Case No. 8**
  - R-443/2022 (Case Id: 0000100025)
  - **Case No. 9**
  - R-121/2022 (Case Id: 0000071827)
  - **Case No. 10**
  - R-386/2022 (Case Id: 0000094140)
  - **Case No. 11**
  - PQCB/R-246/2021 (Case Id: 0000056707)
  - **Case No. 12**
  - R-262/2022 (Case Id: 0000095387)
  - **Case No. 13**
  - R-399/2022 (Case Id: 0000097302)
  - **Case No. 14**
  - R-429/2022 (Case Id: 0000096912)

- **Case No. 15**
- R-664/2021 (Case Id: 0000063483)
- **Case No. 16**
- R-625/2021 (Case Id: 0000064812)
- **Case No. 17**
- R-395/2022 (Case Id: 0000098160)
- **Case No. 18**
- R-623/2021 (Case Id: 0000070324)
- **Case No. 19**
- PQCB/R-575/2021 (Case Id: 0000069764)
- **Case No. 20**
- R-642/2021 (Case Id: 0000068798)
- **Case No. 21**
- R-211,235/2022 (Case Id: 0000085152)
- **Case No. 22**
- R-442/2022 (Case Id: 0000098949)

- **Item No 4**
- **SUBSTANDARD**
  - **Case No. 1**
  - PQCB/R-546/2019 (Case Id: 0000037529)
  - **Case No. 2**
  - R-348/2022 (Case Id: 0000085330)
  - **Case No. 3**
  - R-198/2021 (Case Id: 0000065884)
  - **Case No. 4**
  - PQCB/R-40/2020 (Case Id: 0000038537)
  - **Case No. 5**
  - R-600/2020, R-601/2020 (Case Id: 0000039588)

ITEM No. 1

COURT CASES

Case No. 1

PQCB/R-315/2022

Tehsil & District Vehari

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan** through its CEO/MD Syed Muhammad Wajeeh Uddin 2. Syed Muhammad Wajeeh Uddin CEO/MD 3. Rashid Khan Production Incharge 4. Muhammad Farooq Quality Control Incharge/Warrantor of M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan

BRIEF FACTS OF THE CASE:

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

i. She, on 03-10-2022 inspected medicine store PHFMC Vehari, took subject sample of the drug on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan vides memo no. 142836 dated 03-10-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Capsule Vibramycin [Doxycycline hyclate equi to Doxycycline 100mg] **Mfg. Date:** 06-2022 **Exp. Date:** 05-2025 **Regn. No:** 000456	GF5138	M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan	01-94006760/DTL dated 01-12-2022	**Result of test/ analysis with specifications applied:** USP 2022 **DESCRIPTION:** Yellow color powder filled in green colored hard gelatin capsules having cap printed with "Pfizer" & "VBM 100" on body of capsule packed in ALU-PVC blister of 06 units in a labelled outer hard carton. Each outer carton contains 20 blisters of 06 units i.e., 20*06=120 capsules. **Note**: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states that "All registration holders shall follow official pharmacopeial specifications for all such formulation for which official monograph of drug product is available in the most recent edition of such pharmacopoeia". Product specification of given sample is "Manufacturer's Specification" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "**Doxycycline Hyclate capsules**" monograph in USP 2022. So, the manufacturer's claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drug Act 1976. **Misbranded (Does not comply)** **Uniformity of Dosage unit (Weight variation)** Max. AV=L1: 15% complies **IDENTIFICATION:** Doxycycline Hyclate identified. **ASSAY: Doxycycline** Stated: 100mg/cap Determined: 101.61mg/cap Percentage: 101.61% Limit: 90- 120% complies **Dissolution Test:** **Limit:** NLT 80% of the labelled amount of Doxycycline dissolved in 30mins. complies **RESULT:** The sample is **Misbranded** as per Section 3 (s) (iv) of Drug Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) Human import dated 7th February, 2022.

iii. Storekeeper, medicine store PHFMC Vehari provided Invoice/Warranty No. 3037607285 date 12-09-2022 issued by M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi-Pakistan as proof of its purchase.

iv. Warrantor Portion of subject drug sample was sent to M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi-Pakistan.

v. Copy of Test/ Analysis reports was sent to M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi Pakistan with direction to explain their position and provide requisite information in this regard.

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

i. **Manufacture for sale/ sale of Misbranded drug**

ii. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused dated 08-02-2023

Firm submitted written reply to show cause notice dated 17-03-2023

We are in receipt of the subject Show Cause Notice bearing reference No. P¿CB/R-315 dated 08-02-2023 wherein your good-self has directed M/s Pfizer Pakistan Limited (“Pfizer" or we'") to show cause as to why any legal action, including but not limited to initiation of prosecution before the learned Drug Court along with cancellation/suspension of the Drug Manufacturing License and Drug Registration, may not be taken against us for allegedly contravening the provisions of the Drug Laws and the rules framed thereunder.

2. The Registration Board of the Drug Regulatory Authority of Pakistan ("DRAP") vide the Circular No. F.3-5/2020-1&V-11 (M-297) dated 07-02-2022 ("Circular") had instructed all registration holders to "follow official pharmacopeial specifications for all such formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopeia". In this regard, please note that we have ensured maximum possible compliance with the directives issued in the aforementioned Circular and have adopted the official pharmacopeial specifications for several of our registered products. However, notwithstanding the foregoing, Pfizer is still in the process of transitioning the remaining of its registered products to the latest/most recent version of the official pharmacopeial specifications.

3. The aforementioned process is hindered and delayed on account of various reasons including but not limited to the following:

i) The requirements of Analytical Columns, Reagents/Solvents and Reference Standards to perform verification studies as per current edition of pharmacopeia require a time period of usually 12-16 weeks (may exceed) once a purchase requisition is approved and a purchase order is issued to the respective supplier. However, as a result of the prevailing economic conditions of the country the foregoing process has further slowed down due to the crisis pertaining to the non-issuance of the letter for credit as local vendors are short of supplies in their inventories. The shortage of such supplies has delayed the execution of the analytical test method verification process.

ii) A complete drug product analysis depends on the number of applicable tests including but not limited to "Identification, Assay Test, Dissolution Test, Impurity Testing and CU". Each of the aforementioned tests require several weeks for the creation of protocols, execution of testing

and subsequently the creation and approval of the work report.

iii) Pursuant to the completion of the foregoing process and testing on the available stability station the revision of artwork for all components is initiated in system which then requires several weeks for creation, development and approval.

iv) Approved artworks are then shared with the vendor for Epson Development and PO to be created for commercial supplies for implementation on packs.

v) Other logistical issues faced by the Company in seeking internal and/or external approvals prior to initiating any of the aforementioned procedures.

vi) Delays on account of Covid-19 related lockdowns and supply chain issues during FY 2020-21 and 2021-22.

4. In view thereof, extension has also been sought from DRAP vis-à-vis the implementation of the abovementioned directives vide letter bearing reference No. PFZ-DRAP-2023-028 dated 06-03-2023 whereunder all external factors delaying and hindering the enforcement of the directives of the Registration Board of DRAP have been highlighted in detail. As such, Pfizer has not contravened any provisions of the Drug Laws and the rules framed thereunder.

5. In view of the foregoing, since Pfizer has already ensured compliance with the directions issued by the Drug Regulatory Authority of Pakistan vide the Circular No. F3-5/2020-1&V-II (M-297) dated 07-02-2022, your good-self is very kindly requested to withdraw the Show Cause Notice under reply along with all subsequent proceedings and consign the subject case to record. In the alternative, it is requested to kindly withhold the decision on the subject show cause notice till such time the request for extension is pending before DRAP.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023

Case is placed before the Board for Decision

Summary	Warning to the subject Product	Warning to the firm in different products
Dated	28-10-2021	First warning: 28-10-2021 Total warnings to firm: 10

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 2

PQCB/R-626/2021

Punjab Institute of Neurosciences, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area Karachi, Pakistan** through its Chief Executive Officer/ Warrantor, Shaikh Mohiuddin Chawla 2. Shaikh Mohiuddin Chawla Chief Executive Officer/ Warrantor 3. Muhammad Ishaq Production Manager 4. Imtiaz Ahmed Quality Control Manager of M/s Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area Karachi, Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Punjab Institute of Neurosciences, District Lahore reported that: -

i. She, on 14-07-2021, inspected the premises of Main Medicine Store of Punjab Institute of Neurosciences, District 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. 100649 dated 14-07-2021.

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
Injection. Btrol [Tranexamic Acid BP …. 500mg/5ml] **Mfg Date** June 2021 **Expiry Date** May 2024 **Regn No.** 030791	BT210016	M/s Bosch Pharmaceutical (Pvt) Ltd. 221-223, Sector 23, Korangi Industrial Area Karachi, Pakistan.	01-73009374/DTL dated 10-09-2021	**Analysis with specifications applied:** BP 2021 **PHYSICAL DESCRIPTION:** Colorless liquid in transparent glass ampoule with label printed on it. Claimed volume= 5mL **pH:** Limits: 6.5 – 8.0 Determined: 7.37 at 23.1 °C **IDENTIFICATION:** Tranexamic acid identified. **ASSAY OF TRANEXAMIC ACID:** Stated: 500 mg/ 5mL Determined: **546.575 mg/ 5mL** Percentage: **109.32%** Limit: 95-105% of the stated amount **STERILITY:** Sterile. **RESULT:** The above sample is **SUB-STANDARD**, on the basis of Assay performed as per BP.

iii. The storekeeper of the Main Medicine Store of Punjab Institute of Neurosciences, District Lahore provided Invoice/Warranty bearing no. 2112060511, both dated 28-06-2021 issued by

M/s Bosch Pharmaceutical (Pvt) Ltd. 221-223, Sector 23, Korangi Industrial Area Karachi, Pakistan.

iv. Warrantor portion of the drug sample was sent to M/s Bosch Pharmaceutical (Pvt) Ltd. 221-223, Sector 23, Korangi Industrial Area Karachi, Pakistan.

v. A copy of test/analysis report was sent to M/S Bosch Pharmaceutical (Pvt) Ltd. 221-223, Sector 23, Korangi 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 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 Bosch Pharmaceutical (Pvt) Ltd. 221-223, Sector 23, Korangi Industrial Area Karachi, Pakistan the retesting request of the subject drug sample was considered in the 240th Meeting of the Board held on 15-03-2022 and the subject drug sample was sent to NIH, Islamabad, from where the sample was declared **Sub-standard** as detailed below:

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>NIH Report No. & Dtae</th><th>NIH Test Report Result</th></tr>
<tr><td>Injection. Btrol 500mg/ 5ml</td><td>BT210016</td><td>M/s Bosch Pharmaceutical (Pvt) Ltd. 221-223, Sector 23, Korangi Industrial Area Karachi, Pakistan.</td><td>No. 070-P/2022 dated 17-06-2022</td><td>Analysis with specifications applied: British Pharmacopoeia 2017
<u>ASSAY:</u>
<table>
<tr><th>Assay</th><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td>Tranexamic acid</td><td>500mg/5ml</td><td>275.10mg/ 5ml</td><td>95-105%</td><td>55.02%</td></tr>
<tr><td colspan="5">Does not Comply with BP-2017</td></tr>
</table>
Conclusion: The sample is of <u>Sub-Standard</u> quality on the basis of the tests performed.</td></tr>
</table>

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 09-01-2023

<u>Firm replied to the show cause notice vide letter no. GMQO&RA/Bosch/210123/E dated 21-01-2023</u>

We base our contentions on the following facts and grounds;

i. *That the test report of above batch purporting to declare the sample of drug as Sub-Standard is not reliable, valid or correct for the purposes of the legal requirements for a test report specified under the Drugs Act, 1976 and the Rules framed there under.*

ii. *That the test performed on Assay of Tranexamic acid has been determined at 109.32 % against limits of 95 - 105% as mentioned in the DTL, Lahore test report TRA. 01-73009374/DTL, Lahore dated: 10-09-2021.*

iii. *We have astonished here to see the Appellate Laboratory report i.e. NIH, Islamabad that they have performed the Assay of Tranexamic acid as per our Testing Request through PQCB, Lahore and is determined as 55.02%, which is very strange because Tranexamic acid is a stable salt and Suddenly **the drop of result from 109.32 % to 55.02 % just in nine months which is unexpected**.*

iv. *That it is apparent that the Analyst has not performed the Assay test of Tranexamic acid as per procedure in the **B.P through Potentiometrically or applied the proper formula** for the calculations of the result of Assay as per the test protocol or follow the instructions.*

v. *It may be appreciated that the **same Batch No. BT210016** of Btrol Injection (Quantity 10,000 Ampoules) supplied to CHILDREN HOSPITAL: LAHORE was tested in same DTL- LAHORE and **is of Standard Quality** by the Government Analyst Drug Testing Laboratory, Lahore.*

vi. *That despite the above obvious shortcomings and invalidities of the test report of DTL, Lahore and NIH Islamabad, we have as an abundant precaution **rechecked and retested our reference laboratory sample, warrantor portion and have found the same to be of proper potency and of a Standard Quality**.*

vii. *That in view of the undeniable and established fact of the test reports of DTL Lahore & NIH Islamabad being **incompetent and inaccurate as regards to test performed**, there is no basis, justification or propriety in declaring the samples sub-standard.*

viii. *As per request of the institution and in good texture of the patient **<u>we have already replaced the stock approx. 1500 ampoules lying in the Hospital</u>**,*

***<u>We request to the Honorable Board to kindly withdraw your notice forthwith</u>**.*

Furthermore, the firm verified the names of he accused nominated by the drug inspector.

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: June 2021

Expiry Date: May 2024

Sampling Date (Form 4): 14-07-2021

Sent to DTL (Form 6): 14-07-2021

Date of receipt in DTL: 19-07-2021

DTL Report Date (Form 7): 10-09-2021

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 08-10-2021

Retesting Request of Firm: Yes (09-10-2021)

Fate of Retesting Request: Allowed in 240-M dated 15-03-2022

NIH Report: 17-06-2022 (Substandard)

Investigation Report Dated: 07-09-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 3

Case No.

PQCB/R-274-2022

Tehsil & District Sahiwal

Substandard (pH)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan** through CEO Syed Nophil Rizvi 2. Syed Nophil Rizvi — Chief Executive Officer (CEO) 3. Kamran Awan — Production Incharge 4. Muhammad Fakhir Khaleeq — Quality Control Incharge/ Warrantor of M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.

BRIEF FACTS OF THE CASE

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

2. She, on 21-06-2022 inspected Main Medicine Store CEO DHA Sahiwal, took drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, **Bahawalpur** vides memorandum no**.** 130775 dated 21-06-2022.
3. 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	TRA No & Date	DTL Test Report Results
Suspension Macrobac 15ml [Azithyromycin (as dihydrate): 200mg/5ml] **Mfg. Date:** 04/2022 **Exp. Date**: 04/2024 **Regn. No.:** 082215	S0539	M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan	No. 01-10094000097 dated 26-07-2022	**Results of test/analysis with specifications applied:** USP 2022 **COMPOSITION:** Each 5ml reconstituted suspension contains: Azithromycin Dihydrate USP equivalent to Azithromycin……200mg **DESCRIPTION (MS):** White to off-white color powder in a plastic white bottle having white plastic cap. Powder gives light pink color suspension on reconstitution up to 15ml. stated volume: 15ml when reconstituted **pH (USP):** **Limit**: 8.5-11.0 **Determined**: **8.213** **Does not comply** **IDENTIFICATION:** Azithromycin is identified **ASSAY: Azithromycin** Stated: 200mg/5ml; Found: 183.88mg/5ml; Limit: 90-110%; Percentage: 91.94% **RESULT:** The above sample is **Substandard** on the basis of **pH Test**

4. Storekeeper Main Medicine Store CEO DHA Sahiwal provided Invoice/ warranty No. 0000005390 dated 26-05-2022 issued by M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.
5. Warrantor Portion of drug sample was sent to M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.
6. Copy of Test/ Analysis report was sent to M/s Asian Continental Pvt Limited; D-32 SITE II Super Highway Karachi Pakistan and they were directed to provide requisite information in this regard.
7. 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 Drugs.**
   b. **Issuance of false warranty**

8. Show-cause was issued to accused person(s) vide dated 20.01.2023

Firm submitted written reply to show cause notice dated 20.01.2023

This is with reference to your letter No. PQCB/R-274/2022 dated 20-01-2023 received at our office on 31-01-2023 regarding the subject captioned above.

As per your letter, it has been informed that the subject drug sample withdrawn has been declared as "SUBSTANDARD" by Government Analyst, DTL Bahawalpur vide Report No. TRA 01-10094000097dated 26.07.2022 B.NO. S0539.

Along with documents, you have required us to explain our position for manufacturing, stocking selling of substandard drugs and you have also required us to verify the names of accused persons and also requested to submit the attested documents for board consideration.

In response thereto, we state as follow:

- That letter No. 211/DC/CEO (DHA) dated 04.08.2022 from Provincial Inspector of Drugs, Tehsil & District Sahiwal was received to us on dated 05.08.2022 and same was replied on dated 05.08.2022 with required information and documentations and confirmed that questioned product after cross checked of all quality parameters is of standard quality.
- With regards to above said show cause notice, our justifications and clarifications are as followed:
- Please note that we have received the Warrantor Portion Sample of our product Macrobac 200 mg/ 5 ml. Suspension along with Letter No. 160/DC/CEO (DHA) dated 22.06.2022 on dated 04.08.2022; however, we have analyzed the Warrantor Portion Sample of Batch No. S0539 along with the retention sample of the same batch and found that our product is of STANDARD QUALITY with respect to prescribed parameters of physical characteristics, assay, and pH.
- It is pertinent to mention here that the product in question is dry powder suspension of Azithromycin as Dihydrate, which is reconstituted with water to form liquid suspension dosage form. The pH of the suspension is dependent upon proper reconstitution of the formulation with water. In case the dry powder is not properly mixed in water, it may sediment and alter the pH value, which is evident from the report of DTL Bahawalpur as the pH value of a batch is slightly lower than the specified limits. If the Govt. Analyst properly reconstitute the suspension and took the pH after removal of air bubbles the desired value of pH may be attained.
- Even though we totally unaccepting the DTL Bahawalpur Testing report we are not requesting for the retest of the batch in question and going to replace batch with the fresh stock as an act of curtesy and grace.

Based on above facts it is evident that this is the borderline case, therefore, it is humbly requested to take a kind decision and the case may please be closed amicably and fairly with formal

9. Personnel Hearing notice(s) issued to accused person 18.05.2023

Case was placed before the Board for Decision

Summary:

Manufacturing Date: 04.2022

Expiry Date: 04.2024

Sampling Date (Form 4): 21.06.2022

Sent to DTL (Form 6): 21.06.2022

Date of receipt in DTL: 22.06.2022

DTL Report Date (Form 7): 26.07.2022

Time Extension: N/A

1ST DI Communication with firm on dated: 04.08.2022

Date of Retesting Request of Firm: Yes

Fate of Retesting Request: Withdrawn

Investigation Report Dated: 01.01.2023

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 4

PQCB/R-767/2019

Tehsil & District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Munawar Pharma (Pvt) Ltd., 31-km Ferozepur Road, Lahore-Pakistan** through its Managing Director, Imran Arshad 2. Imran Arshad — Managing Director 3. Sheikh Muhammad Rafi — Director/ Warrantor 4. Khalil-ur-Rehman — Production Incharge 5. Muhammad Iqbal — Quality Control Incharge of M/s Munawar Pharma (Pvt) Ltd., 31-km Ferozepur Road, Lahore-Pakistan

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 15-05-2019, inspected the premises of Main Medicine Store, office of CEO (DHA), Mandi Bahauddin, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide memorandum no. 38288 dated 15-05-2019.

ii. The subject 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. Amikamed [Each 2ml contains: Amikacin Sulphate U.S.P. equivalent to Amikacin … 100mg] **Mfg Date:** April 2019 **Expiry Date:** March 2021 **Regn No.** 029415	FP 95	M/s Munawar Pharma (Pvt) Ltd., 31-km Ferozepur Road, Lahore-Pakistan.	01-56003001/DTL dated: 28 June 2019	**Analysis with specifications applied:** BP/USP 2018 **DESCRIPTION:** Colorless liquid having particles visible with naked eye filled in amber colored glass ampoule packed in outer hard carton. **IDENTIFICATION:** Amikacin Sulphate Identified. **ASSAY:** Stated: 100 mg Amikacin/ 2ml Determined: 90.87 mg Amikacin/ 2ml Percentage 90.87% (Complies) Limit: 90 - 110% (BP 2018) **pH:** Limit: 3.5 - 5.5 (USP 2018) Determined: 5.0 (Complies) **EXTRACTABLE VOLUME:** Stated: Not less than Nominal Volume (USP 2018) Determined: 2.0 ml (Complies) **STERILITY:** Stated: Must be Sterile (USP 2018) Determined: Sterile (Complies) **VISIBLE PARTICULATES IN INJECTION:** Stated: Inspected units must be free of visible particulates when examined without magnification against a black background and against a white background. (USP 2018) Determined: **Out of 20 inspected units, foreign particles visible with naked eye within 5 seconds were observed in two ampoules. (Does Not Comply)** **RESULT:** Given sample is **Sub-Standard** on the basis of Visible particulates in injection.

iii. Storekeeper of M/s Main Medicine Store, office of CEO (DHA), Mandi Bahauddin provided invoice/ warranty bearing No. 302/MP/2018-2019, 304/MP/2018-2019, 301/MP/2018-2019, 306/MP/2018-2019, 303/MP/2018-2019, 305/MP/2018-2019 dated 18-04-2019 issued by M/s Munawar Pharma (Pvt) Ltd., 31-km Ferozepur Road, Lahore-Pakistan.

iv. Warrantor portion of drug sample was sent to M/s Munawar Pharma (Pvt) Ltd., 31-km Ferozepur Road, Lahore-Pakistan.

v. A copy of test/analysis report was sent to M/s Munawar Pharma (Pvt) Ltd., 31-km 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 reports 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 request, the Provincial Quality Control Board in its 14th committee meeting held on 17-12-2020, after due deliberation unanimously decided to turn down the firm's request for retesting of the subject sample.

Previous Proceedings & Decision by the Board: (Regarding Retesting of the Firm)

14th committee meeting held on 17-12-2020

2. The subject retesting request was considered in 14th committee meeting dated 17-12-2020. The committee after scrutiny of the record observed that the firm requested for retesting of drug in PQCB after a lapse of 77 days whereas according to Section 22 (4) of The Drugs Act 1976, as amended the firm is bound to file its request for retesting of drug sample within stipulated time of 10 days. Hence, the Committee after due deliberation decided to turn down the subject request for retesting of the drug sample being time-barred.

3. 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**

4. Show-cause notice(s) issued to accused person(s) dated 02-11-2022

Firm replied to the show cause notice vide letter dated 17-11-2022

Keeping all our legal rights and remedies intact. Despite strong reservation/s on the proceedings of this case till date, conclusiveness of the alleged report and decision of the most honorable Provincial quality Control Board-Punjab of turning down our request for re-testing of sample, merely on the basis of being time barred, without taking in consideration the ***delay of almost more than (09) nine Months by concerned drug inspector in communicating the above said report of Drugs Testing Laboratory*** *and was delivered to our office's gate on 26-03-2022 which was the start of most unusual and unfortunate Lock down of the entire world including Pakistan. Your kind office and the office of the Drug Controller/Drug Inspector, Mandi Bahauddin were also* ***under lock down, due to Covid-19 Pandenmic*** *which was a rare Catastrophe and one of the worst disaster of known recent history.*

It is humbly submitted that at least 02 reports of Standard Quality, by statutory Drugs Testing Laboratories of same batch No. FP 95. ***We have also replaced stock*** *with batch No. FP 96 which was* ***declared of Standard Quality*** *by Drugs Testing Laboratory on 27 April 2020. Hence causing no loss to Government's Exchequer.*

We most humbly request to your good self and the concerned Drugs Inspector sahib to provide complete record, as a right entrusted to us under "Transparency and Right to information Act, 2013, Relying upon very little information, we have. Below mentioned are few more facts of this case. Others may be highlighted later, if required The Batch was released after declaration of being of Standard Quality by our Quality Control Department.

We have provided your kind office (Provincial Quality Control Board, Punjab-Lahore) Complete records of Evidences in contravention of Government Analyst's Report in question, vide our letter Dated:10-07-2020, received in your office on 13-07-2020, which included the following documents

1) Finished Product Specification.

2) Method of Analysis with limits.

3) Warrantor Portion Analysis Report.

4) Q.C. Retain Sample Analysis Report

5) Complete Batch Analysis Report (finished product).

6) Particle Count Report of Retained Sample.

7) Particle Count Report of Warrantor Portion.

8) In Process Quality Control Tests Performed.

9) Optical Checking Record.

. In response to letter from the then Honorable Secretary, Provincial Quality Control Board, Punjab-

Lahore No. PQCB/P-622-6/2019,) DATED 29-June 2020. Which all must be part of our file

for this case, lying with your kind office.

All the attached and already submitted Documentary Evidences speak loud and Clear about Standard Quality of our manufactured Product, our good intention and Innocence in this case. The said report declares THAT the sample as SUB-STANDARD, AS DEFINED IN THE DRUGS ACT, 1976 AND sub-section (zz) of Section 3 of Drugs Act, 1976, substituted by sub-section (z-d) defines

"Sub-Standard drug" as follows

"Sub-Standard drug" means a drug which is not of specification. SPECIFICATION is defined as follows

()"Specifications" when applied to a drug mean-

i. *Such specifications as may be prescribed; or*
ii. *When the specifications are not prescribed, the specifications as contained in the most recent edition of any of the following publications, namely: -*

(1) The Pakistan Pharmacopoeia;

(2) The lnternational Pharmacopoeia;

(3) The European Pharmacopoeia,

(4) The United States Pharmacopoeia;

(5) The British Pharmacopoeia;

(6) The British Pharmaceutical Codex;

(7) The United States National Formulary; and

(8) Such other publication as may be prescribed:

Furthermore, Section 2 of Drugs Specifications Rules, 1978 also says the same and defines "Specifications":

The specifications for the classes of drugs specified in column I of the Schedule shall be those specified against those drugs in Column 2 of the Schedule

The report in question and our label, documents etc., clearly states that ***product in question is manufactured according to USP, whereas at point No. 06 of the report in question as "Result of test/analysis with specifications applied BP/USP****.*

Which is clear cut violation of Sub-Section (zz) amended as (z-d) of Drugs Act, 1976 and Drugs Specification Rules, 1978.

You are hereby requested to please look into the case sympathetically and drop this case as

ab-initio and non-maintainable,

Hope the above submissions satisfies the honorable Provincial Quality Control Board, Punjab regarding this case and our request for dropping of this case as being innocent, if not You are further requested to please give us a chance of being heard in person.

Looking forward to favorable response and assuring you of our complete co-operation, we remain.

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: Apr 2019

Expiry Date: March-2021

Sampling Date (Form 4): 15-05-2019

Sent to DTL (Form 6): 15-05-2019

Date of receipt in DTL: 20-05-2019

DTL Report Date (Form 7): 28-06-2019

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 16-03-2020

Retesting Request of Firm: Yes

Fate of Retesting Request of the Firm: Turned Down in 14th Committee Meeting dated 17-12-2020

Investigation Report Dated: 23-07-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 5

PQCB/R-196,197/2022

Tehsil & District Vehari

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan** through CEO Syed Nophil Rizvi 2. Syed Nophil Rizvi — Chief Executive Officer (CEO) 3. Kamran Awan — Production Incharge 4. Muhammad Fakhir Khaleeq — Quality Control Incharge/ Warrantor of M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan

BRIEF FACTS OF THE CASE:

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

i. She, on 11-08-2022 inspected Main Medicine Store CEO DHA Vehari, and took both drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan vides memorandum no**.** 136410 dated 11-08-2022 and 136527 dated 12-08-2022.

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

<table>
<tr><th>Sr. No</th><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>TRA No & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>1</td><td>Suspension Macrobac 15ml [Azithyromycin (as dihydrate): 200mg/5ml] Mfg. Date: 04/2022
Exp. Date: 04/2024
Regn. No.: 082215</td><td>S0540</td><td>M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan</td><td>No. 01-94005253 dated 11-10-2022</td><td><u>Results of test/analysis with specifications applied:</u> USP 2022
<u>DESCRIPTION:</u> White color powder (when reconstituted forms pink color suspension), contained in white colored labelled plastic bottle sealed with plastic screw cap, packed in a labelled outer hard carton along with leaflet and plastic spoon.
<u>IDENTIFICATION:</u> Azithromycin Dihydrate identified
<u>ASSAY: Azithromycin</u>
Analysis Method: HPLC
<table><tr><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr><tr><td>200mg/5ml</td><td>187.44mg/5ml</td><td>90-110%</td><td>93.72%</td></tr></table>Complies
<u>pH:</u>
Stated: 8.5-11.0
Determined: 8.22 Does not comply
RESULT: The above sample is Substandard on the basis of pH Test</td></tr>
<tr><td>2</td><td>Suspension Macrobac 15ml [Azithyromycin (as dihydrate): 200mg/5ml]
Mfg. Date: 04/2022
Exp. Date: 04/2024
Regn. No.: 082215</td><td>S0541</td><td>M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan</td><td>No. 01-94005254 dated 11-10-2022</td><td><u>Results of test/analysis with specifications applied:</u> USP 2022
<u>DESCRIPTION:</u> White color powder (when reconstituted forms pink color suspension), contained in white colored labelled plastic bottle sealed with plastic screw cap, packed in a labelled outer hard carton along with leaflet and plastic spoon.
<u>IDENTIFICATION:</u> Azithromycin Dihydrate identified
<u>ASSAY: Azithromycin</u>
Analysis Method: HPLC
<table><tr><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr><tr><td>200mg/5ml</td><td>218.12mg/5ml</td><td>90-110%</td><td>109.06%</td></tr></table>Complies
<u>pH:</u>
Stated: 8.5-11.0
Determined: 8.25 Does not comply
<u>RESULT</u>: The above sample is Substandard on the basis of pH Test</td></tr>
</table>

iii. Storekeeper Main Medicine Store CEO DHA Vehari provided Invoice/ warranty No. 0000005571 dated 07-06-2022 issued by M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.

iv. Warrantor Portions of subject batches of drug sample were sent to M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.

v. Copies of Test/ Analysis reports were sent to M/s Asian Continental Pvt Limited; D-32 SITE II Super Highway Karachi; Pakistan and they were directed to provide requisite information in this regard.

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

i. **Manufacture for sale/ sale of Substandard drug**

ii. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused dated 22-12-2022

Firm's reply of show-cause notice dated 10-02-2023

This is with reference to your letter No. PQCB/R-196,197/2022 dated 22-12-2023

As per your letter, it has been informed that the subject drug sample withdrawn has been declared as "SUBSTANDARD" by Government Analyst, DTL Multan vide Report No. TRA 01-94005253 dated 11-10- 2022 B.NO. S0540 and Report No. 01-94005254 dated 11-10-2022 B,No. S0541

Along with documents, you have required us to explain our position for manufacturing, stocking selling of substandard drugs and you have also required us to verify the names of accused persons and also requested to submit the attested documents for board consideration.

In response thereto, we state as follow:

- *That letter No.293/DC dated 26-10-2022 and letter No, 316/DC dated 05-11-2022 from Provincial Inspector of Drugs tehsil Vehari were received to us on dated 01-11-2022 and 10-11-2022 and same were replied on dated 03-11-2022 & 11-11-2022 respectively with required information and documentations and confirmed that questioned product after cross checked of all quality parameters is of standard quality*
- *With regards to above said show cause notice, our justifications and clarifications are as followed:*
- *Please note that we have received the Warrantor Portion Sample of our product Macrobac 200 mg/ 5 ml. Suspension along with letter no. 271/DC dated 15-10-2022 on dated 27-10-2022: however, we have analyzed the Warrantor Portion Sample of Batch No. S0546 along with the retention sample of the same batch and found that our product is of STANDARD QUALITY with respect to prescribed parameters of physical characteristics, assay, and pH.*
- *It is pertinent to mention here that the product in question is dry powder suspension of Azithromycin as Dihydrate, which is reconstituted with water to form liquid suspension dosage form. The pH of the suspension is dependent upon proper reconstitution of the formulation with water. In case the dry powder is not properly mixed in water, it may sediment and alter the pH value, which is evident from the report of DTL Multan as the pH value of a batch is slightly lower than the specified limits. If the Govt. Analyst properly reconstitute the suspension and took the pH after removal of air bubbles the desired value of pH may be attained.*
- *Even though we totally unaccepting the DTL Multan Testing report <u>we are not requesting for the retest</u> of the batches in question and going to replace batch with the fresh stock as an act of curtesy and grace.*

Based on above facts it is evident that this is the borderline case, therefore, it is humbly requested to

take a kind decision and the case may please be closed amicably and fairly with formal

<u>Summary:</u>

Manufacturing Date: 04-2022

Expiry Date: 04-2024

Sampling Date: 11-08-2022

Sent to DTL (Form 6): 11-08-2022

Date of receipt in DTL: 13-08-2022

DTL Report Date: 11-10-2022

1ST DI Communication with firm on dated: 26-10-2022

Date of Retesting Request of Firm: No

Investigation Report Dated: 18-11-2022

4**.** Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023

Case is placed before the Board for Decision

<u>CURRENT PROCEEDINGS & DECISION BY THE BOARD:</u>

Case No. 6

PQCB/ R-693/2020

Benazir Bhutto Hospital, Rawalpindi

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B, Industrial Area, Karachi-Pakistan** through its Directors Muhammad Nazar Talib and Muzamil Nazar 2. Muhammad Nazar Talib Director 3. Muzamil Nazar Director 4. Ghulam Nabi Khoso Production Incharge 5. Naima Khanam Quality Control Incharge/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, Benazir Bhutto Hospital, Rawalpindi reported that:-

i. Her predecessor, on 01-01-2020 inspected the premises of Main Medical Store, Liquid Section, Benazir Bhutto Hospital Rawalpindi and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, **Rawalpindi** vide memo no**.** 55042 dated 01-01-2020.

ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Suspension Flyzol 60mL Suspension [Benzoylmetronidazole eq. to Metronidazole…200mg/5ml] Mfg. Date:12-2019 Exp. Date:12-2021 Reg# 025017	112-19	M/s Lisko Pakistan (Pvt.) Ltd, L-10-D Block-21, F.B Industrial Area, Karachi.	01-67000783/ DTL dated: 29 Feb 2020	**Result of test/ analysis with specifications applied IP 2019** **PHYSICAL DESCRIPTION:** Yellow colured suspension filled in amber colored glass bottle with affixed label, sealed with white colored aluminium screw cap imprinted with company name, further packed in outer unit carton. **pH** Observed: **4.753 (Does not comply)** Limit: 5.0-6.5 **(IP)** **IDENTIFICATION** Benzoylmetronidazole Identified. **ASSAY:** Stated: 200mg/5ml Determined: 205.773mg/5ml Percentage 102.89% LIMIT: 90-110% (IP) **RESULT:** **The above sample is Substandard on the basis of pH test performed.**

iii. The Store Keeper of Main Medical Store, Liquid Section, Benazir Bhutto Hospital Rawalpindi provided invoice/warranty bearing No. 000451 dated 30-12-2019 issued by M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B, Industrial Area, Karachi-Pakistan.

iv. Warrantor Portion 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 and they were directed to provide requisite information in this regard. In response the firm requested for retesting of subject drug sample from Appellate laboratory, National Institute of Health (NIH), Islamabad. But the request of the firm was turned down by the Committee of Provincial Quality Control Board in its15th meeting dated 10-04-2021.

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: -

i. **Manufacturing for Sale /Selling of Substandard drug**
ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s) dated 30.12.2022.

4. Personal Hearing notice(s) issued to accused person(s) dated 18.05.2023.

Case is placed before the Board for decision.

Summary:

Manufacturing Date: 12-2019

Expiry Date: 12-2021

Sampling Date: 01-01-2020

Sent to DTL (Form 6): 01-01-2020

Date of receipt in DTL: 01-01-2020

DTL Report Date: 29-02-2020

Time Extension: N/A

1ST DI Communication with firm on dated: 08-01-2020

Date of Retesting Request of Firm: -04-05-2020

Fate of Retesting Request: -Turned down in 15th Committee Meeting dated 10-04-2021

Investigation Report Dated: 01-09-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 7

PQCB/ R-711/2019

Government Medical Store Depot, Punjab

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan** through its Managing Director, Nadeem Panjatan 2. Nadeem Panjatan Managing Director 3. Zamir-ul-Hassan Production Incharge 4. Sohail Aslam Quality Control Incharge 5. Waheed Shah Warrantor of M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan

ORDER SHEET

IN THE LAHORE HIGH COURT

LAHORE

JUDICIAL DEPARTMENT

Case No: W.P. No.55861/2022.

M/S Global Pharmaceuticals Pvt. Ltd. Vs Provincial Quality Control Board Punjab and others

Date of Order: 09-02-2023

For the reasons recorded in my detailed order of even date passed in connected petition W.P.No. 54146 of 2021 the instant petition is allowed.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Government Medical Store Depot, Gurumangat Road, Gulberg III Lahore, reported that: -

i. He, on 06-07-2019 inspected the premises of IRMNCH warehouse, Maraka, Lahore, and took drug samples of eighteen different types of drugs on Form No. 4 for the purpose of test/analysis.

ii. Three out of eighteen drug samples after test/ analysis were 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. Transolide Inj. [Tranexamic Acid 500mg/5ml]	19A038	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.	01-25004192/DTL dated: 26 Aug 2019	**Result of test/ analysis with specifications applied:** MS/BP 2018 **COMPOSITION:** Each 5ml contains: Tranexamic Acid ….. 500mg **DESCRIPTION (MS):** Colorless solution, filled in transparent glass printed ampoule (stated ampoule: 5mL). 01 out of 20 ampoules containing undissolvable visible particulate matter **(Does not comply with the parenteral specifications)** **Volume (BP) :** Limit: Not less than nominal (5ml) Determined: 5mL **pH (BP):** Limit: 6.5-8.0 Determined: 7.478 **Sterility (BP):** The product is sterile. **Identification (MS):** Tranexamic Acid is identified **Assay (MS):** Tranexamic Acid Stated: 500mg/5ml Determined: 514.83mg/5ml Percentage: 102.96% Limit: 90-105% **Result:** The sample is **Substandard** on the basis of Physical Test

iii. Store Incharge, IRMNCH warehouse, Maraka provided Warranty bearing No. 501874 dated 03-06-2019 issued by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan as proof of its purchase.

iv. Warrantor Portion of drug sample was sent to M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.

v. 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 and they were directed to provide requisite information in this regard.

Firm's Review for the Retesting Requests for the above mentioned three batches has already been turned down in 229-M dated 02-02-2021

The subject review petition was considered by the Provincial Quality Control Board (PQCB) under section 22 of the Drugs Act 1976 in its 229th meeting held on 02-02-2021.

Keeping in view the facts of the case, the Board was of the considered opinion that there is no need of further analysis and it should be considered as evidence that particulate matter is present. Furthermore, it is prerequisite for Injectable preparations that each and every unit of injectable should be free from particulate matter and should be checked before marketing. Even only one injection that has to be administered to a single human being, if it is not free from particulate matter, it consists a potential hazard thus, rendering it a safety risk.

*In view of above, the Board after due deliberation unanimously decided to **uphold** its previous decision taken in **213th** dated **16-11-19** and turn **down** the subject Review Petition of the firm.*

The Board further decided to direct the Drug Inspector concerned to expedite investigation in subject case and submit final report for consideration by the Board.

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: -

i. **Manufacturing for Sale /Selling of Substandard drug**

ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s)

Reply of the Firm to the Show Cause Notice:

All three batches after testing by the Government Analyst, Drug Testing Laboratory of Bahawalpur, purporting to declare sample of the subjected Drug Product as Substandard due to the visible particulate matter and product does not comply with the Parenteral Specifications.

In this context, we applied our request to PQCB to send the samples of said batches to Appellate Laboratory NIH for retesting as report of Government Analyst was controverted. This This application was sent along with evidences including retesting report of aforementioned batches, which were complying with the specifications but the request was declined by PQCB.

Global pharmaceuticals (Pvt) limited also recalled all three batches as a gesture of Goodwill through a public notice in Newspaper dated 20-01-2020 keeping in view the patient safety and in compliance with directions of PQCB. Now all three batches have been expired and still under control of IRMNCH Warehouse Maraka, Punjab Government Depot.

In view of below mentioned aspects we request the honorable board to dissolve this case because:

1. *Global Pharmaceuticals Islamabad is well reputed company working within the legal framework of the DRAP Act 2012, Drugs Act 1976 and rules frame there under. The company is firm in its commitment to quality and adherence to high standards/cGMP guidelines to meet the high expectations of patients as well well as healthcare providers at national and international level. Global Pharmaceuticals has never been convicted under any law including the Drugs Law prevailing in Pakistan.*
2. ***We have already recalled all three batches in compliance with the directions of PQCB and in view of the patient safety through a public notice in Newspaper dated 20-01-2020 (Attached)***
3. ***These batches are manufactured for Punjab Government only and supplied to IRMNCH Maraka. These are still under custody of said warehouse.***
4. ***These batches did not supply to private market, so all stock is placed under government custody as a case property.***
5. ***We were not even given our right of retest the said batches from Appellate lab (NIH) as per Drug Act 1976.***
6. ***All batches have been expired and will be disposed of. It is added that no payment has been received against these three batches.***

However, to fulfill your requirements we are providing the required information including Drug Registration certificate and CNIC copies of Managing director and Technical Staff as per your letter No. PQCB/R-711,712,713/2019

1) Nadeem Panjatan (Managing Director)

CNIC # 42101-1397557-5

Personal Address: House # 102, Street #60, Sector G-9/4, Islamabad.

2) Dr. Zamir ul Hassan (Production Incharge) NIC # 38302-1188338-9 Personal Address: House # 797, Street # 50, Sector 1-1/10, Islamabad.

3) Sohail Aslam (QC Incharge) NIC # 35200-4965749-1 Personal Address: House # 239A, Street # 14A. Block B, PWD Housing Society Islamabad.

We are always available for the further required support, if any.

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **235th meeting** held on **30-11-2021**. Mr. Hassan Saeed, Secretary DQCB, District Lahore and Mr. Ubaid Ullah Anwer, Provincial Inspector of Drugs, Government Medical Store Depot, Punjab was present along with the original case record. Among the nominated accused persons, Dr. Zamir-ul-Hassan (COO/Managing Director) along with Sohail Aslam, Representative of M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan appeared before the Board. Representatives of the firm presented following arguments in their case:

i. Global pharmaceuticals (Pvt) limited also recalled all three batches as a gesture of Goodwill through a public notice in Newspaper dated 20-01-2020 keeping in view the patient safety and in

compliance with directions of PQCB.

ii. These batches are manufactured for Punjab Government only and supplied to IRMNCH Maraka. These are still under custody of said warehouse.

iii. These batches were not supplied to the private market, so all stock is placed under government custody as a case property.

iv. All batches have been expired and will be disposed of. It is added that no payment has been received against these three batches.

6. The Board after careful perusal of the case record and scrutiny of DTL report observed that the above mentioned three batches of the subject drug sample have been declared Substandard by the Drug Testing Laboratory, Bahawalpur on the basis of the Physical Test i.e. the three batches 19A038, 19C053 & 19C051 of the Injection Transolide (Tranexamic Acid 500mg/5ml) contain undissolvable visible particulate matter which does not comply with the parenteral drug specifications.

7. The Board expressed great concern on the presence of particles in the subject drug samples as an injectable preparation is intended to be administered directly into the blood and the presence of such particles could result in serious harmful effects. Such visible particulate matter can be a potent source of blockage of minute vessels and capillaries hence causing obstruction of normal blood supply so all such drug products intended for parenteral purpose must be virtually free from any such kind of particles. Moreover, the appearance of varying numbers of visible particulate matter in only twenty ampoules of each batch implies the certainty of presence of more number of particles in the larger bulk of stock. Such particle containing parenteral drugs, when injected to patients, may cause anaphylactic shock, brain stroke, blockage of the coronary artery, paralysis, pulmonary embolism and death, based upon the number of particles and particle size. Hence, keeping in view the foregoing facts, the Board after due deliberation & discussion, unanimously decided to grant the drug inspector **permission for prosecution** for **M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan** against the following accused persons in the drug court:

6. **M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan** through its Managing Director, Nadeem Panjatan
7. Nadeem Panjatan — Managing Director
8. Zamir-ul-Hassan — Production Incharge
9. Sohail Aslam — Quality Control Incharge
10. Waheed Shah — Warrantor

of M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.

For the offences of:

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

b. **Issuance of false warranty**

8. The firm filed Review Petition vide letter No. REF/GP/080/DTL/22against the orders no. PQCB/R-711,712,713/2019 dated 30-11-2021, which was referred back by the Provincial Quality Control Board office in compliance to directions from the drug Court, Lahore dated 25-08-2021 and subsequent decision of the Committee of Provincial Quality Control Board in its 19th meeting dated 21-10-2021.

REVIEW PETITION:

Subject: Review petition against the orders no. POCBR-711,712,713-/2019 dated 30-11-2021 in case of Substandard Injection Transolide 500mg/5ml (Tranexamic Acid) Batch No. 19A038, 19C053, 19CO51, Mfg. By M/S Global Pharmaceuticals, (Pvt.) Ltd, plot No. 204- 205 Industrial Triangle, Kahuta Road, Islamabad.

Brief facts of the case are as under;

a- That provincial inspector of MSD, Gurumangat road. Gulberg-III Lahore 07-07-2019 took the samples of different types of Drugs from the premises if IRMNCH warehouse, Maraka, Lahore on form 4 for the purpose of test/analysis.
b- That the following drug samples after test analysis were declared as Substandard by the Government Analyst DTL, Bahawalpur vide test report # TRA 01-25004192/DTL dated 26-8- 2019, 01-25004 194/DTL dated 26-8-2019 and 01-25004196/DTL dated 26-8-2019 respectively.

c- That the reason of Substandard mentioned on the test reports are as under;
1- **Batch no. 194038** "colourless solution filled in transparent glass printed ampoule (stated volume 5ml). 01 out of 20 ampoules containing undissolvable visible particulate matter (does not comply with the parenteral specifications) "
2- **Batch no. 19C053** "colorless solution filled in transparent glass printed ampoule (stated volume 5ml). 04 out of 20 ampoules containing undissolvable visible particulate matter (does not comply with the parenteral specifications) "
3- **Batch no. 19C051** "colorless solution filled in transparent glass printed ampoule (stated volume 5ml). 02 out of 20 ampoules containing undissolvable visible particulate matter (does not comply with the parenteral specifications) "

4- That all other tests such as Volume, pH, sterility test, and Assay results are within mandated specifications.
5- That after the receipt of above said test reports from Drug inspector, we submitted our reply vide letter no. REF/GP/069/DTL/19 dated 19-9-2019 (copy attached as Annexure 1), O wherein we shown our distrust on DTL reports and requested you to proceed for retesting of the PQCB's portion of samples from the appellate Lab of NIH, Islamabad as provided under section 22(4) of the Drug Act 1976 and rules framed there under.
6- That in response to your personal hearing notice no. PQCB/P-901-08/19 dated 04-11-2019; we attended the meeting of the Board on 16-11-2019 and argued for justification of request of retesting of the said drug samples from NIH Islamabad. (Earlier meeting of the Board on 12-10-2019 was postponed).
7- That the Board turned down our request of retesting in its 213th meeting held on 16-11-2019 vide order no. P¿CB/P-901-08/19 dated 16-11-2019.
8- That we recalled all batches through a public notice in newspaper dated 20-01-2020
9- That we submitted a review petition in the Board vide our petition no. Global P-901-08/19- RP-2020/04 dated 25-01-2020, against the decision of the Board, rejecting the request of retesting vide order no. PQCB/P-901-08/19 dated 16-11-2019.
10-That in response to your personal hearing notice no. PQCB/P-900-8/2019 dated 25-01-2021; we attended the meeting of the Board on 02-02-2021 with regards to review petition.

11- That the Board turned down the review petition of retesting in its 229th meeting vide order no. PQCB/P-901-08/2019 dated 02-02-2021, issued on 15-03-2021.
12- That after several proceedings, Board decided to grant permission for prosecution in its 235th meeting held on 30-11-2021 vide order no. POCB/R-711,712, 713-/2019 dated 30-11- 2021 received in Global Pharmaceuticals on 10-01-2022. We intend to submit.
13-That the substandard results are based on the presence of particulate matter. Particles of varying sizes have been observed in inject-able products, such as visible and sub visible. The particles of 01-50 micron size are known as sub visible particles and particles of more than 50 micron are considered as visible particles, But, without ascertaining the nature, composition and foreign source of particle or un-dissolvable visible particulate matter, injurious to health or not, the prosecution order has been issued on the basis of said Test Reports, which are unlawful without jurisdiction, the crucial question for legality of similar reports was evaluated in depth by honourable division bench of honourable Lahore High Court in case of PQCB vs Irza pharma reported as I992 MLD 481. What is meant by Analyst when it is reported that the samples of Drugs manufactured by the respondent conformed to the stated specifications chemically but did not conformed to the physical specifications of injection being adulterated with particles. The definitions of "Adulterated drug", spurious and substandard Drug as given in section 3 of the Drug Act 1976 were explained. It was held that

a) if 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 Drug Act and that is true.
c) There was nothing on the record to show, as to what is the nature of the particles found in 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 Drug Act 1976, the drugs tested and reported, fell outside the category of definitions of substandard, spurious and adulterated drugs.
14- That the above results have shown in a crystal clear manner that the sample of Injection a) Transolide 500mg/5ml (Tranexamic Acid\ Batch no. 19C051 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 99.03% which is with in pharmacopoeia limit of 90-105%. *A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 02 out of 20 ampoules containing undissolvable visible particulate matter" without stating its nature/composition and consequence in terms of "injurious to health'. Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183.
b) Transolide 500mg/5ml (Tranexamic Acid) Batch no. 19C053 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 98.25% which is within pharmacopoeia limit of 90-105%. “A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 04 out of 20 ampoules containing stating its undissolvable visible without matter* particulate nature/composition and consequence in terms of "Injurious to health". Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183.
c) Transolide 500mg/5ml (Tranexamic Acid) Batch no 19A038 is standard quality because it has been determined in chemical assay that

therapeutic ingredient Tranexamic Acid is 102.96%o which is within pharmacopoeia limit of 90-105%. “A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 01 out of 20 ampoules without matter" stating it’s containing undissolvable visible particulate nature/composition and consequence in terms of "Injurious to health". Reliance on 1992 MLD 481 1992. 1996 PCr. LJ I183.

15. That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19C051 had been declared as of standard quality by the report dated 21- 08-2019 of DTL Rawalpindi, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.

That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19C053 had been declared as of standard quality by the report dated 10- 08-2019 of DTL Rawalpindi, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.

That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19A038 had been declared as of standard quality by the report dated 06- 05-2019 of DTL Multan, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.

16. That the absence of the full protocols of test in the above is crystal clear violation of Drug Laws. Reports of Analyst have to be conclusive and must disclose the protocols of tests applied to formulate opinion of Government Analyst. The description of the testing procedure must be crystal clear whenever report would be disputed.

Reliance on PLD 2003 Lahore

17. That noncompliance to section 19(3) related to statutory of sending warrantor's portion within seven days, is an illegality. The warrantor's portion has not been sent to the manufacturer within statutory period of seven days as prescribed under section 19(3) (iv) of the Drug Act 1976 and rules framed there under. The non-observance to said procedure is highly doubtful and is an illegality, recently, the PQCB has unanimously dropped a case no. PQCB-R577-09/2016 related to infusion Dorcep Batch no. DC-075 declared as Adulterated and substandard by the Government Analyst DTL Rawalpindi vide DTL report no. 1077/DTL dated 22-09-20 16. The PQCB has observed that this case was fit for prosecution on the basis of report. But, this case was dropped as PQCB had observed that the case would fail in court because warrantor portion was not sent to the manufacturer within statutory period as prescribed under section 19(3)(iv) of the Drug Act 1976 and rules framed there under.

18. That whole quantity of said batches of said drug was supplied to IRMNCH warehouse, Maraka, Lahore and not a single unit of the injection had been used by the institution. All supplied injections are lying and expired in the main Medicine store of IRMNCH warehouse, Maraka, Lahore.

19. That not a single unit of said drug has been supplied in the market, even then we recalled all batches through a public notice in newspaper dated 20-01-2020.

20. That no adverse consequence about said drug is on record.

21. That the drug in question is of standard quality with regards to assay, sterility test, and other physical parameters and thus there is no risk on the use of drug for patients.

22. That in the impugned order has been passed contravene to 1992 MLD 481 Lahore title PQCB and others versus Irza pharma and others in which Hon'ble Court has declared such report against the law which is on the basis of on physical observation o undissolved visible particles. In the reliance Hon'ble Lahore High Court has observed that the size of the particle would have been determine that whether it may be injurious to health or not. In this context. It is further necessary to mention here that Board itself has directed to Director DTL Punjab through written letter in the year 1990.

23. That the said test reports are incomplete, non-conclusive and illegal and thus the same are not admissible evidence in the eye of Law.

PRAY

It is therefore, respectfully prayed that by accepting this review petition for subject captioned impugned order dated 30-11-2021, passed by the P¿CB, Punjab may very kindly be set aside by exercising powers of review jurisdiction as well as in the light of orders passed by Hon'ble Lahore High Court, Lahore in the interest of justice.

It is further prayed that the concerned Drug Inspector may very kindly be directed not to put up the case before the concerned Drug Court till the final disposal of the review petition in hand.

9. The firm resubmitted their Review Petition vide letter No. REF/GP/087/DTL/22 dated 02-02-2022.

10. M/S Global Pharmaceuticals (Pvt.) Ltd filed Writ Petition No. 55861/2022 with The Lahore High Court, Lahore.

This constitutional as well as connected petitions W.P.No.58149 of 202 1, W.P.No.58154 of 2021,.W.P.No.52668 of 2022,W.P.No.6056 of 2022.,W.P.No.55855 of 2022, W.P.No.55861 of 2022. W.P.No.55869 of 2022, W.PNo.42185 of 2022 and W.P.No.10009 of 2022 raise a common question of law. They have laid a challenge to the order dated 25.4.202 1 passed by the Drug Court, Lahore which is to the following effect:

"In view of the above circumstances, court is of the view that powers used by the PQCB in the light of said notification dated 3.5.2022 and issuance of warning to the accused persons is illegal and unlawful because, in the Drugs Act, I976 and Punjab Drugs Rules 2007, there, is no (http://is.no/) provision or section which empowers the Board to review or revision so that illegal practice which was started since 2002 till today has no legal cover rather the same is based on unlawful. Order passed by the Board under the shadow of notification dated 3.5. 2022 is without legal authority in these cases and the same is declared illegal and Unlawful. Secretary PQCB is directed in the light of said order to collect the data of all the cases which are decided by the Board and to proceed in accordance with law; he is further directed to produce report before the Court."

3. In the connected petitions either the same order has been passed or an order of similar nature has been passed which primarily sets aside the Notification dated 3.5.2022 and declares it to be ultra vires the powers of Punjab Quality Control Board (PQCB). By that Notification certain regulations called "The Provincial Quality Control Board Regulations, 2001 have been enacted' under Section 11 of the Drugs Act, 1976. By the impugned order, the Drug Court, Lahore was of the opinion that this was outwith the power of PQCB and was not envisaged by the provisions of cither Drugs Act, 1976 or the Punjab Drugs Rules, 2007. Suffice to say that the power of judicial review of subordinate legislation as well as primary legislation vests in the superior courts and cannot be exercised by the subordinate courts including the Drug Court. No such power vests with the Drug Court under the Act, 1976. Although the Drug Court has declared the Notification as having been issued illegally, yet it did not advert to the question whether the Drug Court itself had the power to make such a declaration or not. The impugned order is, therefore, set aside and the matter shall be deemed pending with the Drug Court for decision in accordance with law from the stage that the impugned order was passed. Petitions allowed.

11. Personal Hearing notice(s) issued to accused person(s) vide dated 26-04-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

12. Case was considered by the Provincial Quality Control Board, under Section 11 of the Drugs Act 1976 in its **260th meeting** held on **04-05-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Mr. Hassan Saeed, Secretary, DQCB Lahore and Mr. Ubaid Ullah Anwer, Drug Inspector Government medical Store Depot, Lahore were present along with the original case record

13. Secretary Provincial Quality Control Board apprised the Board that the firm had submitted request for adjournment Vide letter No. Ref/GP/051/DTL/23 dated 28.04.2023. The Board, after due deliberation and detailed discussion, unanimously decided to **adjourn the case** of **M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad**, and to provide another opportunity of personal hearing in the best interest of justice.

11. Personal Hearing notice(s) issued to accused person(s) vide dated 18-05-2023.

Case is placed before the Board for decision.

Summary:

Manufacturing Date: 01-2019 (B. 19A038), 03-2019 (B. 19C051,19C053)

Expiry Date: 06-2021(B. 19A038),08-2021 (B. 19C051,19C053)

Sampling Date: 06-07-2019

Sent to DTL (Form 6): 11-07-2019

Date of receipt in DTL: 13-07-2019

DTL Report Date: 26-08-2019

Time Extension: N/A

1ST DI Communication with firm on dated: 30-08-2019

Date of Retesting Request of Firm: -19-09-2019

Fate of Retesting Request: -Turned down in 213th-M dated 16-11-2019

Investigation Report Dated: 22-11-2021

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 8

PQCB/ R-712,713/2019

Government Medical Store Depot, Punjab

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan** through its Managing Director, Nadeem Panjatan 2. Nadeem Panjatan Managing Director 3. Zamir-ul-Hassan Production Incharge 4. Sohail Aslam Quality Control Incharge 5. Waheed Shah Warrantor of M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan

ORDER SHEET

IN THE LAHORE HIGH COURT

LAHORE

JUDICIAL DEPARTMENT

Case No: W.P. No.55861/2022.

M/S Global Pharmaceuticals Pvt. Ltd. Vs Provincial Quality Control Board Punjab and others

Date of Order: 09-02-2023

For the reasons recorded in my detailed order of even date passed in connected petition W.P.No. 54146 of 2021 the instant petition is allowed.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Government Medical Store Depot, Gurumangat Road, Gulberg III Lahore, reported that: -

i. He, on 06-07-2019 inspected the premises of IRMNCH warehouse, Maraka, Lahore, and took drug samples of eighteen different types of drugs on Form No. 4 for the purpose of test/analysis.

ii. Three out of eighteen drug samples after test/ analysis were 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. Transolide Inj. [Tranexamic Acid 500mg/5ml]	19C053	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.	01-25004194/DTL dated: 26 Aug 2019	**Result of test/ analysis with specifications applied:** MS/BP 2018 **COMPOSITION:** Each 5ml contains: Tranexamic Acid ….. 500mg **DESCRIPTION (MS):** Colorless solution, filled in transparent glass printed ampoule (stated ampoule: 5mL). 01 out of 20 ampoules containing undissolvable visible particulate matter **(Does not comply with the parenteral specifications)** **Volume (BP) :** Limit: Not less than nominal (5ml) Determined: 5mL **pH (BP):** Limit: 6.5-8.0 Determined: 7.508 **Sterility (BP):** The product is sterile. **Identification (MS):** Tranexamic Acid is identified **Assay (MS):** Tranexamic Acid Stated: 500mg/5ml Determined: 491.25mg/5ml Percentage: 98.25% Limit: 90-105% **Result:** The sample is **Substandard** on the basis of Physical Test
Injection. Transolide Inj. [Tranexamic Acid 500mg/5ml]	19C051	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.	01-25004196/DTL dated: 26 Aug 2019	**Result of test/ analysis with specifications applied:** MS/BP 2018 **COMPOSITION:** Each 5ml contains: Tranexamic Acid ….. 500mg **DESCRIPTION (MS):** Colorless solution, filled in transparent glass printed ampoule (stated ampoule: 5mL). 01 out of 20 ampoules containing undissolvable visible particulate matter **(Does not comply with the parenteral specifications)** **Volume (BP) :** Limit: Not less than nominal (5ml) Determined: 5mL **pH (BP):** Limit: 6.5-8.0 Determined: 7.47 **Sterility (BP):** The product is sterile. **Identification (MS):** Tranexamic Acid is identified **Assay (MS):** Tranexamic Acid Stated: 500mg/5ml Determined: 495.18mg/5ml Percentage: 99.03% Limit: 90-105% **Result:** The sample is **Substandard** on the basis of Physical Test

iii. Store Incharge, IRMNCH warehouse, Maraka provided Warranty bearing No. 501874 dated 03-06-2019 issued by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan as proof of its purchase.

iv. Warrantor Portion of drug sample was sent to M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.

v. 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 and they were directed to provide requisite information in this regard.

Firm's Review for the Retesting Requests for the above mentioned three batches has already been turned down in 229-M dated 02-02-2021

The subject review petition was considered by the Provincial Quality Control Board (PQCB) under section 22 of the Drugs Act 1976 in its 229th meeting held on 02-02-2021.

Keeping in view the facts of the case, the Board was of the considered opinion that there is no need of further analysis and it should be considered as evidence that particulate matter is present. Furthermore, it is prerequisite for Injectable preparations that each and every unit of injectable should be free from particulate matter and should be checked before marketing. Even only one injection that has to be administered to a single human being, if it is not free from particulate matter, it consists a potential hazard thus, rendering it a safety risk.

*In view of above, the Board after due deliberation unanimously decided to **uphold** its previous decision taken in **213th** dated **16-11-19** and turn **down** the subject Review Petition of the firm.*

The Board further decided to direct the Drug Inspector concerned to expedite investigation in subject case and submit final report for consideration by the Board.

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: -

i. **Manufacturing for Sale /Selling of Substandard drug**

ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s)

Reply of the Firm to the Show Cause Notice:

All three batches after testing by the Government Analyst, Drug Testing Laboratory of Bahawalpur, purporting to declare sample of the subjected Drug Product as Substandard due to the visible particulate matter and product does not comply with the Parenteral Specifications.

In this context, we applied our request to PQCB to send the samples of said batches to Appellate Laboratory NIH for retesting as report of Government Analyst was controverted. This This application was sent along with evidences including retesting report of aforementioned batches, which were complying with the specifications but the request was declined by PQCB.

Global pharmaceuticals (Pvt) limited also recalled all three batches as a gesture of Goodwill through a public notice in Newspaper dated 20-01-2020 keeping in view the patient safety and in compliance with directions of PQCB. Now all three batches have been expired and still under control of IRMNCH Warehouse Maraka, Punjab Government Depot.

In view of below mentioned aspects we request the honorable board to dissolve this case because:

1. *Global Pharmaceuticals Islamabad is well reputed company working within the legal framework of the DRAP Act 2012, Drugs Act 1976 and rules frame there under. The company is firm in its commitment to quality and adherence to high standards/cGMP guidelines to meet the high expectations of patients as well well as healthcare providers at national and international level. Global Pharmaceuticals has never been convicted under any law including the Drugs Law prevailing in Pakistan.*
2. ***We have already recalled all three batches in compliance with the directions of PQCB and in view of the patient safety through a public notice in Newspaper dated 20-01-2020 (Attached)***
3. ***These batches are manufactured for Punjab Government only and supplied to IRMNCH Maraka. These are still under custody of said warehouse.***
4. ***These batches did not supply to private market, so all stock is placed under government custody as a case property.***
5. ***We were not even given our right of retest the said batches from Appellate lab (NIH) as per Drug Act 1976.***
6. ***All batches have been expired and will be disposed of. It is added that no payment has been received against these three batches.***

However, to fulfill your requirements we are providing the required information including Drug Registration certificate and CNIC copies of Managing director and Technical Staff as per your letter No. PQCB/R-711,712,713/2019

1) Nadeem Panjatan (Managing Director)

CNIC # 42101-1397557-5

Personal Address: House # 102, Street #60, Sector G-9/4, Islamabad.

2) Dr. Zamir ul Hassan (Production Incharge) NIC # 38302-1188338-9 Personal Address: House # 797, Street # 50, Sector 1-1/10, Islamabad.

3) Sohail Aslam (QC Incharge) NIC # 35200-4965749-1 Personal Address: House # 239A, Street # 14A. Block B, PWD Housing Society Islamabad.

We are always available for the further required support, if any.

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **235th meeting** held on **30-11-2021**. Mr. Hassan Saeed, Secretary DQCB, District Lahore and Mr. Ubaid Ullah Anwer, Provincial Inspector of Drugs, Government Medical Store Depot, Punjab was present along with the original case record. Among the nominated accused persons, Dr. Zamir-ul-Hassan (COO/Managing Director) along with Sohail Aslam, Representative of M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan appeared before the Board. Representatives of the firm presented following arguments in their case:

i. Global pharmaceuticals (Pvt) limited also recalled all three batches as a gesture of Goodwill through a public notice in Newspaper dated 20-01-2020 keeping in view the patient safety and in compliance with directions of PQCB.
ii. These batches are manufactured for Punjab Government only and supplied to IRMNCH Maraka. These are still under custody of said warehouse.
iii. These batches were not supplied to the private market, so all stock is placed under government custody as a case property.

iv. All batches have been expired and will be disposed of. It is added that no payment has been received against these three batches.

6. The Board after careful perusal of the case record and scrutiny of DTL report observed that the above mentioned three batches of the subject drug sample have been declared Substandard by the Drug Testing Laboratory, Bahawalpur on the basis of the Physical Test i.e. the three batches 19A038, 19C053 & 19C051 of the Injection Transolide (Tranexamic Acid 500mg/5ml) contain undissolvable visible particulate matter which does not comply with the parenteral drug specifications.

7. The Board expressed great concern on the presence of particles in the subject drug samples as an injectable preparation is intended to be administered directly into the blood and the presence of such particles could result in serious harmful effects. Such visible particulate matter can be a potent source of blockage of minute vessels and capillaries hence causing obstruction of normal blood supply so all such drug products intended for parenteral purpose must be virtually free from any such kind of particles. Moreover, the appearance of varying numbers of visible particulate matter in only twenty ampoules of each batch implies the certainty of presence of more number of particles in the larger bulk of stock. Such particle containing parenteral drugs, when injected to patients, may cause anaphylactic shock, brain stroke, blockage of the coronary artery, paralysis, pulmonary embolism and death, based upon the number of particles and particle size. Hence, keeping in view the foregoing facts, the Board after due deliberation & discussion, unanimously decided to grant the drug inspector **permission for prosecution** for **M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan** against the following accused persons in the drug court:

6. **M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan** through its Managing Director, Nadeem Panjatan
7. Nadeem Panjatan — Managing Director
8. Zamir-ul-Hassan — Production Incharge
9. Sohail Aslam — Quality Control Incharge
10. Waheed Shah — Warrantor

of M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.

For the offences of:

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

8. The firm filed Review Petition vide letter No. REF/GP/080/DTL/22against the orders no. PQCB/R-711,712,713/2019 dated 30-11-2021, which was referred back by the Provincial Quality Control Board office in compliance to directions from the drug Court, Lahore dated 25-08-2021 and subsequent decision of the Committee of Provincial Quality Control Board in its 19th meeting dated 21-10-2021.

REVIEW PETITION:

Subject: Review petition against the orders no. POCBR-711,712,713-/2019 dated 30-11-2021 in case of Substandard Injection Transolide 500mg/5ml (Tranexamic Acid) Batch No. 19A038, 19C053, 19CO51, Mfg. By M/S Global Pharmaceuticals, (Pvt.) Ltd, plot No. 204- 205 Industrial Triangle, Kahuta Road, Islamabad.

Brief facts of the case are as under;

a- That provincial inspector of MSD, Gurumangat road. Gulberg-III Lahore 07-07-2019 took the samples of different types of Drugs from the premises if IRMNCH warehouse, Maraka, Lahore on form 4 for the purpose of test/analysis.
b- That the following drug samples after test analysis were declared as Substandard by the Government Analyst DTL, Bahawalpur vide test report # TRA 01-25004192/DTL dated 26-8- 2019, 01-25004 194/DTL dated 26-8-2019 and 01-25004196/DTL dated 26-8-2019 respectively.

c- That the reason of Substandard mentioned on the test reports are as under;
1- **Batch no. 194038** "colourless solution filled in transparent glass printed ampoule (stated volume 5ml). 01 out of 20 ampoules containing undissolvable visible particulate matter (does not comply with the parenteral specifications) "
2- **Batch no. 19C053** "colorless solution filled in transparent glass printed ampoule (stated volume 5ml). 04 out of 20 ampoules containing undissolvable visible particulate matter (does not comply with the parenteral specifications) "
3- **Batch no. 19C051** "colorless solution filled in transparent glass printed ampoule (stated volume 5ml). 02 out of 20 ampoules containing undissolvable visible particulate matter (does not comply with the parenteral specifications) "

4- That all other tests such as Volume, pH, sterility test, and Assay results are within mandated specifications.
5- That after the receipt of above said test reports from Drug inspector, we submitted our reply vide letter no. REF/GP/069/DTL/19 dated 19-9-2019 (copy attached as Annexure 1), O wherein we shown our distrust on DTL reports and requested you to proceed for retesting of the PQCB's portion of samples from the appellate Lab of NIH, Islamabad as provided under section 22(4) of the Drug Act 1976 and rules framed there under.
6- That in response to your personal hearing notice no. PQCB/P-901-08/19 dated 04-11-2019; we attended the meeting of the Board on 16-11-2019 and argued for justification of request of retesting of the said drug samples from NIH Islamabad. (Earlier meeting of the Board on 12-10-2019 was postponed).
7- That the Board turned down our request of retesting in its 213th meeting held on 16-11-2019 vide order no. P¿CB/P-901-08/19 dated 16-11-2019.
8- That we recalled all batches through a public notice in newspaper dated 20-01-2020
9- That we submitted a review petition in the Board vide our petition no. Global P-901-08/19- RP-2020/04 dated 25-01-2020, against the decision of the Board, rejecting the request of retesting vide order no. PQCB/P-901-08/19 dated 16-11-2019.
10-That in response to your personal hearing notice no. PQCB/P-900-8/2019 dated 25-01-2021; we attended the meeting of the Board on 02-02-2021 with regards to review petition.

11- That the Board turned down the review petition of retesting in its 229th meeting vide order no. PQCB/P-901-08/2019 dated 02-02-2021, issued on 15-03-2021.
12- That after several proceedings, Board decided to grant permission for prosecution in its 235th meeting held on 30-11-2021 vide order no. POCB/R-711,712, 713-/2019 dated 30-11- 2021 received in Global Pharmaceuticals on 10-01-2022. We intend to submit.
13-That the substandard results are based on the presence of particulate matter. Particles of varying sizes have been observed in inject-able products, such as visible and sub visible. The particles of 01-50 micron size are known as sub visible particles and particles of more than 50 micron are considered as visible particles, But, without ascertaining the nature, composition and foreign source of particle or un-dissolvable visible particulate matter, injurious to health or not, the prosecution order has been issued on the basis of said Test Reports, which are unlawful without jurisdiction, the crucial question for legality of similar reports was evaluated in depth by honourable division bench of honourable Lahore High Court in case of PQCB vs Irza pharma reported as I992 MLD 481. What is meant by Analyst when it is reported that the samples of Drugs manufactured by the respondent conformed to the stated specifications chemically but did not conformed to the physical specifications of injection being adulterated with particles. The definitions of "Adulterated drug", spurious and substandard Drug as given in section 3 of the Drug Act 1976 were explained. It was held that

a) if 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 Drug Act and that is true.
c) There was nothing on the record to show, as to what is the nature of the particles found in 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 Drug Act 1976, the drugs tested and reported, fell outside the category of definitions of substandard, spurious and adulterated drugs.
14- That the above results have shown in a crystal clear manner that the sample of Injection a) Transolide 500mg/5ml (Tranexamic Acid\ Batch no. 19C051 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 99.03% which is with in pharmacopoeia limit of 90-105%. *A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 02 out of 20 ampoules containing undissolvable visible particulate matter" without stating its nature/composition and consequence in terms of "injurious to health'. Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183.
b) Transolide 500mg/5ml (Tranexamic Acid) Batch no. 19C053 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 98.25% which is within pharmacopoeia limit of 90-105%. “A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 04 out of 20 ampoules containing stating its undissolvable visible without matter* particulate nature/composition and consequence in terms of "Injurious to health". Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183.
c) Transolide 500mg/5ml (Tranexamic Acid) Batch no 19A038 is standard quality because it has been determined in chemical assay that

therapeutic ingredient Tranexamic Acid is 102.96%o which is within pharmacopoeia limit of 90-105%. “A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 01 out of 20 ampoules without matter" stating it’s containing undissolvable visible particulate nature/composition and consequence in terms of "Injurious to health". Reliance on 1992 MLD 481 1992. 1996 PCr. LJ I183.

15. That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19C051 had been declared as of standard quality by the report dated 21- 08-2019 of DTL Rawalpindi, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.

That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19C053 had been declared as of standard quality by the report dated 10- 08-2019 of DTL Rawalpindi, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.

That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19A038 had been declared as of standard quality by the report dated 06- 05-2019 of DTL Multan, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.

16. That the absence of the full protocols of test in the above is crystal clear violation of Drug Laws. Reports of Analyst have to be conclusive and must disclose the protocols of tests applied to formulate opinion of Government Analyst. The description of the testing procedure must be crystal clear whenever report would be disputed.

Reliance on PLD 2003 Lahore

17. That noncompliance to section 19(3) related to statutory of sending warrantor's portion within seven days, is an illegality. The warrantor's portion has not been sent to the manufacturer within statutory period of seven days as prescribed under section 19(3) (iv) of the Drug Act 1976 and rules framed there under. The non-observance to said procedure is highly doubtful and is an illegality, recently, the PQCB has unanimously dropped a case no. PQCB-R577-09/2016 related to infusion Dorcep Batch no. DC-075 declared as Adulterated and substandard by the Government Analyst DTL Rawalpindi vide DTL report no. 1077/DTL dated 22-09-20 16. The PQCB has observed that this case was fit for prosecution on the basis of report. But, this case was dropped as PQCB had observed that the case would fail in court because warrantor portion was not sent to the manufacturer within statutory period as prescribed under section 19(3)(iv) of the Drug Act 1976 and rules framed there under.

18. That whole quantity of said batches of said drug was supplied to IRMNCH warehouse, Maraka, Lahore and not a single unit of the injection had been used by the institution. All supplied injections are lying and expired in the main Medicine store of IRMNCH warehouse, Maraka, Lahore.

19. That not a single unit of said drug has been supplied in the market, even then we recalled all batches through a public notice in newspaper dated 20-01-2020.

20. That no adverse consequence about said drug is on record.

21. That the drug in question is of standard quality with regards to assay, sterility test, and other physical parameters and thus there is no risk on the use of drug for patients.

22. That in the impugned order has been passed contravene to 1992 MLD 481 Lahore title PQCB and others versus Irza pharma and others in which Hon'ble Court has declared such report against the law which is on the basis of on physical observation o undissolved visible particles. In the reliance Hon'ble Lahore High Court has observed that the size of the particle would have been determine that whether it may be injurious to health or not. In this context. It is further necessary to mention here that Board itself has directed to Director DTL Punjab through written letter in the year 1990.

23. That the said test reports are incomplete, non-conclusive and illegal and thus the same are not admissible evidence in the eye of Law.

PRAY

It is therefore, respectfully prayed that by accepting this review petition for subject captioned impugned order dated 30-11-2021, passed by the P¿CB, Punjab may very kindly be set aside by exercising powers of review jurisdiction as well as in the light of orders passed by Hon'ble Lahore High Court, Lahore in the interest of justice.

It is further prayed that the concerned Drug Inspector may very kindly be directed not to put up the case before the concerned Drug Court till the final disposal of the review petition in hand.

9. The firm resubmitted their Review Petition vide letter No. REF/GP/087/DTL/22 dated 02-02-2022.

10. M/S Global Pharmaceuticals (Pvt.) Ltd filed Writ Petition No. 55861/2022 with The Lahore High Court, Lahore.

This constitutional as well as connected petitions W.P.No.58149 of 202 1, W.P.No.58154 of 2021,.W.P.No.52668 of 2022,W.P.No.6056 of 2022.,W.P.No.55855 of 2022, W.P.No.55861 of 2022. W.P.No.55869 of 2022, W.PNo.42185 of 2022 and W.P.No.10009 of 2022 raise a common question of law. They have laid a challenge to the order dated 25.4.202 1 passed by the Drug Court, Lahore which is to the following effect:

"In view of the above circumstances, court is of the view that powers used by the PQCB in the light of said notification dated 3.5.2022 and issuance of warning to the accused persons is illegal and unlawful because, in the Drugs Act, I976 and Punjab Drugs Rules 2007, there, is no (http://is.no/) provision or section which empowers the Board to review or revision so that illegal practice which was started since 2002 till today has no legal cover rather the same is based on unlawful. Order passed by the Board under the shadow of notification dated 3.5. 2022 is without legal authority in these cases and the same is declared illegal and Unlawful. Secretary PQCB is directed in the light of said order to collect the data of all the cases which are decided by the Board and to proceed in accordance with law; he is further directed to produce report before the Court."

3. In the connected petitions either the same order has been passed or an order of similar nature has been passed which primarily sets aside the Notification dated 3.5.2022 and declares it to be ultra vires the powers of Punjab Quality Control Board (PQCB). By that Notification certain regulations called "The Provincial Quality Control Board Regulations, 2001 have been enacted' under Section 11 of the Drugs Act, 1976. By the impugned order, the Drug Court, Lahore was of the opinion that this was outwith the power of PQCB and was not envisaged by the provisions of cither Drugs Act, 1976 or the Punjab Drugs Rules, 2007. Suffice to say that the power of judicial review of subordinate legislation as well as primary legislation vests in the superior courts and cannot be exercised by the subordinate courts including the Drug Court. No such power vests with the Drug Court under the Act, 1976. Although the Drug Court has declared the Notification as having been issued illegally, yet it did not advert to the question whether the Drug Court itself had the power to make such a declaration or not. The impugned order is, therefore, set aside and the matter shall be deemed pending with the Drug Court for decision in accordance with law from the stage that the impugned order was passed. Petitions allowed.

11. Personal Hearing notice(s) issued to accused person(s) vide dated 26-04-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

12. Case was considered by the Provincial Quality Control Board, under Section 11 of the Drugs Act 1976 in its **260th meeting** held on **04-05-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Mr. Hassan Saeed, Secretary, DQCB Lahore and Mr. Ubaid Ullah Anwer, Drug Inspector Government medical Store Depot, Lahore were present along with the original case record

13. Secretary Provincial Quality Control Board apprised the Board that the firm had submitted request for adjournment Vide letter No. Ref/GP/051/DTL/23 dated 28.04.2023. The Board, after due deliberation and detailed discussion, unanimously decided to **adjourn the case** of **M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad**, and to provide another opportunity of personal hearing in the best interest of justice.

11. Personal Hearing notice(s) issued to accused person(s) vide dated 18-05-2023.

Case is placed before the Board for decision.

Summary:

Manufacturing Date: 01-2019 (B. 19A038), 03-2019 (B. 19C051,19C053)

Expiry Date: 06-2021(B. 19A038),08-2021 (B. 19C051,19C053)

Sampling Date: 06-07-2019

Sent to DTL (Form 6): 11-07-2019

Date of receipt in DTL: 13-07-2019

DTL Report Date: 26-08-2019

Time Extension: N/A

1ST DI Communication with firm on dated: 30-08-2019

Date of Retesting Request of Firm: -19-09-2019

Fate of Retesting Request: -Turned down in 213th-M dated 16-11-2019

Investigation Report Dated: 22-11-2021

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 9

PQCB R-428/2022

Mumtaz Abad Town, Multan

ATTENDANCE:

Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan** through its CEO/MD Syed Muhammad Wajeeh Uddin 2. Syed Muhammad Wajeeh Uddin CEO/MD 3. Rashid Mohammad Khan Production Incharge 4. Muhammad Farooq Quality Control Incharge/Warrantor of **M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Mumtazabad Town, District Multan, reported that: -

i. He, on 22-09-2022 inspected Main Medicine Store, O/o Chief Executive Officer, (DHA) Multan, and took 43 different 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. 141303 dated 11-10-2022, after test/ analysis was declared as **Misbranded** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Capsule Vibramycin [Doxycycline hyclate equi to Doxycycline 100mg] **Mfg. Date:** 06-2022 **Exp. Date:** 05-2025 **Reg. #** 000456	GG3310	M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan	01-94006243/DTL dated 01-12-2022	**Result of test/ analysis with specifications applied:** USP 2022 **DESCRIPTION:** Yellow color powder filled in green colored hard gelatin capsules having cap printed with "Pfizer" & "VBM 100" on body of capsule packed in ALU-PVC blister of 06 units in a labelled outer hard carton. Each outer carton contains 20 blisters of 06 units i.e., 20*06=120 capsules. **Note**: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states that "All registration holders shall follow official pharmacopeial specifications for all such formulation for which official monograph of drug product is available in the most recent edition of such pharmacopoeia". Product specification of given sample is "Manufacturer's Specification" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "**Doxycycline Hyclate capsules**" monograph in USP 2022. So, the manufacturer's claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drug Act 1976. **Misbranded (Does not comply)** **Uniformity of Dosage unit (Weight variation)** Max. AV=L1: 15% complies **IDENTIFICATION:** Doxycycline Hyclate identified. **ASSAY: Doxycycline** Stated: 100mg/cap Determined: 99.22mg/cap Percentage: 99.22% Limit: 90- 120% complies **Dissolution Test:** **Limit:** NLT 80% of the labelled amount of Doxycycline dissolved in 30mins. complies **RESULT:** The sample is **Misbranded** as per Section 3 (s) (iv) of Drug Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) Human import dated 7th February, 2022.

iii. Storekeeper, Main Medicine Store, O/o Chief Executive Officer, (DHA) Multan provided Invoice/Warranty No. 3037607282 date 12-09-2022 issued by M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi-Pakistan as proof of its purchase.

iv. Warrantor Portion of subject drug sample was sent to M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi-Pakistan.

v. Copy of Test/ Analysis reports was sent to M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi Pakistan 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- 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 Misbranded Drug**

b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 26-04-2023.

Personal Hearing notice(s) issued to accused person(s) on 18-05-2023.

Case is placed before the Committee for Decision.

Summary	**Warning to the subject Product**	**Warning to the firm in different products**
	03 times, In 234th, 244th and 254th meeting.	First warning: 234th meeting dated: 28-10-2021. Total warnings to firm: 10

PROCEEDINGS & DECISION BY THE COMMITTEE:

Case No. 10

PQCB/R-292/2022

Tehsil & District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore- Pakistan** through its Managing Director, Liaqat Ali 2. Liaqat Ali — Managing Director 3. Kashif Liaqat — Managing Partner 4. Khalid Farooq — Production Incharge 5. Muhammad Fazil — Quality Control Incharge /Warrantor of M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore- Pakistan

BRIEF FACTS OF THE CASE

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

i. He, on 01-07-2022 inspected the Main Medicine Store CEO (DHA) office District Mandi Bahauddin, took four different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 132130 dated 01-07-2022.

ii. The subject drug sample, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below: -

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Film Coated Tablet. Losartan [Each film coated tablet contains: Losartan Potassium U.S.P. … 50mg]

Mfg Date:
May 2022

Expiry Date:
May 2024

Regn No.
054441</td><td>545</td><td>M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore-Pakistan.</td><td>01-68016840/ DTL
Dated
16-08-2022</td><td>
<u>Analysis with specifications applied:</u> USP 2022

<u>DESCRIPTION</u>: Grey color, oval shaped, biconvex, scored from one side film coated tablet, contained in ALU-PVC packing of 10 units packed in outer hard carton.

NOTE: Manufacturer in its method of analusis specify “Chocolate brown colored, oval shaped, biconvex, scored from one side film coated tablet” but given sample is “Grey color, oval shaped, biconvex, scored from one side film coated tablet” which does not comply with manufacturer’s description of Tablets. (Does not Comply)

<u>IDENTIFICATION:</u> Losartan Potassium is identified.

<u>ASSAY:</u>
<table>
<tr><td>Stated</td><td>50mg / Tablet</td></tr>
<tr><td>Determined</td><td>50.029 mg / Tablet</td></tr>
<tr><td>Percentage</td><td>100.059 % (Complies)</td></tr>
<tr><td>Limit</td><td>95–105% (USP 2022)</td></tr>
</table>
<u>DISSOLUTION TEST:</u>

Complies with the Dissolution test as per USP as detailed below:

Tolerance Limit: NLT 75% (Q) of the labeled amount of Losartan Potassium is dissolved.
<table>
<tr><th>Level</th><th>Number Tested</th><th colspan="6">Acceptance Criteria</th><th>Remarks</th></tr>
<tr><td rowspan="3">S1</td><td>6</td><td colspan="6">Each unit is not less than Q+5 per cent</td><td rowspan="3">Complies</td></tr>
<tr><td>TIME</td><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit5</td><td>Unit 6</td></tr>
<tr><td>30 minutes</td><td>98.4%</td><td>106.5%</td><td>99.8%</td><td>98.3%</td><td>99.3%</td><td>104.6%</td></tr>
</table>
<u>RESULT:</u> <u>Given sample is Sub-Standard with regards to description (Physical characteristics) of Tablet.</u>
</td></tr>
</table>

iii. Storekeeper of Main Medicine Store CEO (DHA) office District Mandi Bahauddin provided Invoice/Warranty bearing No. T-20304 dated 18-06-2022 issued by M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore- Pakistan as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent to M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore- Pakistan.

v. A copy of test/analysis report was sent to M/s Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore- Pakistan with directions to explain their position and provide requisite information in this regard.

The Drug Inspector, Tehsil & District Mandi Bahauddin seized the drug (Film Coated Tablet. Losartan 50mg, Batch No. 545, Manufactured by: M/s Fynk Pharmaceuticals, declared Substandard vide TRA No. 01-68016840/ DTL Dated 16-08-2022) on Form-5 dated 02-12-2022 under the contravention of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under.

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 20-01-2023

<u>Firm replied to the show cause notice vide letter no. FY/12023/23 dated 03-02-2023</u>

In this regard, it is humbly submitted that:

1. *M/S FYNK Pharmaceuticals (hereafter referred as The Firm) is one of the leading and trusted national companies, best known for its high-quality products, which is fully compliant with Drugs Act 1976 and rules framed there under. Its firm commitment to quality and adherence to high standards/ cGMP guidelines is the hallmark of The Firm to meet the high expectations of the patients as well as Health care providers.*
2. *Regarding allegation of substandard nature of tablet LOSARTAN (50mg) B.No. 545 is concerned; the tablet LOSARTAN (50mg) B.No. 545, manufactured by the Production department headed & operated with full independence & sole responsibility by the Production Incharge of The Firm, is of standard quality as the aforesaid test report transpires that the therapeutic* ***active ingredient Losartan Potasium is 100.059 % against the limit of 95-105%.*** *So the drug is not only complying with all USP specifications but is also therapeutically effective and safe for use in patients.*
3. *As far as colour of tablet LOSARTAN (50mg) B.No. 545 is concerned, it is pertinent to mention here that M/S FYNK Pharmaceuticals i.e. The Firm manufactured tablet LOSARTAN (50mg) with* ***chocolate brown color till batch # 544*** *as the color mentioned in the product dossier submitted in DRAP was chocolate brown and so was in the method of analysis available in drug testing laboratories by then, However on account of certain reasons beyond the manufacturer's control,* ***M/s FYNK Pharmaceuticals with due intimation to DRAP vide its letter FY/9940/22 dated 23-05-2022 changed the color specification of its product in question*** *i.e. tablet LOSARTAN (50mg) from* ***"chocolate brown" to "grey" color*** *and manufactured the Batch No. 545 of the product in discussion with "grey color".*

Furthermore in pursuance of its letter FY/9940/22 dated 23-05-2022 to DRAP, M/S FYNK Pharmaceuticals ***also provided the revised method of analysis with grey color specifications of the questioned product to Drug Testing Laboratory Faisalabad*** *vide its letters dated 10-08-2022 & 01-09-2022* ***wherein it was clearly mentioned that the colour of the questioned batch of tablet LOSARTAN (50mg) is "Grey color".*** *It is pertinent to mention here that subsequently* ***DRAP also issued approval letter for change in color*** *of tablet LOSARTAN (50mg) from "chocolate brown" to "grey".*

4. *It is imperative to mention here that The Quality Control department, headed & operated with full independence & sole responsibility by the Quality Control Incharge of The Firm, notonly tested all the required quality parameters including color of the said product during manufacturing but also at the time of batch release of tablet LOSARTAN (50mg) B.No. 545 and found satisfactory results i.e. grey colour. Relying on these satisfactory reports, this batch was released to be sold.*
5. *Upon the receipt of government analyst report DTL Faisalabad vide report TRA 01-8016840/DTL dated 16-08-2022, the Quality Control department of The Firm tested/analyzed the retained sample of the same batch of the product and found satisfactory results complying with the Specifications of all the tests performed including color.*
6. *It is pertinent to mention here that* ***the same batch of the product i.e. tablet LOSARTAN (50mg) B.No. 545 has also been declared of standard quality by different DTLs*** *vide form-7 serial no. 0000023595 dated 06-09-2022, serial no. 0000020214 dated 12-09-2022, serial no. 0000020211 dated 12-09-2022 and serial no. 0000029907 dated 19-09-2022.*
7. *Therefore the alleged anomaly pointed out by Government Analyst DTL Faisalabad vide test report no. TRA 01-68016840/DTL dated 16-08-2022 is based on his* ***erroneous act of applying old method of analysis*** *with chocolate brown colour specification while ignoring the latest method of analysis with grey colour specification which had already been duly submitted to him. Otherwise, the questioned product is of standard quality fully complying with all its chemical & physical specifications including grey colour.*
8. *Furthermore the* ***dispatch/provision of warrantor portion*** *to us by the drug inspector vide its letter no. 134/DDC/MBDIN dated 16-09-2022 is also time barred as sampling was done on 01-07-2022 as stated in the said letter and warrantor portion is being sent to us vide this letter on 16-09-2022 i.e. after 77 days of sampling. The time barred provision of warrantor portion of the product taken on form # 4 to us by drug inspector is not only clear violation of mandatory provision of law in terms of section 19(3) of Drug Act 1976(as amended) but also violating the principle of NATURAL JUSTICE i-e;*

"WHENA LAW REQUIRED A THING TO BE DONE IN A PARTICULAR MANNER, THEN IT MUST BE DONE IN THAT MANNER".

Thus this time barred provision of warrantor portion has no sanctity in the eye of law.

9. *So this case deserves to be dropped on account of this illegality committed by the Drug Inspector. Recently, PQCB has unanimously dropped a Case No. PQCB R-577-09 / 2016 related to Infusion Dorcip, Batch No. De-075 declared as Adulterated and Sub-Standard by Government Analyst, Drug Testing Laboratory, Rawalpindi vide DTL Report TRA. No. 1077/DTL Dated: 22-09-2016. PQCB had observed that this case was fit for prosecution on the basis of report. But, this case was DROPPED because warrantor portion was not sent to the manufacturer within statutory period as prescribed under Section 19 (3) of the Drug Act 1976.*
10. *So in the light of all above discussion, the questioned product cannot be declared/considered as substandard since it meets all its chemical and physical specifications including color.*

That PARA 2 of SCN alleges that

"In this way you have contra vened the section 23 /27 of the Drug Act 1976 (as amended) / DRAP act 2012 and Rules framed thereunder by way of:

i. Manufacturing for sale/sale of Substandard drug

ii. Issuance of false warranty

Comments /Explanation:

I. The allegation of Manufacturing for sale/sale of Sub-standard drug has been dealt and defended in detail in supra paragraphs and may kindly be considered as reply to this allegation.

II. As far as allegation of issuance of false warranty is concerned, it is groundless and based report by Quality Control Department of The Firm which was good and sufficient reason available at the time of sale of the product and issuance of warranty for believing the product of standard quality. So the offence of issuance of false warranty has been added just to manipulate the scenario.

Section 27(2) (b) is reproduced below:

27 (2) whoever himself or by any other person on his behalf (a) or (b) Gives to the purchaser a false warranty in respect of any drug sold by him that the drug does not in any way contravene the provisions of section 23 and is not able to prove that, when he gave the warranty, he had good and sufficient reason to believe the same to be true.

That PARA 3 of SCN alleges that

"You are therefore required under Section (11) of the Drugs Act, 1976 and Rules (5) Of the Punjab Drug Rules 2007 (as amended) to show cause as to why:-

i. You should not be prosecuted for committing above said contravention [sl in the Drug Court.

i. The licensing Authority/ Drug Registration Authority should not be recommended for cancellation / suspension of your Drug Manufacturing/ Sale License and Drug Registration.

ii. Other suitable legal action (s] should not be taken against you.

Comments / Explanation:

I. It is respectfully submitted that the impugned DTL report which forms basis of this SCN is ultra vires and non-conformity to mandatory provisions of section 16 of the Drugs Act 1976 and is the ***outcome of application of old specifications of the product*** *sampled by the government analyst as discussed in detail in supra paragraphs.*

The prosecution would be unlawful because it would be based upon ***illegal and unlawful test report*** *which cannot be used as evidence in any criminal proceedings/trial.*

III. Furthermore, mandatory provisions of Drugs Act 1976 have been violated by Drug Inspector which creates serious doubts in the whole story and would adversely affect the prosecution culminating into a futile exercise which would ultimately lead to acquittal of the accused.

That PARA 4 of SCN alleges that

"You are hereby directed to verify/ provide the names of accused persons (Chief Executive officer/ Managing Director (s)/ Director (s)/ Partner (s), Production Incharge, Quality Control Incharge) as nominated by Drug inspector in the instant case and details of re-called stock of said drugs, if any"

Comments/ Explanation

The detail of persons (not accused as alleged) who were involved in the manufacturing and checking quality of the said batch of the product, is as follows:

Mr. Khalid Farooq Production Incharge

Mr. Muhammad Fazil Quality Control Incharge

of M/S FYNK Pharmaceuticals, 19-KMGT road, Kalashah Kaku, Lahore.

Please also note that M/S FYNK Pharmaceuticals is not a company rather it is a partnership firm and has no designation of Managing Director as alleged in the show cause notice under reply. ***Mr. Liaqat Ali****, who has been alleged as Managing Director of M/S FYNK Pharmaceuticals in the show cause notice under reply, is mere a* ***silent partner*** *of M/S FYNK Pharmaceuticals who has no concern with the operations of the Firm being silent share holder and he has no nexus with the issues (allegations) under consideration in the said show cause as all routine manufacturing and quality control/assurance operations are done without his prior knowledge and consent.*

II. It is also pertinent to mention here that no involvement or any incriminating material has been shown in the said show cause notice against Mr. Liaqat Ali that the alleged contraventions has been committed by the functionaries of The Firm with the consent, approval or/and knowledge of Mr. Liaqat Ali. So Mr. Liaqat Ali's name cannot be aligned in the aforesaid show cause as per DRAP notification No. F. 11-13/2022-LA and section 34 of the Drugs Act 1976. So, in the light of above, ***it is requested that name of Mr. Liaqat Ali may please be deleted from the Show Cause Notice*** *or any other legal proceedings under the Drug Act 1976 or Rules framed there under in the best interest of justice.*

Further also note that ***Mr. Khalid Faroog Production Incharge, Muhammad Fazil Quality Control Manager & warrantor have left their jobs*** *from M/S FYNK Pharmaceuticals. So their SHOW CAUSE NOTICES be kindly considered as UNSERVED and are being sent back to you along with this reply.*

11. That in addition to above, the undersigned reserves its right to submit further assistance/arguments/contradictory evidence to this honorable forum at personal hearing stage if happened.

So in the light of all aforesaid arguments ***you are requested to drop this case in the supreme interest of justice on account of gross negligence on the part of the drug inspector and erroneous act of applying wrong color specifications by Government Analyst****.*

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: May 2022

Expiry Date: May 2024

Sampling Date (Form 4): 01-07-2022

Sent to DTL (Form 6): 01-07-2022

Date of receipt in DTL: 05-07-2022

DTL Report Date (Form 7): 16-08-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 16-09-2022

Retesting Request of Firm: No

Investigation Report Dated: 20-12-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 11

DISTRICT DERA GHAZI KHAN

PQCB/R-111/2022

Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Convell Laboratories Saidu Sharif, Swat-Pakistan** through its Managing Director Muhammad Javed 2. Muhammad Javed Managing Director 3. Fazal Mabood Production Incharge 4. Kamal Shafiq Umar Quality Control Incharge/ Warrantor Of **M/s Convell Laboratories Saidu Sharif, Swat-Pakistan**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan reported that:-

i. He, on 20-04-2022, inspected the business premises of M/s Al-Haj Ahmad Qadri Medical Store Near Jugnu Commercial Centre, General Bus Stand Dera Ghazi Khan and took sample of drug on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Multan vide memorandum no. 0000124255 dated 20-04-2022.

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

iii. M/s Al-Haj Ahmad Qadri Medical Store Near Jugnu Commercial Centre, General Bus Stand Dera Ghazi Khan submitted Invoice/warranty No. 172 dated 14-04-2022 issued by M/s Akhtar Pharmacy, Balakh Sarwar City, Dera Ghazi Khan as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/s Akhtar Pharmacy, Balakh Sarwar City, Dera Ghazi Khan who in turn submitted invoice/ warranty No. 1280 dated 30-12-2021 issued by M/s Convell Laboratories Saidu Sharif, Swat-Pakistan as a proof of its purchase of the said drug.

v. A copy of test/analysis report was sent to M/s Convell Laboratories Saidu Sharif, Swat-Pakistan and they were asked to provide the requisite information in this regard.

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>Eta (Each 5mL contains Acefyline piperazine… 45mg & Diphenhydramine HCl…8mg) Cough Syrup 120ml.
Mfg.date:
Aug-2021
Exp. date:
Jul-2023
Regn No.
032396</td><td>L038</td><td>M/s Convell Laboratories Saidu Sharif, Swat-Pakistan</td><td>TRA No. 01-94003365/DTL
Dated:-18-08-2022</td><td><u>Analysis with specifications applied:</u>
Manufacturer Specification
<u>Description:</u>
Greenish yellow color liquid contained in amber colored labeled plastic bottle sealed with silver screw cap, packed in a labeled outer hard carton.
The product claims BP Finished Drug Product Specifications and in BP the monograph for Acefyline Piperazine & Diphenhydramine HCl Cough Syrup is not given which is false & misleading.
Mis-Branded (Does not comply)
<u>Identification:</u>
Acefyline Piperazine & Diphenhydramine HCl Identified.
<u>Assay:</u> UV-Visible Spectroscopy
Acefyline Piperazine
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>45.0 mg / 5mL</td><td>56.42 mg / 5 mL</td><td>125.37 %</td><td>90-110 %</td></tr>
</table>
(Does Not Comply)
<u>Assay:</u> Titration
Diphenhydramine HCl
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>8.0 mg / 5mL</td><td>7.34 mg / 5 mL</td><td>91.18 %</td><td>90-110 %</td></tr>
</table>
(Complies)
<u>PH:</u>
Stated: 5.5-7.5
Determined: 7.10 (Complies)
<u>RESULT:</u>
The above sample is <u>Sub-Standard</u> on the basis of Assay of Acefyline Piperazine & Misbranded with regards to labelling as per section 3(s) (iv) of Drugs Act 1976.</td></tr>
</table>

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

a. **Manufacture for Sale/Sale of the Substandard & Misbranded drug**

b. **Issuance of false warranty**

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 nil:</u>

1. In 2021 our same product ETA syrup is declared as misbranded by DTL Bahawalpur.

The PQCB Punjab 234th meeting board which is held on 28 oct 2021, the chairman of PQCB order to M/S convell laboratory that submit application for finished product specification to DRAP, also submit the copy of this file to PQCB Lahore. Convell laboratory applied for finished product specification of Eta syrup and DRAP issued letter on 17th Dec 2021 as ''Innovator's specification'' for ETA syrup. (copy attached) so this product Eta syrup B.NO. ;038 is manufactured before oct 2021.

2. This Batch.No: L038 is recalled with letter reference No. CL/1-060 dated 02-02-2022, copy of this letter is send to Drug Inspector D.G. Khan and PQCN Lahore Punjab. (receipt attached)

3. The result of DTL Multan for Acefylline piperazine is 125.37% which is doubtful and M/S Convell laboratory is requesting the Board to send our product to NIH for retest.

4. The names of technical staff personnel, registration of Eta syrup and license copy is attached. Anticipating your positive cooperation this regard.

4. Personal Hearing notice(s) issued to accused person(s) dated 20-04-2023.

<u>PROCEEEDINGS & DECISION BY THE BOARD:</u>

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **260th meeting** held on **04-05-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. M. Asif Abbas, Secretary DQCB, District Dera Ghazi Khan & Mr. Faisal Mahmood Khan, Drug Inspector, Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan were present along with the original case record. No one among the nominated accused persons of **M/s Convell Laboratories Saidu Sharif, Swat-Pakistan** appeared before the Board. 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 20-04-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 08-2021**
- **Expiry Date: 07-2023**
- **Sampling Date (Form 4): 20-04-2022**
- **Sent to DTL (Form 6): 20-04-2022**
- **Date of receipt in DTL: 22-04-2022**
- **DTL Report Date (Form 7): 18-08-2022**
- **Time Extension: Granted in 246th meeting dated 05-07-2022**
- **1ST DI Communication with firm on dated: 27-08-2022**
- **Date of Retesting Request of Firm: In response to show cause notice dated nil received in office of PQCB dated 18-11-2022 (not entertained).**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 17-09-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 12

PQCB R-05/2023

The Children's Hospital and Institute of Child Health, Multan

ATTENDANCE:

Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Life Pharmaceutical Company, 24-III, Industrial Estate, Multan, Pakistan** through its Managing Director Zeeshan Haider 2. Zeeshan Haider — Managing Director 3. Muhammad Asif — Production Manager 4. Muhammad Anjum Sattar — Quality Control Manager 5. Ali Haider — Warrantor of M/S **Life Pharmaceutical Company, 24-III, Industrial Estate, Multan, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, The Children's Hospital and Institute of Child Health, Multan, reported that: -

i. He, on 02-11-2022, inspected the premises of Pharmacy store of The Children's Hospital and Institute of Child Health, Multan, and took a drug sample on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Multan.

ii. Following drug sample, sent vide memo no.146852, dated 02-11-2022, after test/ analysis was declared as **Misbranded** by Government Analyst, Drug Testing laboratory **Multan** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Syrup ADD-Zinc 60ml [Each 5ml contains: Elemental zinc (as Zinc Sulphate Monohydrate 20mg)] **Mfg. date**: Oct-2022 **Exp. Date**; Sep-2024 **Regs. #** 068091	24522	M/S Life Pharmaceutical Company, 24-III, Industrial Estate, Multan, Pakistan	01-89007893/DTL dated: 03-01-2023	**Result of test/ analysis with specifications applied:** MS **DESCRIPTION**: Colorless, clear liquid, packed in amber colored glass bottle. Product Claims USP Finished Drug Product Specifications, According to USP monograph of Zinc Sulfate Oral solution, under labeling **"Label the oral solution in terms of Zinc Sulfate monohydrate and in terms of elemental Zinc"** while the label claim of the product states "elemental zinc as Zinc Sulphate monohydrate…20mg/5ml" which is false and misleading. **(Misbranded) (Does Not Comply)** **pH:** Range: 2.5-4.5 Determined:3.46 **IDENTIFICATION USP:** Elemental Zinc identified **ASSAY:** Elemental Zinc Stated 20mg/ 5ml Determined 19.61mg/ 5ml Percentage 98.08**%** Limit: 90-110% **(Complies)** **RESULT:** The sample is **Misbranded** as defined under clause (vi) of subsection (s) of section 3 of the Drug Act 1976.

iii. Store Keeper, Pharmacy store of The Children's Hospital and Institute of Child Health, Multan, provided invoice/warranty No. 38 dated 27-10-2022 issued by M/S Life Pharmaceutical Company, 24-III, Industrial Estate, Multan, Pakistan as a proof of purchase.

iv. Warrantor Portion was sent to M/S Life Pharmaceutical Company, 24-III, Industrial Estate, Multan, Pakistan.

v. Copy of test/analysis report was sent to M/S Life Pharmaceutical Company, 24-III, Industrial Estate, Multan, Pakistan. with directions to provide the requisite information and explain their position 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 Misbranded Drug**

b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 19-04-2023.

Personal Hearing notice(s) issued to accused person(s) on 18-05-2023.

Summary	**Warning to the subject Product**	**Warning to the firm in different products**
	1st time	First warning: No waring before. Total warnings to firm: 0

Case is placed before the Committee for Decision.

PROCEEDINGS & DECISION BY THE COMMITTEE:

Case No. 13

PQCB/R-347/2022

Lahore General Hospital, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Mass Pharma (Pvt.) Ltd., 17-Km, Ferozepur Road, Lahore-Pakistan** through its Chief Executive Officer/GM, Ashfaq Ahmad 2. Ashfaq Ahmad Chief Executive Officer/GM 3. Nazar Abbas Production Incharge 4. Riffat Saima Quality Control Incharge/ Warrantor of M/s Mass Pharma (Pvt.) Ltd., 17-Km, Ferozepur Road, Lahore-Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Lahore General Hospital, Lahore reported that: -

i. She, on 24-01-2022, inspected the premises of Main Medicine Store of Lahore General Hospital, Lahore, took sample of below-mentioned drug on Form-4 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Lahore vide memorandum no. 116482 dated 24-01-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report No. & Date	DTL Test Report Result
Lotion. MALIN 60mL [Permethrin BP 5% w/w in a lotion base] **Mfg Date:** Dec 2021 **Expiry Date:** Nov 2023 **Regn No.** 048052	7984	M/s Mass Pharma (Pvt.) Ltd., 17-Km, Ferozepur Road, Lahore-Pakistan.	01-166002701/DTL dated: 21-02-2022	**Analysis with specifications applied:** MS **PHYSICAL DESCRIPTION:** White color liquid preparation claimed to be lotion having adequate flow, uniform consistency and smooth texture, in an opaque white plastic bottle with a sealed screw cap. **pH:** Determined: **4.53 at 25.0°C** Limits: 5.0 - 7.0 **(DOES NOT COMPLY)** **IDENTIFICATION OF PERMETHRIN:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in the standard chromatogram. (PERMETHRIN identified). **ASSAY OF PERMETHRIN:** Stated: 5% w/w Determined: 4.61% w/w Percentage: 92.11% Limit: 90 - 110% of the stated amount **RESULT:** The above sample is **SUB-STANDARD,** on the basis of pH performed as per Manufacturer provided method of analysis.

iii. Store keeper of Main Medicine Store of Lahore General Hospital, Lahore provided invoice/warranty no. 2112086 dated 29-12-2021 issued by M/s Mass Pharma (Pvt.) Ltd., 17-Km, Ferozepur Road, Lahore-Pakistan as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent to M/s Mass Pharma (Pvt.) Ltd., 17-Km, Ferozepur Road, Lahore-Pakistan.

v. A copy of test report was sent to M/s Mass Pharma (Pvt.) Ltd., 17-Km, 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 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 Mass Pharma (Pvt.) Ltd., 17-Km, Ferozepur Road, Lahore-Pakistan the retesting request of the subject drug sample was considered in the 251st Meeting of the Provincial Quality Control Board held on 20-10-2022 and the

drug sample was sent 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
Lotion. MALIN 60ml [Permethrin BP 5% w/w in a lotion base]	7984	M/s Mass Pharma (Pvt.) Ltd., 17-Km, Ferozepur Road, Lahore-Pakistan.	No. 0262-P/2022 dated 01-12-2022	**Analysis with specifications applied:** Manufacturer Specification **pH:** **Determined:** 4.5 ± 0.06 **Limit:** 5.0 - 7.0 **Does not comply with manufacturer specification.** **Result:** 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 17-02-2023

Firm replied to the show cause notice vide letter no. MPL/2023/03 dated 28-03-2023

Reference is made to the office memo No # PQCB/R-347/2022 dated 17-02-2023 regarding "Show Cause Notice" on Malin Lotion 60ml (Permethrin B.P 5% w/w) Batch# 7984 which has bcen declared Substandard Vide TRA No# 01-166002701 Dated, February, 21, 2022. We hereby submit that the report of NIH has flaws on the following grounds amongst others:

1. *The NIH report did not provide* ***details regarding correct electrode*** *while its selection.*

a. *The choice of correct electrode becomes particularly important in case of* ***viscous samples*** *where the general-purpose glass electrode is subject to various error sources. (As Hydrofluoric acid, hot phosphoric acid and strong alkaline solution destroy the glass membrane.)*
b. *Moreover, in case of lotion, while determining pH, it is prerequisite to* ***keep dip the electrode in a simple solution till its pH becomes stable****. NIH report did not provide the detail.*
c. *Astonishingly,* ***the NIH report provided a single determined value instead of providing mean or average value of three readings****. Hence the NIH report cannot be construed as Conclusive evidence of the facts stated therein and we are confident in quality of our product is within these prescribed specifications*

2- Moreover, ***we had not been asked to submit the Testing specifications/Method, by DTL Lahore So obviously we did not submit the updated testing method****.*

3- The pH of said drug product as reported by NIH is 4.5 + 0.06 ***This value is much closer to the limit and even tolerable by the skin****. Very minute difference of determined value from the limit strongly suggests that the testing or experimental conditions were compromised.*

4- The ***skin natural pH is somewhat acidic and it can tolerate pH 4 or above up to 7.0*** *Therefore, scientific studies recommend that the skincare products should have a pH of 4 to 7 to restore the skin acid mantle. However,* ***we at our own adopted more stringent approach and fixed pH limits of 5.0-7.0*** *for our product Malin Lotion [Permethrin BP 5% w/w in a lotion base].*

5- For optimal pH measurement the factors such as chemical composition, homogeneity, pH range, container size worth consideration. ***Hopefully all the said parameters have been taken care by the Analyst at NIH.***

6- The retained sample of this particular batch (Batch # 7984) is tested thoroughly. The current test results of ***retained samples also meet the prescribed specifications****.*

7- The ***warrantor portion of this particular batch is also tested*** *and found the complies the standard specifications especially the pH is within the range.*

8- It is an external preparation in lotion dosage form and used for the treatment of scabies. This product is being consumed throughout Pakistan in public and private sector and producing very excellent results of treatment. ***We had supplied batches to the public sector after this particular batch*** *and all were released by the concerned DTL which is a sound proof that our product is a stable and quality is not compromised at all.*

9- The said Batch comprises 5K units & it is only provided to Lahore General Hospital. Lahore and ***did not supply anywhere else****. We the management are of opinion that the* ***"RECALL" of this particular batch seems to be an invalid practice as it is supplied to only one place****/institution where it is kept in store and had not been used elsewhere.*

10- ***We have replaced this stock*** *(supplied to Lahore General Hospital) as per contract/ agreement. We are sure that it will meet the standard specifications and finally release by the concerned D'TL Lahore. Hence the contract agreement has been duly fulfilled and there will be no loss to the Hospital in specific and to the Public in General.*

11- Taking into consideration the lenient view of the skin pH, we have decided to opt this limit which is 4-7 we have changed our testing procedure accordingly.

Mass Pharma (Pvt) Ltd is ***an ethical pharmaceutical company*** *and has been working since 1998. We are committed to provide quality medicines to the ailing humanity. The company possesses a very good reputation among the pharma sector. This particular product is almost a brand and* ***regularly supplied to the Government Institutions without fail and very good results****. Keeping in view, We the Management of M/S Mass Pharma (Pvt) Ltd. would like to assure that all steps will be strictly followed in future to meet the standard specifications. So,* ***we the members of management of Mass Pharma and its technical team request the honorable members of PQCB to please Drop the proceedings against the company.***

Furthermore, the firm verified the names of he accused nominated by the drug inspector.

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: Dec 2021

Expiry Date: Nov 2023

Sampling Date (Form 4): 24-01-2022

Sent to DTL (Form 6): 24-01-2022

Date of receipt in DTL: 25-01-2022

DTL Report Date (Form 7): 21-02-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 22-03-2022

Retesting Request of Firm: Yes

Fate of Retesting Request: Allowed in 251-M dated 20-10-2022

NIH Report: 01-12-2022 (Substandard)

Investigation Report Dated: 10-01-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 14

PQCB/ R-443/2021

Tehsil & District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Highnoon Laboratories Ltd., 17.5 Km, Multan Road, Lahore-Pakistan** through its Managing Director/ CEO, Dr. Adeel Abbas 2. Dr. Adeel Abbas — Managing Director/ CEO 3. Rehana Bibi — Production Incharge 4. Dr. Ahsan Zamir Siddiqi — Quality Control Incharge 5. Muhammad Ramzan — Warrantor of M/s Highnoon Laboratories Ltd., 17.5 Km, Multan Road, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 14-12-2020, inspected the business premises of M/s Premier Sale Private Limited Mandi Bahauddin, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Enteric Coated Tablet.
Loprin
[Each enteric coated tablet contains Aspirin B.P. 150mg]</td><td>193133</td><td>M/S Highnoon Laboratories Ltd., 17.5 Km, Multan Road, Lahore-Pakistan.</td><td>01-68006392/DTL
dated
04-02-2021</td><td>
Analysis with specifications applied: BP 2020

<u>DESCRIPTION:</u> Deep orange colored, round shaped, deep biconvex enteric coated tablet, contained in Alu-PVC strip of 10’s packed in outer hard carton.

<u>IDENTIFICATION:</u> Aspirin identified.

<u>ASSAY:</u>
<table>
<tr><td>Stated:</td><td>150 mg / Tablet</td></tr>
<tr><td>Determined:</td><td>145.973 mg/ Tablet</td></tr>
<tr><td>Percentage:</td><td>97.315% (Complies)</td></tr>
<tr><td>Limit:</td><td>95–105% (BP 2020)</td></tr>
</table>
<u>DISSOLUTION TEST:</u> Does not comply with Dissolution test as per BP 2020 as detailed below:

<u>Acid Stage</u>:

Tolerance Limit: The amount of aspirin released is not more than 5% of the stated amount of Aspirin in 2 Hours in 1000 ml of 0.1M HCl in Apparatus 1 at 100 rpm.
<table>
<tr><th>Level</th><th>Number Tested</th><th colspan="6">Acceptance Criteria</th><th>Remarks</th></tr>
<tr><td rowspan="2"></td><td rowspan="2">6</td><td colspan="6">No individual value exceeds 5% dissolved</td><td rowspan="2">Complies</td></tr>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit5</td><td>Unit 6</td></tr>
<tr><td>A1</td><td>After 2 Hours</td><td>0.9%</td><td>3.5%</td><td>0.8%</td><td>1.2%</td><td>0.8%</td><td>0.4%</td><td></td></tr>
</table>
<u>Buffer Stage:</u>

Tolerance Limit: The amount of aspirin released is not less than 75% (Q) of the labelled amount of Aspirin in 45 minutes in 900 ml of pH 6.8 mixed phosphate buffer in Apparatus 1 at 100 rpm.
<table>
<tr><th>Level</th><th>Number Tested</th><th colspan="6">Acceptance Criteria</th><th>Remarks</th></tr>
<tr><td rowspan="2"></td><td rowspan="2">6</td><td colspan="6">Not unit is not less than Q+5%</td><td rowspan="2">Does Not Comply</td></tr>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit5</td><td>Unit 6</td></tr>
<tr><td>B1</td><td>After 45 Minutes</td><td>6.0%</td><td>8.8%</td><td>3.6%</td><td>6.5%</td><td>23.3%</td><td>6.3%</td><td></td></tr>
</table>
NOTE: Percentage release of Aspirin among all six units tested at first level (B1) is found less than 80% (Q+5%) of the labelled amount. Furthermore, percentage release of Aspirin in all six units is found less than Q-25% (i.e., 50%) at B1 level. Therefore, Dissolution test is stopped at level 1. (Does Not Comply)

<u>RESULT:</u> Given sample is <u>Sub-Standard</u> with regards to Dissolution Test.
</td></tr>
</table>

iii. Qualified Person of M/s Premier Sale Private Limited Mandi Bahauddin provided invoice/warranty bearing No. 435 dated 10-01-2020 issued by M/s Highnoon Laboratories Ltd., 17.5 Km, Multan Road, Lahore-Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Highnoon Laboratories Ltd., 17.5 Km, Multan Road, Lahore-Pakistan.

v. A copy of test/analysis report was sent to M/s Highnoon Laboratories Ltd., 17.5 Km, Multan Road, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 02-06-2022

Firm submitted written reply to the Show Cause Notice vide letter no. HN/LRA-023/2022 dated 17-06-2022

We would like to submit as under:

1. *Loprin Tablet 150mg Batch No 193133 was checked by Highnoon QC at the time of release of batch; the Initial results showed that Loprin 150mg B.# 193133 complied with standard specification.*
2. *The sample was drawn by Deputy Drug Controller Mandi Bahauddin for the purpose of test analysis on 14-12-2020 from the Business premises of M/s Premier Sales, Mandi Bahauddin who provided the invoice /warranty No. 435 dated 10-01-2020 to the concerned Authority.*
3. *DTL report No TRA 01-68006392 annexed with the letter of DDC Mandi Bahauddin mentions that the sample was tested by DTL Faisalabad and the report was issued on 04-02-2021. However, DTL report was received by us on 2-02-2022 along with letter from DDC/Drug Inspector Mandi Bahauddin i.e., 12 months after issuance of DTL report when the sample was expired (Exp Date: Jan 2021). Resultantly* ***we are deprived of our right of appeal for re-testing of the alleged sample by the Appellate Laboratory, otherwise we would have requested you to allow retesting of the said sample.***
4. *We were not even provided with the warrantor portion at the time of sample drawn. We have received warrantor portion on 02-02-2022 with your letter No. 14 DDC/MBDIN dated 29-01-2022 that is around 14 months after sample was drawn and 12 months after DTL report was issued. The warrantor portion has been expired in Jan 2021 (i.e. The warrantor portion received after 13 months of expiry of the sample).*

In the light of above detail, ***we request you that please close the case as the batch was expired in Jan. 2021 and before the time of intimation of DTL report to us. Therefore, we lost the opportunity to request for re-testing under Drug Act, 1976. We also lost the chances of voluntarily recall of the batch.***

Moreover, firm verified the names of the CEO, Production In-charge & Quality Control In-charge nominated by the drug inspector in the instant case.

4. Personal hearing notice(s) issued to accused person(s) dated 06-07-2022

Previous Proceedings & Decision By The Board:

247th meeting held on 21-07-2022

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **247th meeting** held on **21-07-2022** under the Chairmanship of Vice-Chairperson in the presence of Board members as mentioned above. Ms. Uzma Mazhar, Secretary DQCB, District Mandi Bahauddin and Mr. M. Afzal, Provincial Inspector of Drugs, Tehsil & District Mandi Bahauddin was present along with the original case record. Among the nominated accused persons, Dr. Ahsan Zamir Siddiqi (Quality Control Incharge) along with Iram Naila (Director Regulatory Affairs), Representative of M/s Highnoon Laboratories Ltd., 17.5 Km, Multan Road, Lahore-Pakistan appeared before the Board. Firm re-stated the arguments already submitted in response to the show cause notice and reiterated that they received expired warrantor portion of the subject sample which was delivered after almost a lapse of one year from sampling date. Firm further shared that they have done stability studies on the subject drug product and they have found no such observation as depicted in the DTL report. Have they been provided with the DTL report and warrantor portion on time, they must have challenged the results of DTL report and hopefully appellate testing would have revealed satisfactory results.

6. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample has been declared substandard by the Drug Testing Laboratory, Faisalabad on the basis of the dissolution test. Percentage release of Aspirin among all six units tested at first level (B1) is found less than 80% (Q+5%) of the labelled amount. Furthermore, percentage release of Aspirin in all six units is found less than Q-25% (i.e., 50%) at B1 level. The Board was of the opinion that in an enteric coated tablet, enteric coating is the core point of consideration while manufacturing such formulation. Failure of all of the six tested units to release their required percentage of aspirin even in the buffer stage of testing implies that the subject drug will miserably fail to fulfil its intended purpose and hence would be of no clinical use. The Board observed with grave concern that there are unexplained delays in correspondence of the drug inspector with the firm. The drug inspector Tehsil & District Mandi Bahauddin respectfully apprised the Board that the post of drug inspector in Tehsil Mandi Bahauddin remained vacant for almost eight months, and afterwards after assuming charge it took time to verify the warranty provided by Premier Sale Private Limited Mandi Bahauddin.

7. The Board, after due deliberation and detailed discussion, keeping in view the serious nature of noticeable observations in the subject case, unanimously decided to **pend the case** of M/s Highnoon Laboratories Ltd., 17.5 Km, Multan Road, Lahore-Pakistan and decided to **forward the matter to Deputy Secretary (General),** Primary & Secondary Healthcare Department to dig out the root cause of delays in the investigation of the case and other lacunas in the subject case, with the request to submit report accordingly.

Deputy Secretary (Establishment) submitted the report through Section Officer (Drugs Control-I) vide letter dated 18-04-2023 which is as follows:

Technical Report regarding PQCB Order dated 21-07-2022

Provincial Inspector of Drugs, Tehsil & District Mandi Bahauddin (MB Din) took a drug sample from M/s Premier Sale Private Limited, which was declared **Sub-Standard** by the Drugs Testing Laboratory (DTL). Details of the report are as under:

Name of Drug: Enteric Coated Tablet. Loprin

Batch No: 193133

Manufacturer: M/s Highnoon Laboratories Ltd. Lahore Pakistan

Report/ TRA No. & Date: 01-68006392/DTL dated 04-02-2021

Reason of Failure: Dissolution Test

Expiry Date: Jan 2021/ Oct 2021 (as per Form-4)

A chronological history of events relevant to the case, is presented below:

Sr. No.	Event	Date
1	Sample taken	14-12-2020
2	DTL Report issued	04-02-2021
3	Warranty provided by Distributor (Premier)	18-02-2021
4	Mr. Saqib Javed Bhatti (raiding DI) transferred	23-02-2021
5	Mr. Afzal notified as DI	13-10-2021
6	Letter to Distributor by Mr. Afzal (Warranty provided by Distributor on 18-02-2021 was invalid)	07-01-2022
7	Valid warranty provided by distributor	24-01-2022
8	Letter to Manufacturer by Mr. Afzal, delivery of Warrantor Portion	29-01-2022
9	Reply by Manufacturer	07-02-2022
10	Reply of Manufacturer received by DI	15-02-2022
11	Show cause notice issued	02-06-2022
12	Firm submitted reply of the show cause	17-06-2022
13	Personal Hearing Notice Issued	06-07-2022
14	PQCB issued order to submit enquiry report	21-07-2022

4. Personal hearing notice(s) issued to accused person(s) dated 06-07-2022

Case is placed before the Board for decision.

Summary:

Manufacturing Date: Oct-2019

Expiry Date: Oct-2021

Sampling Date (Form 4): 14-12-2020

Sent to DTL (Form 6): 15-12-2020

Date of receipt in DTL: 19-12-2020

DTL Report Date (Form 7): 04-02-2021

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 29-01-2022

Retesting Request of Firm: NA

Investigation Report Dated: 31-03-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 15

PQCB/R-251/2022

Tehsil Phalia & District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s MTI Medical (Pvt.) Ltd. 586-587 Sundar Industrial Estate, Lahore- Pakistan** through its Chief Executive Officer, Muhammad Amjad Iqbal 2. Muhammad Amjad Iqbal — Chief Executive Officer 3. Muhammad Adrees Khan Niazi — Production Incharge 4. Amir Razzaq — Quality Control Incharge 5. Muhammad Raza Shafaat — Warrantor of M/s MTI Medical (Pvt.) Ltd. 586-587 Sundar Industrial Estate, Lahore- Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Phalia, District Mandi Bahauddin reported that: -

i. He, on 01-09-2022 inspected the main medicine store of Tehsil Headquarter Hospital Phalia District Mandi Bahauddin, took four different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 138849 dated 01-09-2022.

ii. The subject 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	DTL Report No. & Date
Capsule. Gribok [Each capsule contains: Fluconazole B.P. …. 150mg] **Mfg Date** **Expiry Date** **Regn No.** June 2022 June 2024 078867	506	M/S MTI Medical (Pvt.) Ltd. 586-587 Sundar Industrial Estate, Lahore- Pakistan.	01-68018304/ DTL Dated 08-10-2022

DTL Test Report Results

Analysis with specifications applied: BP 2022

DETAIL RESULT OF TEST/ANALYSIS:

DESCRIPTION: White colored powder encapsulated in hard gelatin capsule of red colored opaque cap and off-white colored opaque body, contained in Alu-Alu packing of 01 unit, packed in outer hard carton.

UNIFORMITY OF WEIGHT (Mass): Does not Comply the BP's acceptance criteria of Uniformity of weight.

(Average weight of Content of Capsule: 253.9 mg)

Tolerance Limit: ± 10% of Average weight (BP 2022)

Reference Limit: 228.5-279.3 mg

Determined Limit: 167.8 - 314.7mg (Does Not Comply)

Tablet No.	1	2	3	4	5	6	7	8	9	10	Average (mg)
Individual weight (mg)	**283**	**288**	276.2	**314.7**	234.5	**288.6**	244.3	246.9	258.2	**188.0**	
Allowed % Deviation (± 10%)	**11.5**	**13.4**	8.8	**24.0**	-7.6	**13.7**	-3.8	-2.7	1.7	**-25.9**	
Tablet No.	11	12	13	14	15	16	17	18	19	20	
Individual weight (mg)	252.0	**225.3**	250.7	**285.8**	244.2	274.1	270.8	246.7	237.8	**167.8**	
Allowed % Deviation (± 10%)	-0.7	**-11.3**	-1.3	**12.6**	-3.8	8.0	6.7	-2.8	-6.3	**-33.9**	253.9

NOTE: As per BP 2022, Not more than two of the individual masses deviate from the average mass by more than the percentage deviation (± 10%) and none deviates by more than twice of that percentage. In case of given sample, 08 units out of 20 deviates more than ± 10% and 03 out of these 08 deviate by more than twice of that limit (i.e., ± 20%)

IDENTIFICATION: Fluconazole is identified.

ASSAY:

Stated	150mg / Capsule
Determined	144.822 mg / Capsule
Percentage	96.548 % (Complies)
Limit	95–105% (BP 2022)

DISSOLUTION TEST:

Complies with the Dissolution test as per BP as detailed below:

Tolerance Limit: The amount of fluconazole released is not less than 75% (Q) of the stated amount.

Level	Number Tested	Acceptance Criteria						Remarks
S1	6	Each unit is not less than Q + 5%						
	TIME	**Unit 1**	**Unit 2**	**Unit 3**	**Unit 4**	**Unit5**	**Unit 6**	
	45 minutes	108.8%	109.6%	106.2%	108.5%	110.5%	108.2%	Complies

RESULT: Given sample is Sub-Standard with regards to Uniformity of weight (mass) test.

iii. Storekeeper of Main Medicine Store of Tehsil Headquarter Hospital Phalia District Mandi Bahauddin provided Invoice/Warranty bearing No. 2062 dated 21-07-2022 issued by M/s MTI Medical (Pvt.) Ltd. 586-587 Sundar Industrial Estate Lahore Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s MTI Medical (Pvt.) Ltd. 586-587 Sundar Industrial Estate Lahore Pakistan as a proof of its purchase.

V. A copy of test/analysis report was sent to M/S MTI Medical (Pvt.) Ltd. 586-587 Sundar Industrial Estate Lahore Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 23-01-2023

Firm replied to the show cause notice vide letter no. MTI/001/PQCB/2023 dated 01-02-2023

The same batch 506 of capsule Gribok (Each capsule contains: Fluconazole B.P.... 150mg) has already been passed from following DTL:

Sr. No.	*DTL*	*Institution/ Organization*	*Result Status*
1	*DTL Lahore*	*DHQ Kasur*	*Pass*
2	*DTL Bahawalpur*	*Tehsil Khanpur*	*Pass*
3	*DTL Multan*	*DHQ Hospital Khanewal*	*Pass*
4	*DTL Faisalabad*	*THQ Sambrial*	*Pass*
5	*DTL Faisalabad*	*Drug Inspector Toba Tek Singh*	*Pass*
6	*DTL Faisalabad*	*Drug Controller Tehsil Narowal*	*Pass*

We replaced the product Gribok Capsule 150mg, having batch no. 506 with new batch to concerned THQs & DHA with fresh batch No. 586.

*It is further explained that the **Assay % age and dissolution and all other parameter of all the above***

mentioned sample having same batch was up to the standard specifications.

1-Your kind attention is invited to our numerous letters send to concerned authorities on the same context.

2-Your good self-appreciate that we have done our best to satisfy all concerned by providing all the relevant results and other actions taken from time to time, few of actions so far taken are

listed below;

a. ***We have already provided the replacement*** *of the requisite drug as per requirement of the hospital authority.*

Further, the product was already being informed the THQ Hospital Phalia, THQ Hospital Malakwal and DHA Mandi Bahauddin.

b. *A preliminary enquiry was conducted* ***to compare standard specification****.*

3-In the view of position explained above we are further submitting complete detail as desired.

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: June 2022

Expiry Date: June-2024

Sampling Date (Form 4): 01-09-2022

Sent to DTL (Form 6): 01-09-2022

Date of receipt in DTL: 06-09-2022

DTL Report Date (Form 7): 08-10-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 07-11-2022

Retesting Request of Firm: No

Investigation Report Dated: 14-12-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 16

PQCB/R-233/2022

Tehsil & District Hafizabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan** through its Chief Executive Officer, Syed Nophil Rizvi 2. Syed Nophil Rizvi — Chief Executive Officer 3. Kamran Awan — Production Incharge 4. Mohammad Fakhir Khaleeq — Quality Control Incharge/ Warrantor of M/s Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Tehsil & District Hafizabad reported that: -

i. His Predecessor, on 29-06-2022, inspected the premises of Main Medicine Store, Office of the CEO Health District Complex Hafizabad, took following drug sample on Form No. 04 for the purpose of test and analysis and sent to Government Analyst Drug Testing Laboratory, Faisalabad vide memorandum no. 132441 dated 04-07-2022

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 No. & Date	DTL Test Report Result
Powder for Reconstitution. Macrobac 15ml [Each 5mL reconstituted suspension contains: Azithromycin Dihydrate (USP) equivalent to Azithromycin …. 200mg] **Mfg Date** March 2022 **Expiry Date** March 2024 **Regn No.** 082215	S0301	M/s Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan.	01-68017024/ DTL Dated 18-08-2022	**Analysis with specifications applied:** USP 2022 **DESCRIPTION:** White powder contained in white plastic bottle with child resistance cap packed in outer hard carton along with leaflet and measuring device. After reconstitution, it forms light pink color suspension. **IDENTIFICATION:** Azithromycin is identified **ASSAY:** Stated: 200mg / 5ml Determined: 182.636 mg / 5ml Percentage: 91.318 % (Complies) Limit: 90–110% (USP 2022) **pH:** Stated: 8.5 – 11 (USP 2022) Determined: **8.37 (Does Not Comply)** **DELIVERABLE VOLUME:** Stated: 15ml (USP 2022) Determined: 15.15ml (Avg. of 10 bottles) (Complies) **RESULT: Given sample is declared Sub-Standard with regards to pH Test.**

iii. Storekeeper of the Main Medicine Store, Office of the CEO Health District Complex Hafizabad provided Invoice/Warranty bearing number 0000005221 dated 16-05-2022 issued by M/s Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan, as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan.

v. A copy of test/analysis report was sent to M/S Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 23-01-2023

Firm replied to the show cause notice vide letter dated 03-02-2023

This is with reference to your letter No. PQCB/R-233/2022 dated 17-02-2023 received at our office on 02-03-2023 regarding the subject captioned above.

Along with documents, you have required us to explain our position for manufacturing, stocking selling of substandard drugs and you have also required us to verify the names of accused persons and also requested to submit the attested documents for board consideration.

In response thereto, we state as follow:

- *That First letter from Provincial Inspector of Drugs, Lyallpur Town Faisalabad was received to us on dated 20-09-2022 and same was replied on dated 26-09-2022 with required information and documentations and confirmed that questioned product after cross checked of all quality parameters is of standard quality.*
- *With regards to above said show cause notice, our justifications and clarifications are as followed:*
- *Please note that we have received the Warrantor Portion Sample of our product Macrobac 200 mg/ 5 ml. Suspension on the same day dated 02-11-2022 along with the letter No. 73/DI-DC/HZD dated 29-10-2022; however, we have analyzed the Warrantor Portion Sample of Batch No. S0301 along with the retention sample of the same batch and found that our product is of Standard Quality with respect to prescribed parameters of physical characteristics, assay, and pH.*
- *It is pertinent to mention here that the product in question is dry powder suspension of Azithromycin as Dihydrate, which is reconstituted with water to form liquid suspension dosage form. The pH of the suspension is dependent upon proper reconstitution of the formulation with water.* ***In case the dry powder is not properly mixed in water, it may sediment and alter the pH value****, which is evident from the report of DTL Faisalabad as the pH value of a batch is slightly lower than the specified limits. If the Govt. Analyst properly reconstitute the suspension and took the pH after removal of air bubbles the desired value of pH may be attained.*
- *Even though we totally unaccepting the DTL Faisalabad Testing report we are not requesting for the retest of the batch in question and* ***going to replace batch*** *with the fresh stock as an act of curtesy and grace.*

Based on above facts it is evident that this is the borderline case, therefore, it is humbly requested to take a kind decision and the case may please be closed amicably and fairly with formal.

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: March-2022

Expiry Date: March-2024

Sampling Date (Form 4): 29-06-2022

Sent to DTL (Form 6): 04-07-2022

Date of receipt in DTL: 07-07-2022

DTL Report Date (Form 7): 18-08-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 29-10-2022

Retesting Request of Firm: No

Investigation Report Dated: 10-12-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 17

DISTRICT JHANG

PQCB/R-478/2021

(Tehsil Ahmedpur Sial, District Jhang)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Trison Research Laboratories Pvt Ltd, 27-A, Punjab Small Industrial Estate, Sargodha** through its Chief Executive Officer, Mubasher Javed 2. Mubasher Javed — Chief Executive Officer 3. Mubasher Javed — Production Manager/Warrantor 4. Fatima Tahir — Quality Control Manager of M/s Trison Research Laboratories Pvt Ltd, 27-A, Punjab Small Industrial Estate, Sargodha.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Ahmedpur Sial, District Jhang reported that:-

i. He, on 21-12-2020 inspected the business premises named M/s Makkah Medical Store, Chowk Garh More, Tehsil Ahmedpur Sial, District Jhang took sample of subject drug along with other drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Faisalabad vide memo No. 80533 Dated 22-12-2020.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result

Film Coated Tablet. Hismin [Each film coated tablet contains: Cetirizine Di-Hydrochloride.10mg] **Manufacturing Date:** Jul-2020 **Expiry Date:** Jul-2022 **Registration No**. 063341	32195	M/s Trison Research Laboratories Pvt. Ltd, 27-A, Punjab Small Industrial Estate, Sargodha.	01-68006529/ DTL dated: 18 Feb 2021	**Result of test/ analysis with specifications applied:**BP 2021 **DESCRIPTION:** Off white colored, oval shaped biconvex tablets, contained in ALU-PVC packing of 10's packed in outer hard carton. **NOTE: According to British Pharmacopoeia, coated tablets have a smooth surface which is often colored and may be polished but in case of given sample the coating surface of tablets is not smooth. (Does not comply)** **UNIFORMITY OF WEIGHT (Mass) Does not comply** the BP's acceptance criteria of Uniformity of weight (Average weight of Tablet: 168.97mg) **Tolerance Limit:** ±7.5% of Average weight. (BP 2021) **Reference Limit:** 156.3-181.6mg **Determined Limit: 137.8-194.0mg (Does not comply)**

Tablet #	1	2	3	4	5	6	7	8	9	10	Average (mg)
Individual weight (mg)	163.8	180.1	182.3	151.0	194.0	171.2	175.1	156.5	164.2	137.8	168.97
Allowed % Deviation (±7.5%)	-3.1	6.6	**7.9**	**-10.6**	**14.8**	1.3	**3.6**	-7.4	-2.8	**-18.4**	
Tablet #	11	12	13	14	15	16	17	18	19	20	
Individual weight (mg)	150.3	157.2	163.1	161	188.7	190.2	189.1	152.2	175.3	176.3	
Allowed % Deviation (±7.5%)	**-11.0**	-7.0	-3.5	-4.7	**11.7**	**12.6**	**11.9**	**-9.9**	3.7	4.3	

NOTE: As per BP 2021, Not more than two of the individual masses deviate from the average mass by more than the percentage deviation (±7.5%) and none deviates by more than twice of that percentage. In case of given sample, 09 units out of 20 deviates more than ±7.5% and 01 units out of these 09 deviates more than twice (i.e., ±15%) of that percentage.

IDENTIFICATION: Cetirizine 2HCl identified

ASSAY:

Stated: 10mg/Tablet

Determined: 10.488mg/ Tablet

Percentage 104.88% (Complies)

Limit: 95-105% (BP 2021)

DISSOLUTION TEST:

Complies with the dissolution test of BP 2021 as detailed below: -

Tolerance Limit: NLT 80% (Q) of the labeled amount of Cetirizine dihydrochloride is dissolved in 45minutes in 900ml of water in Apparatus II at 50rpm.

Level	Number Tested	Acceptance Criteria						Average	Remarks
S1	6	Each unit is not less than Q+5 percent						S1	**Does not Comply**
		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
		88.3%	85.5%	99.7%	66.1%	92.3%	101.4		
S2	6	Average of 12 units (S1+S2) is equal to or greater than Q and no unit is less than Q-15 percent						S1+S2	**Complies**
		Unit 7	Unit 8	Unit 9	Unit 10	Unit 11	Unit 12		
		92.5%	98.2%	102.2%	97.1%	101.1%	92.5%	93.1%	

RESULT: Given sample is Sub-standard, with regards to Uniformity of weight (mass) and Physical characteristics of Tablets.

iii. The Proprietor, M/s Makkah Medical Store, Chowk Garh More, Tehsil Ahmedpur Sial, District Jhang provided warranty/invoice bearing No. 935 dated 17-07-2020 issued by M/s Trison Research Laboratories (Pvt) Ltd.

iv. Warrantor Portion was sent to M/s Trison Research Laboratories (Pvt) Ltd.

v. A copy of Test/ Analysis report was sent to M/s Trison Research Laboratories (Pvt) Ltd and they were directed to provide requisite information in this regard. In response the firm requested for retesting of subject drug sample from Appellate laboratory, National Institute of Health (NIH), Islamabad. But the request of the firm was turned down by the Committee of Provincial Quality Control Board in its19th meeting dated 21-10-2021.

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: -

i. **Manufacture for sale /sale of Substandard drug**

ii. **Issuance of false warranty**

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

Reply to Showcause letter

Refer to your letter No. PQCB/R-478/2021 received by us on 17-08-2022 regarding the subject cited above. As per your direction, we, hereby verifying the names of the Prima Facie involved in the manufacturing of the said drug. Names are as follows:

Mubasher Javed (CEO/Production Manager/Warrantor)

Address: House # 31/1 Al Noor Town, Walton road Post Office, Tehsil Lahore Cantt., District Lahore.

Fatima Tahir (Quality Control Manager)

Address: street # 1 Shadab town Sargodha.

4. Personal Hearing notice(s) issued to accused person(s) dated 12-09-2022.

Reply to Personal hearing letter

It is stated that the company has tested retained sample of Hismin Tablets of the same batch No 32195 kept under prescribed conditions at our Quality Control laboratory. The results had shown that the retained samples of the said batch are in compliance with the specifications.

The company then challenged the results of Govt. Analyst report and made a request to PQCB for retesting from NIH appellate laboratory Islamabad. But the request for retesting has been Turned Down by the PQCB on the basis of Time Barred. For compliance of section 22(4) of the Drugs Act 1976 (as amended), through which stipulated time was 10 days. We were unable to comply the stipulated time frame (10 days), because our manufacturing unit (factory) was remain closed for couple of months (March, April) 2021 due to severe third wave of Covid-19 pandemic keeping in view of the current situation, we had replied to the honourable drug inspector at the earliest as we received the letter.

Further the subjected case is from the time of previous management and for further correspondence we have intimated them for their record and information about the said case and the personal hearing notice (copy attached). The names of the concerned are already disclosed to you in show cause notice.

So in light of the above, a favourable response is requested.

Fatima Tahir (Quality Control Manager)

Trison Research Laboratories (Pvt.) Ltd.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

250th meeting dated 22-09-2022:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **250th meeting held on 22-09-2022** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab, in the presence of board members. Miss Dr. Farwa Mansoor Secretary DQCB District Jhang and Mr. Amir Liaqat Drug Inspector Tehsil Ahmadpur Sial were present along with original record of the case. Drug Inspector Tehsil Ahmadpur Sial briefed the Board about facts of the case and asked for permission for prosecution against the accused persons. No one among the nominated accused appeared before the Board on the behalf of M/sTrison Research Laboratories Pvt. Ltd, 27-A, Punjab Small Industrial Estate, Sargodha.

6. The Board after discussion 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.

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

254th meeting dated 13-12-2022:

3. 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. M. Khurram Shahzad, Secretary DQCB District Jhang and Mr. Amir Liaqat, Drug Inspector, Tehsil Ahmedpur Sial, District Jhang were present along with original record of the case. Drug Inspector, Tehsil Ahmepur Sial briefed the Board about facts of the case. No one among the nominated accused appeared before the Board on the behalf of **M/s Trison Research Laboratories Pvt. Ltd, 27-A, Punjab Small Industrial Estate, Sargodha.**

6. The Board after discussion 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.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 07-2020**
- **Expiry Date: 07-2022**
- **Sampling Date (Form 4): 21-12-2020**
- **Sent to DTL (Form 6): 22-12-2020**
- **Date of receipt in DTL: 24-12-2020**
- **DTL Report Date (Form 7): 18-02-2021**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 15-03-2021**
- **Date of Retesting Request of Firm:09-05-2021**
- **Fate of Retesting: Turn Down (19th meeting dated 21-10-2021)**
- **Investigation Report Dated: 27-06-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

ITEM No. 2

ADJOURNED CASES OF PREVIOUS MEETING

Case No. 1

PQCB/R-471/2022

Tehsil Phalia & District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan** through its Chief Executive Officer, Muhammad Hanif 2. Muhammad Hanif — Chief Executive Officer 3. Shakeel Ahmad — Production Incharge 4. Irfan Amin — Quality Control Incharge 5. Adnan Zahid — Warrantor of M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Phalia, District Mandi Bahauddin, reported that: -

i. He, on 19-10-2022 inspected the Main Medicine Store of THQ Hospital Phalia, District Mandi Bahauddin, took four different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 145167 dated 20-10-2022.

ii. The subject drug sample, after test/analysis was declared as **Misbranded** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below: -

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report</th><th>DTL Test Report Result</th></tr>
<tr><td>Powder for Reconstitution.
Artheget Junior 30ml [Each reconstituted 5mL contains: Artemether ….15mg, Lumefantrine …. 90mg]

Mfg. Date:
Sep-2022

Exp. Date:
Sep-2024

Reg. No: 057886</td><td>497D05</td><td>M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan.</td><td>01-68019709/DTL dated: 15-12-2022</td><td>Result of test/ analysis with specifications applied: IP 2020

<u>DESCRIPTION</u>: Yellow colored granular powder contained in white colored sealed plastic bottle with child resistant cap, packed in outer hard carton. After reconstitution forms yellow colored suspension having pleasant odor.

Note: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022 states that “all registration holders shall follow official pharmacopeial specifications for all such formulation for which official monographs of the drug product is available in the most recent edition of such pharmacopeia”. Product specifications of the given sample is “Product Specs: Getz Pharma” and it is manufactured after the expiration of the timeline to apply such specifications despite the availability of its monograph in Pharmacopoeia (International Pharmacopoeia 2020), so, the manufacturer’s claim regarding product specifications is in contradiction to DRAP circular and in violation to Drug Act 1976. (Does not Comply)

<u>IDENTIFICATION:</u> Artemether and Lumefantrine are identified.

<u>ASSAY:</u>
<table>
<tr><th>Generic</th><th>Artemether</th><th>Lumefantrine</th></tr>
<tr><td>Stated Potency</td><td>15mg/5ml</td><td>90 mg/5ml</td></tr>
<tr><td>Determined Potency</td><td>14.606 mg/5ml</td><td>88.990 mg/5ml</td></tr>
<tr><td>Percentage</td><td>97.373%</td><td>98.878%</td></tr>
<tr><td>Reference Limit</td><td>90-110%</td><td>90-110%</td></tr>
<tr><td>Remarks</td><td>Complies</td><td>Complies</td></tr>
</table>
<u>RESULT:</u> Given sample is Misbranded as per Section 3 (s) (iv) of The Drugs Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022.</td></tr>
</table>

iii. Store keeper, Main Medicine Store of THQ Hospital Phalia, District Mandi Bahauddin provided warranty No. 610336424 dated 15-10-2022 issued by M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan as a proof of its purchase.

iv. Warrantor Portion of subject drug sample was sent to M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan.

v. A Copy of Test/ Analysis report was sent to M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan and they were directed 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 Misbranded drug**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 09-05-2023

<u>Firm replied to the show cause notice vide letter no. Getz/ Artheget Junior/497D05/23/033 dated 11-05-2023 whose operative part is as follows:</u>

The label of the drug bears Manufacturer's Specifications thus in our humble view, they do not fall under the category of misbranded drugs.

The Government Analyst analyzed the product in accordance with International Pharmacopoeia 2020 and not raised any concerns regarding the quality of the product, which confirms the quality of the product.

To ensure the compliance of order no. F.3-5/2020-I&V-11(M-297) dated 7th February 2022, after the cutoff date from DRAP we have already developed artwork as per International Pharmacopoeia and revised artworks have already been commercialized.

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary	**Warning to the subject product**	**Warning to the product in different firms**
Dated	17-05-2023 (20th Committee Meeting)	24-06-2021 (232-M) Total Warning to Firm: 2

Manufacturing Date: Sep 2022

Expiry Date: Sep 2024

Sampling Date (Form 4): 19-10-2022

Sent to DTL (Form 6): 20-10-2022

Date of receipt in DTL: 25-10-2022

DTL Report Date (Form 7): 15-12-2022

Time Extension: Not Time Barred

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

Retesting Request of Firm: No

Investigation Report Dated: 03-04-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 2

Case No.

PQCB/R-309/2021

Bahawalpur Saddar

Misbranded & Sub-Standard (Physical Test

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township Kohat Road Bannu** through its Managing Director/Warrantor Naeem Hayat. 2. Naeem Hayat Managing Director/Warrantor 3. Shaukat Ullah Khan Production Incharge 4. Syed Asif Kamal Quality Control Incharge of **M/S Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township Kohat Road Bannu.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Tehsil Bahawalpur Saddar, District Bahawalpur reported that: -

i. His Predecessor, on 27-01-2021, inspected the business premises of M/S New Bismillah Medical Store Situated at Samma Satta Road Khanqa Shareef 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, Bahawalpur.

ii. One out of these three drug samples, after test/ analysis was declared **Substandard & Misbranded** 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 Results
Injection Treafen [Diclofenac Sodium:75mg/3ml]	055	M/S Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township Kohat Road Bannu	TRA No.01-77003148/DTL Dated: -03-04-2021	**Analysis with specifications applied: USP 2020/MS.** **Composition:** Each 3ml Ampoule contains: Diclofenac Sodium (USP)……75mg **Description:** Transparent Liquid solution in sealed transparent glass ampoule. (Stated volume: 03ml**). 07 out of 17 ampoules have visible particulate matter seen with the naked eye. (Does not comply with the parenteral specifications).** **Product specifications on the label claims that product is of USP Specifications. However, "Diclofenac Sodium Injection" Monograph is not present in USP" (The product is misbranded).** **Volume (MS):** Limit: 3.05-3.15ml Determined: 3.06ml **PH (MS):** Limit: 7.5-9.0 Determined: 8.393 **Sterility Test (USP):** The Product is sterile. **Identification (MS):** Diclofenac Sodium is identified. **Assay (MS):** Diclofenac Sodium: Stated: 75mg/3ml Determined: 79.97mg/3ml Percentage: 106.63% Limit: 90.0-110.0% **Result:** The sample is declared **Substandard** on the basis of Physical Test & **Misbranded** as defined under clause (vi) of subsection (s) of section 3 of the Drug Act 1976.

iii. M/S New Bismillah Medical Store Situated at Samma Satta Road Khanqa Shareef provided invoice/ Warranty No. 18378, Dated. 06-06-2020 & 13683 Dated 22-02-2020 issued by M/S Ikhlaq Medicine Company House No. 203-B Muhammadia Colony Bahawalpur

who in turn provided invoice/warranty No. 4835, Dated. 01-01-2020 issued by M/S Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township Kohat Road Bannu as a proof of its purchase.

iv. Warrantor portion and copy of test report was sent to M/S Ikhlaq Medicine Company House No. 203-B Muhammadia Colony Bahawalpur and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township Kohat Road Bannu 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 18th Committee Meeting of PQCB dated 13.09.2021 and the Committee of PQCB after unanimous decision decided to turn down the said retesting request.

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. **Manufacturing for sale /selling of Substandard & Misbranded drug**

   b. **Issuance of false warranty**

3. Show-cause was issued to accused person(s) vide dated 07.03.2022

4. Personnel Hearing notice(s) issued to accused person 20.04.2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board in compliance to the Orders of Honourable Lahore High Court, Lahore dated 09.02.2023 in writ petition no. 10009/2022, Under Section 11 of the Drug Act 1976 in its **260th meeting held on 04-05-2023** under the chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab/ Chairperson, Provincial Quality Control Board, Punjab. Mr. Attiq Ur Rehman Secretary DQCB District Bahawalpur attended the meeting online via Zoom Link. No one appeared before the Board on behalf of M/s Treat Pharmaceutical Industry (Pvt.) Ltd. However, counsel for the firm submitted written request for adjournment, received in the office of the Secretary, Provincial Quality Control Board, Punjab on dated 02-05-2023.

6. The Board after due deliberation and discussion unanimously accepted the firm's request for adjournment and 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.

Summary:

Manufacturing Date: 10.2019

Expiry Date: 10.2021

Sampling Date (Form 4): 07.01.2021

Sent to DTL (Form 6): 03.02.2021

Date of receipt in DTL: 03.02.2021

DTL Report Date (Form 7): 03.04.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 27.07.2021

Date of Retesting Request of Firm: 05.05.2021

Fate of Retesting Request: Turn Down (Particulate Matter)

Investigation Report Dated: 04.01.2022

7. Personnel Hearing notice(s) issued to accused person 18.05.2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 3

PQCB/R-415/2022

Punjab Health Facilities Management Company & District Hafizabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Pfizer Pakistan Ltd. B-2, S.I.T.E Karachi, Pakistan** through its CEO/ Managing Director, Syed Muhammad Wajeehuddin 2. Syed Muhammad Wajeehuddin CEO/ Managing Director 3. Rashid Mohammad Khan Production In-charge 4. Muhammad Farooq Quality Control In-charge/ Warrantor of M/s Pfizer Pakistan Ltd. B-2, S.I.T.E Karachi, Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Punjab Health Facilities Management Company reported that: -

i. He, on 25-10-2022, inspected the premises of Medicine Store of Punjab Health Facility Management Company Hafizabad, took different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide memorandum no. 145412 dated 25-10-2022.

ii. The subject drug sample after test/analysis was declared as **Misbranded** by Government Analyst Drug Testing Laboratory **Faisalabad**, as detailed below:

<table>
<tr><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>DTL Report No. & Date</th><th>DTL Test Report Results</th></tr>
<tr>
<td>Capsule. Vibramycin [Each capsule contains: Doxycycline Hyclate … USP …. equivalent to Doxycycline … 100mg]

Mfg Date
June 2022

Expiry Date
May 2025

Regn No.
000456</td>
<td>GE8080</td>
<td>M/S Pfizer Pakistan Ltd., B-2, S.I.T.E Karachi, Pakistan.</td>
<td>01-68019764/DTL dated

02-12-2022</td>
<td>
Result of test/ analysis with specifications applied: BP 2022

<u>DESCRIPTION:</u> Yellow powder free from visible contaminants, contained in Dark green opaque body imprinted with “VBM-100” and opaque dark green cap imprinted with “pfizer” packed in ALU-PVC packing of 6 units.

NOTE: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states “all registration holders shall follow official pharmacopeial specifications for all such formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia”. Product Specifications of the given sample is “Pfizer Specs,” and it is manufactured after the expiration of the timeline to apply such specifications despite the availability of its monograph in Pharmacopoeia (USP 2022 and BP 2022), so the manufacturer’s claim regarding product specifications is in contradiction to DRAP circular and in violation to Drugs Act 1976. (Does not Comply)

<u>UNIFORMITY OF WEIGHT (Mass):</u> Comply the acceptance criteria of Uniformity of weight as per BP 2022.

(Average weight of contents of capsule: 305.625 mg)

<u>Tolerance Limit:</u> ± 7.5% of Average weight (BP 2022)

<u>Reference Limit:</u> 282.7 - 328.5 mg

<u>Determined Limit:</u> 296.1 - 318.7mg (Complies)

<u>IDENTIFICATION:</u> Doxycycline Hyclate is identified.

<u>ASSAY OF DOXYCYCLINE:</u>

Stated: 100 mg Doxycycline/Capsule

Determined: 99.157 mg Doxycycline/Capsule

Percentage: 99.157% (Complies)

Limit: 95 – 105% (BP 2022)

<u>DISSOLUTION TEST</u>; Complies with the dissolution test as per BP 2022 as detailed below:

Tolerance Limit: Not less than 70 % of the stated amount of Doxycycline is dissolved in 30 minutes in 900ml of 0.1M hydrochloric acid using Apparatus 1 at 100 rpm.

<table>
<tr><th>Level</th><th>Unit Tested</th><th colspan="6">Acceptance Criteria</th><th>Remarks</th></tr>
<tr><td rowspan="3">1</td><td>6</td><td colspan="6">Each unit is Not less than 70% of the stated amount</td><td rowspan="3">Complies</td></tr>
<tr><td>TIME</td><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit5</td><td>Unit 6</td></tr>
<tr><td>30 minutes</td><td>106.7%</td><td>107.7%</td><td>109.7%</td><td>109.1%</td><td>104.6%</td><td>105.6%</td></tr>
</table>

RESULT: Given sample is Misbranded as per Section 3 (s) (iv) of The Drugs Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022
</td>
</tr>
</table>

iii. M/s Punjab Health Facility Management Company Hafizabad provided invoice/warranty bearing No. 19008760 dated 18-09-2020 issued by M/s Pfizer Pakistan Ltd. B-2, S.I.T.E Karachi Pakistan

iv. Warrantor portion of drug sample was sent to M/s Pfizer Pakistan Ltd. B-2, S.I.T.E Karachi Pakistan.

V. A copy of test/analysis report was sent to M/s Pfizer Pakistan Ltd. B-2, S.I.T.E Karachi Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 09-05-2023

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary	Warning to the subject product	Warning to the product in different firms
Dated	28-10-2021	First Warning: 28-10-2021 (234-M) Total Warning to Firm: 10

Summary:

Manufacturing Date: June 2022

Expiry Date: May-2025

Sampling Date (Form 4): 22-10-2022

Sent to DTL (Form 6): 25-10-2022

Date of receipt in DTL: 26-10-2022

DTL Report Date (Form 7): 02-12-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 30-12-2022

Retesting Request of Firm: No

Investigation Report Dated: 09-03-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 4

DISTRICT LODHRAN

PQCB/R-525/2021

(Tehsil & District Lodhran)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Lisko Pakistan (Pvt) Ltd. L-10-D, Block-21 F.B Industrial Area, Karachi, Pakistan** through its Director, M. Muzammil Nazar 2. M. Muzammil Nazar 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, Tehsil & District Lodhran reported that: -

i. He, on 23-08-2021 inspected the premises of Main Medicine Store of office of the Chief Executive Officer (DHA), District Lodhran, took following drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Multan vide memorandum no. 104516 dated 24-08-2021.

ii. The following drug sample, 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	DTL Test Report Result
Capsule. LIBRACIN [DOXYCYCLINE HYCLATE Eq. to DOXYCYCLINE 100MG] **Mfg Date:** May 2021 **Expiry Date:** May 2023 **Regn. Date** 004597	423-21	M/s Lisko Pakistan (Pvt) Ltd. L-10-D, Block-21 F.B Industrial Area, Karachi, Pakistan.	01-89006638/ DTL dated: 21-12-2021	**Result of test/ analysis with specifications applied:** USP 2021 **DESCRIPTION:** Yellow to lemon color powder filled in green color hard gelatin (body & cap) capsule in ALU-PVC blister of ten (10) units packed in a labeled outer carton. Each outer carton contains 12 blister of 10 units i.e 12*10 = 120 Capsules. **UNIFORMITY OF DOSAGE UNIT (Weight Variation):** Does not comply the acceptance criteria of Uniformity of dosage unit (weight variation). (Average weight of Contents of Capsule: 281.28 mg) **Acceptance Criteria:** 1) Acceptance value of first 10 dosage units is less than or equal to L1 % (i.e. 15%) 2) Final acceptance value of 30 dosage units is ≤ L1% and no individual content of any dosage unit is less than [1 -(0.01) (L2)]M nor more than [1+(0.01) (L2)]M. L2 =25 **Determined:** Acceptance value of 10 dosage units= **26.60 (Does Not Comply)** Acceptance value of 30 dosage units= **22.48 (Does Not Comply)** **DISSOLUTION TEST:** NLT 80% (Q) of the labeled amount of doxycycline is dissolved in 30 minutes. **(Complies)** **IDENTIFICATION:** Doxycycline as Hyclate Identified. **ASSAY:** Analysis Method: UPLC **Doxycycline** Stated: 100 mg/ Capsule Determined: 90.90 mg/ Capsule Percentage: 90.90% **(Complies)** Limit: 90-120% **RESULT:** The above sample is **Sub-Standard** on the basis of Uniformity of Dosage Units (Weight Variation).

iii. Storekeeper of Main Medicine Store of office of the Chief Executive Officer (DHA), District Lodhran, provided invoice/warranty bearing numbers 000061 dated 17-07-2021 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 the 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 the 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- 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: -

i. **Manufacture for sale /sale of Substandard drug**

ii. **Issuance of false warranty**

iii. **Disobedience of lawful authority of Drug Inspector by non-provision of requisite information**

3. Show cause notice(s) issued to the accused person(s) dated 19-10-2022.

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

PREVIOUS PROCEEEDINGS & DECISION BY THE BOARD:

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. Misbah-ud-Din, Secretary DQCB, District Lodhran and Dr. Naveed Aslam, Drug Inspector, Tehsil & District Lodhran were present along with the original case record. No one among the nominated accused persons of **M/s Lisko Pakistan (Pvt) Ltd. L-10-D, Block-21 F.B Industrial Area, Karachi, Pakistan** appeared before the Board. However, a written request for adjournment was received from Naeema Khanam (Quality Control Incharge/Manager) vide letter no. Nil dated 12-12-2022 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.

Case is placed before the board for decision.

Summary:

- **Manufacturing Date: 05-2021**
- **Expiry Date: 05-2023**
- **Sampling Date (Form 4): 23-08-2021**
- **Sent to DTL (Form 6): 24-08-2021**
- **Date of receipt in DTL: 26-08-2021**
- **DTL Report Date (Form 7): 21-12-2021**
- **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: NA**
- **Fate of Retesting: Not applicable**
- **Investigation Report Dated: 25-07-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 5

DISTRICT DERA GHAZI KHAN

PQCB/R-310/2022

Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Whitesun Pharma, Marri Road Tehsil Kamoke, District Gujranwala** through its Managing Director Haji Bashir Ahmad 2. Haji Bashir Ahmad — Managing Director 3. Faisal Bashir — Managing Partner and Warrantor 4. Hassan Farooq — Quality Control Incharge 5. Ruqayya Nawaz — Production Incharge Of **M/s Whitesun Pharma, Marri Road Tehsil Kamoke, District Gujranwala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan reported that:-

i. He, on 23-07-2022, inspected the business premises of M/s Muhammad Surgical Plus Pharmacy situated at Balakh-e-Serwar City Dera Ghazi Khan and took samples of two different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum No. 0000134393 dated 25-07-2022.

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

iii. M/s Muhammad Surgical Plus Pharmacy situated at Balakh-e-Serwar City Dera Ghazi Khan submitted Invoice/warranty no. 0099 dated 15-05-2021 issued by M/s Whitesun Pharma, Marri Road Tehsil Kamoke, District Gujranwala as a proof of its purchase of the said drug.

iv. Warrantor Portion of the drug sample was sent to M/s Whitesun Pharma, Marri Road Tehsil Kamoke, District Gujranwala and they were asked to provide requisite information in this regard.

v. A copy of test report was sent to M/s Whitesun Pharma, Marri Road Tehsil Kamoke, District Gujranwala and they were asked to provide requisite information in this regard.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Nexcare Bandage [Cotton Bandage (15cm * 3m)] **Mfg.date:** Jan-2021 **Exp. date:** Jan-2024 **Regn No.** Not Legible	NX004	M/s Whitesun Pharma, Marri Road Tehsil Kamoke, District Gujranwala	TRA No. 01-94004879/DTL Dated:-25-11-2022	**Result of Test/ Analysis with specifications applied**: BP **Description**: Open wove bandage of fabric of plain weave, bleached to good white. It is odorless and reasonably free from weaving defects. It is in one continuous length. The edges are cut evenly. **Note:** According to ''BP'' under Labelling of Open-wove Bandage stated as ''The label on the unit container, the label on the shelf container and the label on the outer transit container state whether the bandage complies with the requirements for Type 1, for Type 2 or for Type 3 Open-wove Bandage. The product contains BP as Finished Drug Product Specifications but does not contain the Type of bandage which is misleading. **(Mis-Branded-Does Not Comply)** **Warps (BP + MOH 5%):** Limits: 128.25 to 171.5/10 cm Determined: **121.45/10 cm (Does Not Comply)** **Wefts (BP + MOH 5%):** Limits: 79.8 to 100.8/10 cm Determined: **78.17/ 10 cm (Does Not Comply)** **Weight g / m^2:** Limit: NLT 33G/ m^2 Determined: **31.88 g/ m^2 (Does Not Comply)** **RESULT:** The above sample is **Sub-Standard** on the basis of tests performed **& Misbranded** as defined under section 3 (s)(i) of the Drugs Act, 1976..

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

a. **Manufacture for Sale/Sale of the Substandard & Misbranded drug**

b. **Issuance of false warranty**

3. Show cause Notice (s) issued to the accused person(s) Dated 06-02-2023.

Reply of the firm to Show cause notice vide letter no. nil dated nil:

1. In the initial correspondence with Drug Inspector Dera Ghazi Khan, (copy of letter is attached)
2. We have established a unit WHITESUN PHARMA situated at marri road tehsil kamoke and have got the manufacturing license of Medical Device items (copy of license is attached)
3. In further we had requested to Drug Inspector to Dera Ghazi Khan that please test the above said product sample under the specification of Medical Devices Standard.
4. According to above said the Nexcare Bandage 15cm*3m does not fall in Drug Act.
5. It is requested that please test the above said sample according to Medical Devices standard, than we will be able to clear our position.

4. Personal Hearing notice(s) issued to accused person(s) dated 20-04-2023.

PREVIOUS PROCEEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **260th meeting** held on **04-05-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. M. Asif Abbas, Secretary DQCB, District Dera Ghazi Khan & Mr. Faisal Mahmood Khan, Drug Inspector, Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan were present along with the original case record. No one among the nominated accused persons of **M/s Whitesun Pharma, Marri Road Tehsil Kamoke, District Gujranwala** appeared before the Board. 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.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 01-2021**
- **Expiry Date: 01-2024**
- **Sampling Date (Form 4): 23-07-2022**
- **Sent to DTL (Form 6): 25-07-2022**
- **Date of receipt in DTL: 29-07-2022**
- **DTL Report Date (Form 7): 25-11-2022**
- **Time Extension: Granted in 251st meeting dated 20-10-2022**
- **1ST DI Communication with firm on dated: 06-12-2022**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 06-01-2023**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 6

DISTRICT LODHRAN

PQCB/R-367/2022

Tehsil & District Lodhran

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 Director M. Muzammil Nazar 2. M. Muzammil Nazar Director 3. Naima Khanam Quality Control Manager/ Warrantor 4. Ghulam Nabi Khoso Production Manager 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 Tehsil & District Lodhran reported that:-

i. His Predecessor, on 11-11-2021, inspected the premises of Main Medicine Store, office of CEO (DHA) Lodhran, took sample of four different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum no. 0000110765 dated 11-11-2021.

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

iii. Store Keeper, Main Medicine Store, office of CEO (DHA) Lodhran submitted Invoice/warranty no. 000267 dated 14-10-2021 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 the said drug.

iv. Warrantor portion of the drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan and they were asked to provide the requisite information in this regard.

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 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 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:

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>Artilis (Artemether 15mg/5ml + Lumefantrine 90 mg/5ml) Powder for Oral Suspension.
Mfg.date:
Oct-2021
Exp. date:
Oct-2023
Regn No.
082151</td><td>G001-22</td><td>M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan</td><td>TRA No. 01-94000581/DTL
Dated:-28-01-2022</td><td><u>Result of test/ analysis with specifications applied:</u>
IP 2020
<u>Description:</u>
Yellow color dry powder, which upon reconstitution gives yellow to lemon color suspension in a labeled amber glass bottle, sealed with aluminum cap packed in a labeled outer hard carton.
<u>Identification:</u> Artemether & Lumefantrine Identified.
<u>Assay:</u>
Artemether
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>15mg/5ml</td><td>14.13mg/5ml</td><td>94.22 %</td><td>90-110%</td></tr>
</table>
(COMPLIES)
Lumefantrine
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>90mg/5ml</td><td>64.11mg/5ml</td><td>71.23 %</td><td>90-110%</td></tr>
</table>
(DOES NOT COMPLY)
<u>RESULT:</u>
The above sample is <u>Sub-Standard</u> on the basis of the Assay of Lumefantrine.</td></tr>
</table>

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>NIH Test Report No.</th><th>NIH Test Report Result</th></tr>
<tr><td>Powder for oral Suspension Artilis 60 ml.</td><td>G001-22</td><td>M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan</td><td>0216-P/2022 dated 07-09-2022</td><td><u>ASSAY:</u>
<u>Lumefantrine</u>
<table>
<tr><td>Stated</td><td>Found</td><td>Limit</td><td>Percentage</td></tr>
<tr><td>90mg/5ml</td><td>11.9668mg/5ml</td><td>90-110%</td><td>13.29%</td></tr>
</table>
Does not comply with manufacturer specification.
<u>CONCLUSION:</u> The sample is of Sub-Standard quality on the basis of tests performed.</td></tr>
</table>

vii. The Copy of NIH report was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan

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

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

b. **Issuance of false warranty**

c. **Disobeying the lawful authority of drug inspector by non-provision of requisite information**

3. Show cause Notice (s) issued to the accused person(s) Dated 20-04-2023.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023.

5. Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 10-2021**
- **Expiry Date: 10-2023**
- **Sampling Date (Form 4): 11-11-2021**
- **Sent to DTL (Form 6): 11-11-2021**
- **Date of receipt in DTL: 16-11-2021**
- **DTL Report Date (Form 7): 28-01-2022**
- **Time Extension: Granted in 238th meeting dated 09-02-2022**
- **1ST DI Communication with firm on dated: 19-07-2022**
- **Date of Retesting Request of Firm: 10-02-2022**
- **Fate of Retesting: Allowed in 248th meeting dated 04-08-2022**
- **Investigation Report Dated: 01-02-2023**

PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 7

PQCB/R-475/2022

Sheikh Zayed Hospital, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf, Karachi** through its Managing Director Erum Shakir Rahim. 2. Erum Shakir Rahim Managing Director 3. Muhammad Nasir Khan Production Manager 4. Faheem Uddin Bhutto Quality Control Manager 5. Hafiz Nadeem Warrantor of M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf, Karachi

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Sheikh Zayed Hospital, Lahore reported that: -

i. The then Drug Inspector, on 28-11-2021 inspected the Central medical store, Sheikh Zayed Hospital, Lahore, took subject sample of drug on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Lahore vide memorandum no 111732 dated 29-11-2021.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA	DTL Test Report Result
Ointment Polyfax skin Ointment 20g [Polymyxin B (Sulphate) BP 10000U/g, Bacitracin Zinc: 500 Units, Petrolatum Base 1gm] **Mfg date**: 10-2021 **Exp. Date**: 10-2026 **Regn. No**: 000371	6C8V	M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf, Karachi	01-73010661/DTL Dated. 12-01-2022	**Analysis with specifications applied: USP 2021** **Description:** Translucent colorless semi-solid preparation, claimed to be ointment n sealed metal collapsible tube with a screw cap. **Assay: Polymyxin B Sulphate:** Stated: 10,000 U/g Determined: 12760.51 U/g Percentage: 127.61% Limit: 90-130% **Assay: Bacitracin** Stated: 500 U/g Determined: 623.14 U/g Percentage: 124.63% Limit: 90-130% **LABELLING REQUIREMENTS:** **Stated**: According to Drugs Act 1976 section 3 s iv "misbranded means a drug: its label or container or anything accompanying which bears any statement design or device which makes any false claim for the drug or which is false or misleading in any particular." **Determined**: in the case of given sample **USP Specifications are printed on the label as per USP 2021 "Bacitracin Zinc and Polymyxin B Sulphate Ointments contains the equivalent of NLT 90.0% and NMT 130.0% of the labelled amount of Bacitracin & Polymyxin B" whereas the label claim on product is "Polymyxin B sulphate BP…10000units, Bacitracin Zinc BP…..500units, Petrolatum Base to 1.0gm"** which is contradictory to USP Specifications so manufacturer's claim regarding product specifications is false/misleading information. **(The product is Misbranded)** **Result: given** sample is **Misbranded** with regards to Labelling as per Section 3 **(s)** (iv) of the Drugs Act 1976.

iii. Store keeper Main Medicine store, Sheikh Zayed Hospital, Lahore, provided Invoice/warranty No. 5395950047 dated 27-11-2021 issued by M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf, Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf, Karachi.

v. A copy of test/analysis report was sent to M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf, Karachi and they were asked to provide the requisite information in this regard.

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

i. **Manufacture for sale/ sale of Misbranded drug**

ii. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused dated 05-05-2023

Firm submitted rectified label and undertaking

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023

Case is placed before the Board for Decision

Summary	Warning to the subject Product	Warning to the firm in different products
Dated	09-02-2022	First warning: 27-11-2020 Total warnings to firm: 89

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 8

Case No.

PQCB/R-438/2021

Tehsil & District Sahiwal

Misbrande

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi,** through its Chief Executive Officer/ Managing Director Sayed Muhammad Wajeehuddin, 2. Sayed Muhammad Wajeehuddin Chief Executive Officer/ Managing Director 3. Rashid Mohammad Khan Production In-charge 4. Muhammad Farooq Quality Control In-charge/ Warrantor **of M/S Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi.**

BRIEF FACTS OF THE CASE

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

i. Her Predecessor, on 28-10-2022, inspected the premises of Medicine Store o/o DM PHFMC, Ganj Shakir Colony Sahiwal and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo. No. 146241, dated 28-10-2022.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report
TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Capsule Vibramycin (Doxycycline hyclate equivalent to doxycycline: 100mg)

Mfg Date:
June- 2022

Exp Date:
May-2025

Registration No.
000456</td><td>GF5138</td><td>M/S Pfizer Pakistan Limited</td><td>01-10097000825/DTL
Dated. 30-12-2022</td><td>
<u>Analysis with specifications applied:</u> USP 2022.

<u>Composition: Each capsule contains:</u> Doxycycline hyclate equivalent to doxycycline: 100mg

<u>Description:</u>

Yellow color powder filled in green color hard gelatin capsule shell with Pfizer imprinted on cap and VBX100 imprinted on body. Packed in a blister pack (Primary packing) of 06 Capsules. 20 blisters are packed in outer hard carton (Secondary packing).

Note: As per DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022 states, “All registration holders shall follow official pharmacopeial specification for all such formulations for which official monographs of drug product is available in the most recent edition of such pharmacopoeia”. Product specification of given sample is “Pfizer Specs” and it is manufactured after the expiration of timeline to apply such specifications despite the availability of “Doxycycline Hyclate Capsules” monograph in USP, 2022. So the manufacturer’s claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drugs Act 1976. Therefore, the product is Misbranded.

<u>WT. VARIATION (USP):</u> Limit AV10≤L1% (15.0)

Determined 2.89

<u>DISSOLUTION TEST (USP):</u>

<u>Tolerance limit;</u> Each unit is not less than 85% (Q) in 60 minutes.

<table>
<tr><td colspan="6">Acceptance criteria</td><td>Average</td></tr>
<tr><td colspan="6">Each unit is not less than 85% in 60 minutes</td><td rowspan="3">96.59%</td></tr>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit 5</td><td>Unit 6</td></tr>
<tr><td>91.85%</td><td>99.16%</td><td>97.24%</td><td>95.70%</td><td>97.43%</td><td>98.20%</td></tr>
</table>
<u>IDENTIFICATION (USP):</u> Doxycycline is identified.

<u>Assay (USP):</u> Doxycycline

Stated: 100mg/Cap

Determined: 98.46mg/Cap

Percentage: 98.46%

Limit: 90.0-120.0%

<u>Result:</u>

The sample is declared as “Misbranded” as per section 3(s)(iv) of the Drugs Act 1976, in compliance to DRAP Order No. F.3-5/2020-I&V-II(M-297)/Human Import, Dated 7th February, 2022
</td></tr>
</table>

iii. Store keeper of Medicine Store o/o DM PHFMC, Ganj Shakir Colony Sahiwal provided delivery challan/ Invoice/warranty No. 3037607280 dated 12.09.2022 issued by M/S Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi.

v. A copy of test/analysis report was sent to M/S Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi and they were directed to explain their position and to provide the requisite information in this regard.

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 Misbranded drug.**

   b. **Issuance of false warranty**

3. Show-cause was issued to accused person(s) vide dated 12-04-2023

4. Personnel Hearing notice(s) issued to accused person 18.05.2023

Case was placed before the Board for Decision

Summary:

Manufacturing Date: 06.2022

Expiry Date: 05.2025

Sampling Date (Form 4): 28.10.2022

Sent to DTL (Form 6): 28.10.2022

Date of receipt in DTL: 31.10.2022

DTL Report Date (Form 7): 30.12.2022

Time Extension: N/A

1ST DI Communication with firm on dated: 10.01.2023

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated: 28.02.2023

Warning to the Subject Product	**Warning to the firm in different products**
28.10.21	First Warning: 28.10.2021 Total Warnings to firm: 10

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 9

PQCB R-240/2022

Jinnah Burn and Reconstructive Surgery Centre, AIMC, Lahore

ATTENDANCE:

Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Surgical Fiber, 1-Km, Katar Band Road, Near Mandi Chowk, Thokar Niaz Baig, Multan Road, Lahore, Pakistan,** through its Chief Executive Officer, Naeem Iqbal 2. Naeem Iqbal CEO/ Quality Control Incharge/Warrantor 3. Naveed Shahzad Production Incharge of M/S Surgical Fiber, 1-Km, Katar Band Road, Near Mandi Chowk, Thokar Niaz Baig, Multan Road, Lahore, Pakistan**.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Jinnah Burn and Reconstructive Surgery Centre, AIMC, Lahore, reported that:

i. She, on 05-07-2022, inspected the premises of Main Medicine Store of Jinnah Burn and Reconstructive Surgery Centre, AIMC, Lahore, and took a drug sample 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.132722 dated: 05-07 -2022, after test/ analysis was declared as **Misbranded** by Government Analyst, Drug Testing laboratory **Lahore,** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Cotton-Crape 4*4.5 [4*4.5] **Mfg. date**: April-2022 **Exp. Date**; April-2025 **Regs. #** 025500	00156	M/S Surgical Fiber, 1-Km, Katar Band Road, Near Mandi Chowk, Thokar Niaz Baig, Multan Road, Lahore, Pakistan	01-177001881/DTL dated: 05-09-2022	**Result of test/ analysis with specifications applied: BPC 1973** **DESCRIPTION**: Characteristic fabric of Leno Weave in one continuous length, containing no joins, clean, free from weaving defects leaf and shell and has fast edge. Claimed size=4*4.5. **LABELLING:** The sample label bears dimensions of length and width of bandage **without units of measurement**, i.e., 4*4.5 **(Misbranded)** **Wraps:** Limit: NLT 17.1/cm Determined: 18.11/cm **Wefts:** Limit: NLT 78/10cm Determined: 102.36/10cm **Weight per unit area:** Limit: NLT 140g/m^2 Determined: 154.28g/ m^2 **Length:** Determined: 450cm **Width:** Determined: 10.16cm **RESULT:** The sample is **Misbranded** as per The Drugs Act, 1976, 3(s)(i).

iii. Store Keeper, Main Medicine Store of Jinnah Burn and Reconstructive Surgery Centre, AIMC, Lahore, provided invoice/warranty No. S.F/ 00192 dated 16-06-2022 issued by M/S Surgical Fiber, 1-Km, Katar Band Road, Near Mandi Chowk, Thokar Niaz Baig, Multan Road, Lahore, Pakistan.

iv. Warrantor Portion was sent M/S Surgical Fiber, 1-Km, Katar Band Road, Near Mandi Chowk, Thokar Niaz Baig, Multan Road, Lahore, Pakistan.

v. Copy of test/analysis report was sent to M/S Surgical Fiber, 1-Km, Katar Band Road, Near Mandi Chowk, Thokar Niaz Baig, Multan Road, Lahore, Pakistan, with directions to provide the requisite information and explain their position 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 Misbranded Drug**

b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 10-02-2023.

Personal Hearing notice(s) issued to accused person(s) on 18-05-2023.

Case is placed before the Board for Decision.

Summary	Warning to the subject Product	Warning to the firm in different products
	1st time	First warning: no Total warnings to firm: 0

PROCEEDINGS & DECISION BY THE COMMITTEE:

Case No. 10

PQCB/R-496/2022

Tehsil & District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan** through its Chief Executive Officer, Muhammad Hanif 2. Muhammad Hanif — Chief Executive Officer 3. Shakeel Ahmad — Production Incharge 4. Irfan Amin — Quality Control Incharge 5. Adnan Zahid — Warrantor of M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan

BRIEF FACTS OF THE CASE

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

i. He, on 20-10-2022 inspected the Main Medicine Store, CEO (DHA) Office District Mandi Bahauddin, took five different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 145125 dated 20-10-2022.

ii. The subject drug sample, after test/analysis was declared as **Misbranded** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Powder for Reconstitution. Artheget Junior 30ml [Each reconstituted 5mL contains: Artemether ….15mg, Lumefantrine …. 90mg] **Mfg**. **Date**: Sep-2022 **Exp**. **Date**: Sep-2024 **Reg**. **No**: 057886	500D05	M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan.	01-68019732/DTL dated: 15-12-2022	**Result of test/ analysis with specifications applied: IP 2020** **DESCRIPTION**: Yellow colored granular powder contained in white colored sealed plastic bottle with child resistant cap, packed in outer hard carton. After reconstitution forms yellow colored suspension having pleasant odor. **Note**: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022 states that "**all registration holders shall follow official pharmacopeial specifications for all such formulation for which official monographs of the drug product is available in the most recent edition of such pharmacopeia**". Product specifications of the given sample is **"Product Specs: Getz Pharma"** and it is manufactured after the expiration of the timeline to apply such specifications despite the availability of its monograph in Pharmacopoeia (International Pharmacopoeia 2020), so, the manufacturer's claim regarding product specifications is in contradiction to Drug Act 1976. **(Does not Comply)** **IDENTIFICATION:** Artemether and Lumefantrine are identified. **ASSAY:**

Generic	Artemether	Lumefantrine
Stated Potency	15mg/5ml	90 mg/5ml
Determined Potency	14.556 mg/5ml	91.634 mg/5ml
Percentage	97.04%	101.816%
Reference Limit	90-110%	90-110%
Remarks	Complies	Complies

RESULT: Given sample is **Misbranded** as per Section 3 (s) (iv) of The Drugs Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022.

iii. Storekeeper, Main Medicine Store, CEO (DHA) Office District Mandi Bahauddin provided warranty No. 610337352 dated 20-10-2022 issued by M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan as a proof of its purchase.

iv. Warrantor Portion of subject drug sample was sent to M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan.

v. A Copy of Test/ Analysis report was sent to M/s Getz Pharma (Pvt) Ltd., 29-30/27, K.I.A. Karachi-Pakistan and they were directed 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 Misbranded drug**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 09-05-2023

Firm replied to the show cause notice vide letter no. MTI/001/PQCB/2023 dated 01-02-2023

The label of the drug bears Manufacturer's Specifications thus in our humble view, they do not fall under the category of misbranded drugs.

The Government Analyst analyzed the product in accordance with International Pharmacopoeia 2020 and not raised any concerns regarding the quality of the product, which confirms the quality of the product.

To ensure the compliance of order no. F.3-5/2020-I&V-11(M-297) dated 7th February 2022, after the cutoff date from DRAP we have already developed artwork as per International Pharmacopoeia and revised artworks have already been commercialized.

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary	**Warning to the subject product**	**Warning to the product in different firms**
Dated	17-05-2023 (20th Committee Meeting)	24-06-2021 (232-M) Total Warning to Firm: 3

Summary:

Manufacturing Date: Sep 2022

Expiry Date: Sep 2024

Sampling Date (Form 4): 19-10-2022

Sent to DTL (Form 6): 20-10-2022

Date of receipt in DTL: 25-10-2022

DTL Report Date (Form 7): 15-12-2022

Time Extension: Not Time Barred

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

Retesting Request of Firm: No

Investigation Report Dated: 03-04-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

ITEM No. 3

MISBRANDED

Request No. 1

PQCB/R-783,784/2019

District Headquarter Hospital, Pakpattan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan** through its Country Manager & CEO, S M Wajeeh Uddin 2. S M Wajeeh Uddin CEO & Country Manager 3. Rashid Muhammad Khan Production Incharge 4. Muhammad Farooq Quality Control Incharge/Warrantor of M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, District Headquarter Hospital Pakpattan, District Pakpattan reported that: -

i. Her predecessor, on 24-05-2019 inspected the Main Medicine store of DHQ Hospital Pakpattan, took following batches of the drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memorandum no 40470 & 40472 dated 29-05-2019**.**

ii. Both subject drug samples, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below: -

Sr. No	Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
1	Tablet Ponstan Forte [Mefenamic Acid: 500mg] **Mfg. Date:** 03-2019 **Exp. Date:** 02-2024 **Regn. No:** 006978	1950131	M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan	01-25003914/DTL dated 20-07-2019	**Result of test/ analysis with specifications applied:** BP 2018 **COMPOSITION:** Each tablet contains: Mefenamic acid BP…….500mg **DESCRIPTION:** A light yellow colored, elliptical biconvex tablet, one side engraved with **"PONSTAN FORTE"** and other side is plain. Packed in a blister packing of 10units. **DISINTEGRATION:** ***Determined:*** Four (04) tablets out of eighteen were not disintegrated within specified time, i.e., 15minutes. ***LIMIT:*** *All of the tablets must be disintegrated within specified time, i.e., not more than 15minutes. If 1 or 2 tablets fail to disintegrate completely then repeat the test on addition 12 tablets.* **(Does not comply with specifications)** **DISSOLUTION:** Not applicable **WEIGHT VARIATION:** **Determined**: 97.52-102.52% **Limit:** ±5% from average weight **IDENTIFICATION:** Mefenamic acid is identified. **ASSAY: Mefenamic Acid** Stated: 500mg Determined: 511.56mg Percentage: 102.31% Limit: 95 - 105% **RESULT:** The sample is **Substandard** on the basis of Disintegration Test
2	Tablet Ponstan Forte [Mefenamic Acid: 500mg] Mfg. Date: 03-2019 Exp. Date: 02-2024 Regn. No: 006978	1950130	M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan	01-25003915/DTL dated 20-07-2019	**Result of test/ analysis with specifications applied:** BP 2018 **COMPOSITION:** Each tablet contains: Mefenamic acid BP…….500mg **DESCRIPTION:** A light yellow colored, elliptical biconvex tablet, one side engraved with **"PONSTAN FORTE"** and other side is plain. Packed in a blister packing of 10units. **DISINTEGRATION:** ***Determined:*** **Four** (04) tablets out of six were not disintegrated within specified time, i.e., 15minutes. ***LIMIT:*** *All of the tablets must be disintegrated within specified time, i.e., not more than 15minutes. If 1 or 2 tablets fail to disintegrate completely then repeat the test on addition 12 tablets.* **(Does not comply with specifications)** **DISSOLUTION:** Not applicable **WEIGHT VARIATION:** **Determined**: 97.86-102.74% **Limit:** ±5% from average weight **IDENTIFICATION:** Mefenamic acid identified. **ASSAY: Mefenamic Acid** Stated: 500mg Determined: 482.60mg Percentage: 96.52% Limit: 95 - 105% **RESULT:** The sample is **Substandard** on the basis of Disintegration Test

iii. Storekeeper, DHQ Hospital Pakpattan provided Invoice/Warranty No. 18005365 date 17-05-2019 issued by M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi-Pakistan as proof of its purchase.

iv. Warrantor Portion of subject batches of drug samples were sent to M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi-Pakistan.

v. Copies of Test/ Analysis reports were sent to M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi Pakistan with direction to explain their position and provide requisite information in this regard.

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

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

ii. **Issuance of false warranty**

Summary:

Manufacturing Date: 03-2019

Expiry Date: 02-2024

Sampling Date: 24-05-2019

Sent to DTL (Form 6): 29-05-2019

Date of receipt in DTL: 01-06-2019

DTL Report Date: 20-07-2019

1ST DI Communication with firm on dated: 02-08-2019

Date of Retesting Request of Firm: No

Investigation Report Dated: 28-11-2022

3. Show cause notice(s) issued to the accused dated 23-12-2022

Firm submitted Reply of showcause notice dated 10-03-2023

We are in receipt of the Show Cause Notice No. POCB/R-783 & 784/2019 dated 23-12-2022 and seek to reply to the same as under:

i. *Since the inclusion of the Mefenamic Acid Tablets in the British Pharmacopeia (BP), Pfizer Pakistan Limited (the "Pizer") has been performing the dissolution test on its product, namely, Ponstan Forte Tablets 500 mg. In this regard, the BP specifications clearly specify that where the dissolution test is applicable the disintegration test may not be performed. Considering that Pfizer was already carrying out the dissolution tests on its product, the disintegration test could not have been performed by the Government Analyst Drug Testing Laboratory Bahawalpur. As such, all findings obtained in pursuance thereof are incapable of being relied upon.*

ii. *The foregoing view has also been endorsed by the Provincial Quality Control Board vide its order No. PQCB/DTL-B-02/1 88/2018 dated 28-06-2018 wherein it has accepted the stance of Pfizer regarding the redundancy of the disintegration test. Accordingly, the matter has already been decided so, you are very kindly requested to withdraw the show cause notice under reply.*

iii. *Even otherwise and without any prejudice to the foregoing, it is submitted that the product specifications provided by Pfizer to the Government Analyst also only envisage the dissolution test hence the disintegration test is neither applicable to the product nor the same could have been performed.*

2. Notwithstanding the complete innocence of the Company and its officials in the subject matter, the information requested in the letter under reply is being provided as under:

Name of CEO/ Managing Director: Syed Muhammad Wajeehuddin

Name of Production In-charge: Rashid Mohammad Khan

Name of Quality Control In-charge: Muhammad Farooq

3. Accordingly, it is submitted that Pfizer and its officials have not contravened the provisions of the Drug Laws and the rules framed thereunder rather they have shown strict compliance thereof. Since, the findings contained in the TRA No. 01-25003914/DTL dated 20-07-2019 and TRA No. 01-25003915/DTL dated 20-07-2019 are without any merit therefore the same cannot be considered conclusive evidence regarding the quality of the product.

4. In view thereof, it is very kindly requested that the titled Show Cause Notice under reply along with all subsequent proceedings may kindly be withdrawn in the interest justice and the case be consigned to record.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Request No. 2

PQCB/R-303,304,305/2022

Tehsil & District Okara

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan** through CEO Syed Nophil Rizvi 2. Syed Nophil Rizvi Chief Executive Officer (CEO) 3. Kamran Awan Production Incharge 4. Muhammad Fakhir Khaleeq Quality Control Incharge/Warrantor of M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 13-06-2022 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**.** 130063, 130064 and 130065 dated 13-06-2022.

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

<table>
<tr><th>Sr. No</th><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>TRA No & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>1</td><td>Powder for reconstitution Macrobac [Azithyromycin (as dihydrate): 200mg/5ml]

Mfg. Date:
03-2022
Exp. Date:
03-2024
Regn. No.: 082215</td><td>S0464</td><td>M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan</td><td>No. 01-10094000013 dated 26-07-2022</td><td><u>Results of test/analysis with specifications applied:</u> USP 2022

<u>Composition:</u> Each 5ml reconstituted suspension contains: azithromycin dihydrate eq. to Azithromycin…….200mg

<u>DESCRIPTION:</u> White to off white color powder in plastic white bottle having white plastic cap. Powder gives light pink color suspension on reconstitution up to 15ml. stated volume: 15ml when reconstituted

<u>pH:</u>
Stated: 8.5-11.0
Determined: 8.219 Does not comply

<u>IDENTIFICATION:</u> Azithromycin identified

<u>ASSAY: Azithromycin</u>
<table><tr><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr><tr><td>200mg/5ml</td><td>201.60mg/5ml</td><td>90-110%</td><td>100.80%</td></tr></table>RESULT: The above sample is Substandard on the basis of pH Test</td></tr>
<tr><td>2</td><td>Powder for reconstitution Macrobac [Azithyroycin (as dihydrate): 200mg/5ml]

Mfg. Date: 4/2022
Exp. Date: 04/2024
Regn. No.: 082215</td><td>S0500</td><td>M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan</td><td>No. 01-10094000014 dated 26-07-2022</td><td><u>Results of test/analysis with specifications applied:</u> USP 2022

<u>Composition:</u> Each 5ml reconstituted suspension contains: azithromycin dihydrate eq. to Azithromycin…….200mg

<u>DESCRIPTION:</u> White to off-white color powder in plastic white bottle having white plastic cap. Powder gives light pink color suspension on reconstitution up to 15ml. stated volume: 15ml when reconstituted

<u>IDENTIFICATION:</u> Azithromycin Dihydrate identified.

<u>ASSAY: Azithromycin</u>
<table><tr><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr><tr><td>200mg/5ml</td><td>201.10mg/5ml</td><td>90-110%</td><td>100.55%</td></tr></table><u>pH:</u>
Stated: 8.5-11.0
Determined: 8.219 Does not comply

RESULT: The above sample is Substandard on the basis of pH Test</td></tr>
<tr><td>3</td><td>Powder for reconstitution Macrobac [Azithyromycin (as dihydrate): 200mg/5ml]

Mfg. Date: 04/2022
Exp. Date: 04/2024
Regn. No.: 082215</td><td>S0501</td><td>M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan</td><td>No. 01-10094000015 dated 26-07-2022</td><td><u>Results of test/analysis with specifications applied:</u> USP 2022

<u>Composition:</u> Each 5ml reconstituted suspension contains: azithromycin dihydrate eq. to Azithromycin…….200mg

<u>DESCRIPTION:</u> White to off-white color powder in plastic white bottle having white plastic cap. Powder gives light pink color suspension on reconstitution up to 15ml. stated volume: 15ml when reconstituted

<u>IDENTIFICATION:</u> Azithromycin Dihydrate identified

<u>pH:</u>
Stated: 8.5-11.0
Determined: 8.210 Does not comply

<u>ASSAY: Azithromycin</u>
<table><tr><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr><tr><td>200mg/5ml</td><td>1820.52mg/5ml</td><td>90-110%</td><td>91.26%</td></tr></table>RESULT: The above sample is Substandard on the basis of pH Test</td></tr>
</table>

iii. Storekeeper Main Medicine Store CEO DHA Okara provided Invoice/ warranty No. 0000005389 dated 26-05-2022 issued by M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.

iv. Warrantor Portions of subject batches of drug sample were sent to M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.

v. Copies of Test/ Analysis reports were sent to M/s Asian Continental Pvt Limited; D-32 SITE II Super Highway Karachi Pakistan and they were directed to provide requisite information in this regard.

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

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

ii. **Issuance of false warranty**

Previous Proceeding regarding Retesting Request:

253rd Board meeting dated 29-11-2022:

The Board unanimously decided to accept the firm's request of withdrawal of retesting request.

Summary:

Manufacturing Date: 04-2022

Expiry Date: 04-2024

Sampling Date: 13-06-2022

Sent to DTL (Form 6): 13-06-2022

Date of receipt in DTL: 14-06-2022

DTL Report Date: 26-07-2022

1ST DI Communication with firm on dated: 23-12-2022

Date of Retesting Request of Firm: 12-08-2022

Fate of Retesting Request: withdrawal

Investigation Report Dated: 02-01-2023

3. Show-cause notice(s) issued to the accused dated 13-02-2023

Firm submitted reply of Show cause vide letter dated 23-02-2023

This is with reference to your letter No. PQCB/R-303,304,305/2022 dated 13-2-2023

As per your letter, it has been informed that the subject drug sample withdrawn has been declared as "SUBSTANDARD" by Government Analyst, DTL Bahawalpur vide Report No. TRA 01-10094000013 dated 26-07- 2022 B.NO. S0464 and Report No. 01-10094000014 dated 26-07-2022 B,No. S0500 & Report no. 01-10094000015/DTL dated 26-0-72022 B. No. S0501

Along with documents, you have required us to explain our position for manufacturing, stocking selling of substandard drugs and you have also required us to verify the names of accused persons and also requested to submit the attested documents for board consideration.

In response thereto, we state as follow:

- *That letter No.21/DI/OK dated 01-8-2022 and letter No, 22/DI/OK dated 01-8-2022 & letter No. 23/DI/OK dated 01-08-2022 from Provincial Inspector of Drugs tehsil Okara were received to us on dated 10-8-2022 and same were replied on dated 12-08-2022 with required information and documentations and confirmed that questioned product after cross checked of all quality parameters is of standard quality*
- *With regards to above said show cause notice, our justifications and clarifications are as followed:*
- *Please note that we have received the Warrantor Portion Sample of our product Macrobac 200 mg/ 5 ml. Suspension along with letter no. 21-22-23/DI/OK dated 14-06-2022 on dated 04-08-2022: however we have analyzed the Warrantor Portion Sample of Batch No. S0464, S0500, S0501 along with the retention sample of the same batches and found that our product is of STANDARD QUALITY with respect to prescribed parameters of physical characteristics, assay, and pH.*
- *It is pertinent to mention here that the product in question is dry powder suspension of Azithromycin as Dihydrate, which is reconstituted with water to form liquid suspension dosage form. The pH of the suspension is dependent upon proper reconstitution of the formulation with water. In case the dry powder is not properly mixed in water, it may sediment and alter the pH value, which is evident from the report of DTL Multan as the pH value of a batch is slightly lower than the specified limits. If the Govt. Analyst properly reconstitute the suspension and took the pH after removal of air bubbles the desired value of pH may be attained.*
- *Even though we totally unaccepting the DTL Bahawalpur Testing report we are not requesting for the retest of the batches in question and going to replace batch with the fresh stock as an act of curtesy and grace.*

Based on above facts it is evident that this is the borderline case, therefore, it is humbly requested to

take a kind decision and the case may please be closed amicably and fairly with formal

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023

Case is placed before the Board for Decision

PROCEEDINGS & DECISION BY THE BOARD:

Request No. 3

PQCB/R-572/2018

Sheikh Zayed Hospital Rahim Yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Pfizer Pakistan Limited, 12-Dockyard Road, West Wharf, Karachi Pakistan** through its Managing Director, Syed Muhammad Wajeehuddin 2. Syed Muhammad Wajeehuddin Managing Director 3. Rashid Khan Production Incharge 4. Muhammad Farooq Quality Control Incharge/Warrantor of M/S Pfizer Pakistan Ltd., 12-Dockyard Road, West Wharf, Pakistan

BRIEF FACTS OF THE CASE:

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

i. He, on 13-04-2018 inspected the M/s Central Pharmacy (Main Medicine Store) Sheikh Zayed Hospital Rahim Yar Khan and took sample of drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing laboratory, Bahawalpur vide memo no. 418/DI-SZH-RYK dated 13-04-2018.

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
Tablet Ponstan Forte [Mefenamic Acid: 500mg] **Mfg. Date:** 02-2018 **Exp. Date:** 01-2023 **Regn No.** 006978	1850178	M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan	01-54000658/DTL dated 11 Aug 2018	**Result of test/ analysis with specifications applied:** BP 2018 **COMPOSITION:** Each tablet contains: Mefenamic acid BP…….500mg **DESCRIPTION:** A light yellow colored, elliptical biconvex tablet, one side engraved with **"PONSTAN FORTE"** and other side is plain. Packed in a blister packing of 10 units. **DISINTEGRATION:** Five tablets out of six were not disintegrated within specified time, i.e., 15 minutes. ***LIMIT: All of the tablets must be disintegrated within specified time, i.e., not more than 15 minutes. If 1 or 2 tablets fail to disintegrate completely then repeat the test on addition 12 tablets.*** **(Does not comply with specifications)** **DISSOLUTION:** Not applicable **WEIGHT VARIATION:** **Determined**: 98.26-101.49% **Limit:** ±5% from average weight **IDENTIFICATION:** Mefenamic acid identified. **ASSAY: Mefenamic Acid** Stated: 500mg Determined: 517.60mg Percentage: 103.52% Limit: 95 - 105% **RESULT:** The sample is **Substandard** on the basis of Disintegration Test

iii. Central Pharmacy (Main Medicine store) Sheikh Zayed Hospital Rahim Yar Khan provided invoice/ warranty No. 17004129 dated 04-04-2018 issued by M/s Pfizer Pakistan Ltd., 12-Dockyard Road, West Wharf**,** Pakistan.

iv. Warrantor Portion was sent to M/s Pfizer Pakistan Ltd., 12-Dockyard Road, West Wharf**,** Pakistan.

v. A copy of Test/ Analysis report was also sent to M/s Pfizer Pakistan Ltd., 12-Dockyard Road, West Wharf Karachi, Pakistan and they were directed to provide requisite information in this regard.

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

i. **Manufacture for sale/ sale of Substandard drug**

ii. **Issuance of false warranty**

Summary:

Manufacturing Date: 02-2018

Expiry Date: 01-2023

Sampling Date: 13-04-2018

Sent to DTL (Form 6): 13-04-2018

Date of receipt in DTL: 20-04-2018

DTL Report Date: 11-08-2018

Time Extension granted: 188-M dated 28-06-2018

1ST DI Communication with firm on dated: 12-09-2018

Date of Retesting Request of Firm: No

Investigation Report Dated: 06-09-2022

3. Show cause notice(s) issued to the accused dated 26-09-2022

Firm submitted Reply of show-cause notice vide letter Misc./199/2022 dated 10-11-2022

1.This is in reference to show cause notice No. POCB/R-572/2018 dated 26-09-2022:

2 At the very outset it is submitted that M/s Pfizer Pakistan Ltd., is engaged in the manufacturing of high quality and effacious pharmaceuticals products which are being manufactured at the state-of-the art manufacturing site of the company. No complaint with respect to the quality of the pharmaceutical's product manufactured by the Company has been received from anywhere which are not only affirms the excellent quality of the pharmaceutical's products

3 Since the inclusion of the Mefenamic Acid Tablets in the British Pharmacopeia (BP), Pfizer Pakistan Limited (the "Pizer") has been performing the dissolution test on its product, namely, Ponstan Forte Tablets 500 mg. In this regard, the BP specifications clearly specify that where the dissolution test is applicable the disintegration test may not be performed. Considering that Pfizer was already carrying out the dissolution tests on its product, the disintegration test could not have been performed by the Government Analyst Drug Testing Laboratory Bahawalpur. As such, all findings obtained in pursuance thereof are incapable of being relied upon.

4 Please note that Mefenamic acid tablets have been included in the official pharmacopoeia. This is in consonance with the Drug Specification Rules, 1978 along with the directions of the Federal Ministry of Health conveyed vide letter No. F/3/2006-Reg-II South (M-197) dated 05-06-2006. It has been expressly provided in BP Specs that the Disintegration test may not be performed in the event the Dissolution test is being performed. In view therefore, the Company has duly been following the BP Specs and has been performing the Dissolution test on the said products. The Disintegration test was only performed by the Company as an abundant precaution for its own internal standards for release. In view of the parameter laid under the BP specs. The Disintegration test cannot be deemed as a conclusive parameter to determine the quality of the product. The foregoing view also been endorsed by the Provincial quality control Board Punjab vide Order No. PQCB/DTL-B-02/188/20218 dated 28-06-2018

5 Even otherwise and without any prejudice to the foregoing, it is submitted that the product specifications provided by Pfizer to the Government Analyst also only envisage the dissolution test hence the disintegration test is neither applicable to the product nor the same could have been performed.

6. Notwithstanding the complete innocence of the Company and its officials in the subject matter, the information requested in the letter under reply is being provided as under:

Name of Production In-charge: Rashid Mohammad Khan

Name of Quality Control In-charge: Muhammad Farooq

7. Accordingly, it is submitted that Pfizer and its officials have not contravened the provisions of the Drug Laws and the rules framed thereunder rather they have shown strict compliance thereof. Since, the findings contained in the TRA No. 01-25003914/DTL dated 20-07-2019 and TRA No. 01-25003915/DTL dated 20-07-2019 are without any merit therefore the same cannot be considered conclusive evidence regarding the quality of the product.

4. In view thereof, it is very kindly requested that the titled Show Cause Notice under reply along with all subsequent proceedings may kindly be withdrawn in the interest justice and the case be consigned to record.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Request No. 4

PQCB/ R-689/2021

Sir Ganga Ram Hospital, Lahore

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee, District Haripur, K.P.K-Pakistan** through its Chief Executive Officer Ashfaq Safdar 2. Ashfaq Safdar Chief Executive Officer 3. Mohammad Javed Hashmi Production Incharge 4. Mohammad Yasir Khan Quality Control Incharge/Warrantor Of M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee, District Haripur, K.P.K

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sir Ganga Ram Hospital, Lahore reported that:-

i. The then Drug Inspector, on 25-01-2021 inspected the premises of Medicine Store, Sir Ganga Ram Hospital, Lahore and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Lahore vide memo no. 000075548 dated 25-01-2021.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Infusion ZEE-MET [Metronidazole 500mg/100mL] Mfg. Date:12-2019 Exp. Date:11-2021 Reg# 076873	912852	Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee, Distt. Haripur, K.P. K	01-166000256/DTL Dated: 24-03-2021	**Result of test/ analysis with specifications applied BP 2020** **PHYSICAL DESCRIPTION:** Colourless liquid for infusion in transparent sealed plastic infusion bottle with no leakage. Claimed Volume=100ml As per Manufacturer provided method of analysis document number: SPIL/QC/SAP/FG/03 "Should be free from particulate matter" As per BP 2020 Appendix XIII B "Particulate contamination of injections and infusions consists of extraneous, mobile undissolved particles, other than gas bubbles". **Observation: Undissolved dark particles were observed in the bottle when observed with naked eye. (Not Complies)** **pH** Limit: 5.0-6.5 Observed: 5.75 at 24.3C (complies) **ASSAY OF METRONIDAZOLE** Stated: 500mg/100ml: Determined: 500. 3mg/100ml Percentage 100.06% LIMIT: 95-110% STERILITY: **STERILITY:** Must be sterile **The product is non-sterile (Not Complies)** **RESULT:** **The above sample is SUBSTANDARD on the basis of Physical Description and Sterility Test performed as per BP.**

iii. The Store Keeper of Medicine Store, Sir Ganga Ram Hospital, Lahore provided warranty bearing Diary No.676 dated 14-12-2020, which was supplied by M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee, Distt. Haripur, K.P. K as donation.

iv. Warrantor Portion was sent to M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee, Distt. Haripur, K.P. K

v. A copy of Test/ Analysis report was sent to M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee, Distt. Haripur, K.P. K and they were directed to provide requisite information in this regard.

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: -

i. **Manufacturing for Sale /Selling of Substandard drug**

ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s) dated 27.04.2023

Reply of the Firm to the Show Cause Notice:

Subject: Show Cause Notice

It is regretted that the author of the SCN under reply has concealed the facts either due to innocence or negligence or maliciously. The above drug was supplied at the request of Management of SGRH Lahore as a part of Donation of 5000 units for the use in appropriate patients attended at the Sir Ganga Ram Hospital Lahore. Kindly provide the following copies of documents tor appropriate preparation of the written defence to the SCN.

1. *The report of the Drug Inspector submitted under section 19(6) of the Drug Act 1976*
2. *The warranty bearing Diary No. 676 dated 14-12-2020.*
3. *The receipt of Warrantor Portion which was sent to M/S Shazeb Pharmaceutical Industries Limited. Hazara Trunk Road Sarai Gadaee Distt Haripur, KPK.*
4. *What is the law authorizing Secretary PQCB to issue SCN for Contravention of the DRAP Act 2012 because prevailing Drug Act l376(With Amendments of 2017 and 2018) is not the part of Schedule VI of the DRAP Act 2012?*
5. *When this case was examined under Rule 5of the Punjab Drug rules 2007 framed under the Drug Act 1976?*

The above attested copies of documents and information may kindly be provided at the earliest possible convenience because it is the right of the company to examine the documents etc. which are to be used against the company.

4. Personal Hearing notice(s) issued to accused person(s) dated 18.05.2023.

Case is placed before the Board for decision.

Summary:

Manufacturing Date: 12-2019

Expiry Date: 11-2021

Sampling Date: 25-01-2021

Sent to DTL (Form 6): 25-01-2021

Date of receipt in DTL: 25-01-2021

DTL Report Date: 24-03-2021

Time Extension: N/A

1ST DI Communication with firm on dated: 25-01-2021

Date of Retesting Request of Firm: -N/A

Fate of Retesting Request: -N/A

Investigation Report Dated: 27-04-2021

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Request No. 5

Case No.

PQCB/R-273 & 275-2022

Tehsil & District Sahiwal

Substandard (pH)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan** through CEO Syed Nophil Rizvi 2. Syed Nophil Rizvi — Chief Executive Officer (CEO) 3. Kamran Awan — Production Incharge 4. Muhammad Fakhir Khaleeq — Quality Control Incharge/ Warrantor of M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.

BRIEF FACTS OF THE CASE

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

2. She, on 15-06-2022 inspected Main Medicine Store CEO DHA Sahiwal, and took both drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vides memorandum no**.** 130320 dated 15-06-2022 and 130319 dated 15-06-2022.
3. Following drug samples, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, Bahawalpur as detailed below: -

<table>
<tr><th>Sr. No</th><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>TRA No & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>1</td><td>Suspension Macrobac 15ml [Azithyromycin (as dihydrate): 200mg/5ml]

Mfg. Date: 04/2022
Exp. Date: 04/2024
Regn. No.: 082215</td><td>S0502</td><td>M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan</td><td>No. 01-10094000077 dated 26-07-2022</td><td><u>Results of test/analysis with specifications applied:</u>
USP 2022
<u>COMPOSITION:</u> Each 5ml reconstituted suspension contains:
Azithromycin Dihydrate USP equivalent to Azithromycin……200mg
<u>DESCRIPTION (MS):</u> White to off-white color powder in a plastic white bottle having white plastic cap. Powder gives light pink color suspension on reconstitution up to 15ml.
Stated volume: 15ml when reconstitution
<u>pH (USP):</u>
Limit: 8.5-11.0
Determined: 8.156 Does not comply
<u>IDENTIFICATION:</u> Azithromycin is identified
<u>ASSAY: Azithromycin</u>
<table>
<tr><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td>200mg/5ml</td><td>198.2mg/5ml</td><td>90-110%</td><td>99.10%</td></tr>
</table>
RESULT: The above sample is Substandard on the basis of pH Test</td></tr>
<tr><td>2</td><td>Suspension Macrobac 15ml [Azithyromycin (as dihydrate): 200mg/5ml]

Mfg. Date: 04/2022
Exp. Date: 04/2024
Regn. No.: 082215</td><td>S0501</td><td>M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan</td><td>No. 01-10094000076 dated 26-07-2022</td><td><u>Results of test/analysis with specifications applied:</u>
USP 2022
<u>COMPOSITION:</u> Each 5ml reconstituted suspension contains: Azithromycin Dihydrate USP equivalent to Azithromycin…….200mg
<u>DESCRIPTION (MS):</u> White to off-white color powder in a plastic white bottle having white plastic cap. Powder gives light pink color suspension on reconstitution up to 15ml.
Stated volume: 15ml when reconstitution
<u>pH (USP):</u>
Limit: 8.5-11.0
Determined: 8.273 Does not comply
<u>IDENTIFICATION:</u> Azithromycin is identified
<u>ASSAY: Azithromycin</u>
<table>
<tr><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td>200mg/5ml</td><td>197.88mg/5ml</td><td>90-110%</td><td>98.94%</td></tr>
</table>
RESULT: The above sample is Substandard on the basis of pH Test</td></tr>
</table>

4. Storekeeper Main Medicine Store CEO DHA Sahiwal provided Invoice/ warranty No. 0000005390 dated 26-05-2022 issued by M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.
5. Warrantor Portions of subject batches of drug sample were sent to M/s Asian Continental Pvt Limited, D-32 SITE II Super Highway Karachi, Pakistan.
6. Copies of Test/ Analysis reports were sent to M/s Asian Continental Pvt Limited; D-32 SITE II Super Highway Karachi Pakistan and they were directed to provide requisite information in this regard.
7. 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 Drugs.**
    b. **Issuance of false warranty**
8. Show-cause was issued to accused person(s) vide dated 20.01.2023

Firm submitted written reply to show cause notice dated 20.01.2023

This is with reference to your letter No. PQCB/R-273 & 275/2022 dated 20-01-2023 received at our office on 27-01-2023 regarding the subject captioned above.

As per your letter, it has been informed that the subject drug sample withdrawn has been declared as "SUBSTANDARD" by Government Analyst, DTL Bahawalpur vide Report No. TRA 01-10094000076 dated 26.07.2022 B.NO. S0501 and Report No. TRA 01-10094000077 dated 26.07.2022 B.NO. S0502.

Along with documents, you have required us to explain our position for manufacturing, stocking selling of substandard drugs and you have also required us to verify the names of accused persons and also requested to submit the attested documents for board consideration.

In response thereto, we state as follow:

- That letter No. 210/DC/CEO (DHA) dated 04.08.2022 and letter No. 209/DC/CEO (DHA) dated 04.08.2022 from Provincial Inspector of Drugs, Tehsil & District Sahiwal was received to us on dated 05.08.2022 and same was replied on dated 05.08.2022 with required information and documentations and confirmed that questioned product after cross checked of all quality parameters is of standard quality.
- With regards to above said show cause notice, our justifications and clarifications are as followed:
- Please note that we have received the Warrantor Portion Sample of our product Macrobac 200 mg/ 5 ml. Suspension along with Letter No. 156/DC/CEO (DHA) dated 15.06.2022 on dated 04.08.2022; however, we have analyzed the Warrantor Portion Sample of Batch No's. S0501 & S0502 along with the retention samples of the same batches and found that our product is of STANDARD QUALITY with respect to prescribed parameters of physical characteristics, assay, and pH.
- It is pertinent to mention here that the product in question is dry powder suspension of Azithromycin as Dihydrate, which is reconstituted with water to form liquid suspension dosage form. The pH of the suspension is dependent upon proper reconstitution of the formulation with water. In case the dry powder is not properly mixed in water, it may sediment and alter the pH value, which is evident from the report of DTL Bahawalpur as the pH value of a batch is slightly lower than the specified limits. If the Govt. Analyst properly reconstitute the suspension and took the pH after removal of air bubbles the desired value of pH may be attained.
- Even though we totally unaccepting the DTL Bahawalpur Testing report we are not requesting for the retest of the batch in question and going to replace batch with the fresh stock as an act of curtesy and grace.

Based on above facts it is evident that this is the borderline case, therefore, it is humbly requested to take a kind decision and the case may please be closed amicably and fairly with formal

9. Personnel Hearing notice(s) issued to accused person 18.05.2023

   Case was placed before the Board for Decision

Summary:

Manufacturing Date: 04.2022

Expiry Date: 04.2024

Sampling Date (Form 4): 15.06.2022

Sent to DTL (Form 6): 15.06.2022

Date of receipt in DTL: 18.06.2022

DTL Report Date (Form 7): 26.07.2022

Time Extension: N/A

1ST DI Communication with firm on dated: 04.08.2022

Date of Retesting Request of Firm: Yes

Fate of Retesting Request: Withdrawn

Investigation Report Dated: 01.01.2023

PROCEEDINGS & DECISION BY THE BOARD:

Request No. 6

Case No.

PQCB/R-98/2021

Bahawalpur Saddar

Misbranded & Sub-Standard (Assay Test)

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan** through **M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan** through its Managing Director Muhammad Javeed. 2. Muhammad Javeed Managing Director 3. Saboor Ahmad Production Incharge 4. Buzarg Jamhir Quality Control Incharge/Warrantor of **M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan.**

Provincial Inspector of Drugs, Bahawalpur Saddar, District Bahawalpur reported that: -

i. He, on 03-03-2021, inspected the business premises of M/S Ikhlaq Brothers Medical Store Situated at Chak No. 7-BC, Bahawalpur and took samples of three different types of drug samples on Form No.04 for the purpose of test/analysis.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Solution. Dynate [Dimenhydrinate 12.5mg/4ml, 60ml oral solution.]</td><td>L489</td><td>M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan</td><td>01- 77003414/DTL
Dated. 06-05- 2021</td><td>
<u>Analysis with specifications applied:</u> MS.
<u>Composition:</u>
Each 4ml contains: Dimenhydrinate B.P……12.5mg <u>Description:</u>
Clear Colorless liquid in sealed amber plastic bottle. (Stated Volume:60ml).
Product Specifications on label claims that product is of BP Specifications. However, “Dimenhydrinate Oral Solution” monograph is not present in BP”. (The product is misbranded).
<u>PH:</u>
Limit: 5-7 Determined: 6

<u>Identification</u>: Dimenhydrinate is identified. <u>Assay:</u>
<table>
<tr><td>Stated</td><td>12.5mg/4ml</td></tr>
<tr><td>Determined</td><td>2.103mg/4ml</td></tr>
<tr><td>Percentage</td><td>16.83%</td></tr>
<tr><td>Limit</td><td>90.0-110.0%</td></tr>
</table>
<u>Dimenhydrinate:</u>

<u>Result:</u>
The sample is declared Substandard on the basis Assay Test and Misbranded, as defined under clause (vi) of sub-section (s)
of section 3 of Drugs Act 1976.
</td></tr>
</table>

iii. M/S Ikhlaq Brothers Medical Store Situated at Chak No. 7-BC, Bahawalpur provided Invoice/warranty No 46397 dated 24-02-2021 issued by M/S Zam Zam Pharma Bahawalpur who in turn provided invoice/warranty No. 1202, dated 18-01-2020 issued by M/s Convell Laboratories, Saidu Sharif, Sawat, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Zam Zam Pharma Bahawalpur and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, 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 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. **Manufacturing for sale /Stocking for sale/selling of Misbranded & Substandard drug**

b. **Issuance of false warranty**

3. Showcause was issued to accused person(s) vide dated 02.08.2021

4. Personnel Hearing notice(s) issued to accused person 12.09.2022

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its **250th** meeting held on **22-09-2022** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department, Punjab. Mr. Atiq-ur-Rehman Secretary DQCB District Bahawalpur and Mr. Muhammad Farrukh Saleem Drug Inspector Tehsil Bahawalpur Saddar were present along with original record of the case. Drug Inspector Tehsil Bahawalpur Saddar briefed the Board about facts of the case and asked for permission for prosecution against the accused persons. No one among the nominated accused appeared before the Board on the behalf of **M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan.**

6. The Board after discussion decided to **adjourn** the case due to non-appearance of accused persons in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

7. Personnel Hearing notice(s) issued to accused person 20.04.2023

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its **260th** meeting held on **04-05-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department, Punjab. Mr. Attiq Ur Rehman, Secretary DQCB, District Bahawalpur attended the meeting online via zoom link along with the original case record. No one among the nominated accused appeared before the Board on the behalf of **M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan.**

9. The Board after discussion decided to **adjourn** the case due to non-appearance of accused persons in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

Summary:

Manufacturing Date: 12.2019

Expiry Date: 12.2022

Sampling Date (Form 4): 03.03.2021

Sent to DTL (Form 6): 04.03.2021

Date of receipt in DTL: 09.03.2021

DTL Report Date (Form 7): 06.05.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 23.06.2021

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated: 26.07.2021

10. Personnel Hearing notice(s) issued to accused person 18.05.2023

Case is placed before the Board for Decision**.**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Request No. 7

PQCB/ R-641/2021

Tehsil and District Attock

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area Karachi** through its Managing Director, Shaikh Mohiuddin Chawla 2. Shaikh Mohiuddin Chawla Managing Director/Warrantor 3. Muhammad Ishaq Production Incharge 4. Muhammad Irfan Incharge Quality Control Of M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area Karachi.

BRIEF FACTS OF THE CASE

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

i. He, on 27-09-2021 inspected the premises of Main Medicine Store, CEO (DHA) Office, Attock, took sample of Tab. Calamox 625mg, Batch No. C210889, manufactured by M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area Karachi on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo No. 0000107886 Dated 27-09-2021.

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 TRA No. & Date
Film Coated Tablet Calamox 625 Mg (Amoxicillin Trihydrate Eq. To Amoxicillin: 500 Mg, Clavulanate Potassium Eq. To Clavulanic Acid: 125mg)	C210889	M/S Bosch Pharmaceuticals (Pvt) Ltd., 221-223, Sector 23, Korangi Industrial Area, Karachi	01-74002939/DTL RWP 24-12-2021

Specification applied: USP 2021

PHYSICAL DESCRIPTION

White coloured, oblong shaped tablets, plain from both sides packed in Alu-Alu blister of 1 * 6 pack size, further packed in labelled outer carton.

DISSOLUTION TEST (USP Test 2): **Amoxicillin:** Q = 85% at 45 mins,

Clavulanic Acid: Q = 80% at 30 mins

S 1		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6
	Amoxicillin	90.93	98.19	96.86	95.76	91.57	97.81
	Clavulanic Acid	98.15	98.96	18.76	95.66	21.09	99.85

Limit: Each unit should be NLT Q + 5% (Amoxicillin NLT 90%, Clavulanic Acid NLT 85%)

It: Release of Amoxicillin complied at S 1.

Release of Clavulanic Acid is <85% in 2 units. **(DOES NOT COMPLY)**

Sample was not proceeded to S 2 and S 3 as Release of clavulanic acid is < 55% in 2 units and Acceptance Criteria of S 3 States that "Average of 24 units (S1 + S2 +S3) is ≥ Q, NMT 2 units are < Q – 15%, and no unit is <Q – 25%".

IDENTIFICATION: Amoxicillin Trihydrate and Clavulanate Potassium Identified.

ASSAY:

	Amoxicillin	Clavulanic Acid
Stated:	500 mg/Tab	125 mg/Tab
Determined:	520.533 mg/Tab	125.653 mg/Tab
Percentage:	104.11 %	100.52 %
Limit:	90% - 120%	90% - 120%

RESULT: The above sample is **"Substandard"** as it failed to comply with the **Dissolution Test.**

iii. The Store keeper, Main Medicine Store CEO (DHA) Office Attock provided warranty/invoice bearing No. 2112050187 dated 25-05-2021 issued by M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area Karachi.

iv. The remaining stock of Tablet Calamox 625mg, Batch No. C210889 **was made not to dispose** of on Form 3.

V. Warrantor Portion was sent to M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area Karachi.

vi. A copy of Test/ Analysis reports was sent to M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area Karachi and they were directed to provide requisite information in this regard.

vii. The firm's request for re-testing by Appellate Laboratory was forwarded to Secretary, provincial Quality Control Board, Punjab on 17-01-2022.

viii. Re-testing was allowed in 244th meeting of Provincial Quality Control Board dated 31-05-2022.

ix. Sample was sent to Appellate Laboratory, National Institute of Health (NIH), Islamabad from where the sample was declared substandard.

e of Drug	Batch No.	Name of Manufacturer	Test Report No.	Details of Result of Test/analysis (With protocols of test applied)
t Calamox [Co-iclav 625mg]	C210889	M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area Karachi	0145-P/2022 dated: 29th August 2022	**Reference: United States Pharmacopoiea-39** **DISSOLUTION TEST:** **Determined:** **Amoxicillin** 2 tablets out of six deviated from the limit **Clavulanic acid** 3 tablets out of six deviated from the limit **Limit:** **Amoxicillin** Not less than 85% (Q) of the labelled amount is dissolved **Clavulanic acid** Not less than 80% (Q) of the labelled amount is dissolved **(DOES NOT COMPLY WITH USP-39)** **RESULT:** **The above sample is SUB-STANDARD on the basis of tests performed.**

The Drug Inspector directed not to **dispose of stock** of the said product, quantity of 850 tablets dated 05-01-2022

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: -

i. **Manufacturing for Sale /Selling of Substandard drug**

ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s) dated 20.01.2023

Reply of the Firm to the Show Cause Notice:

Subject: Show Cause Notice.

Tablet Calamox 625mg (Batch No. C210889)

(Supplied to M/S Main Medicine Store, CEO (DHA) Office, Attock).

We refer to your show cause Notice No, PQCB/R-641/2021, dated 20-01-2023 received on 01-02-2023 regarding Tablet Calamox 625mg (Batch No. C210889) and requiring us to clarify the position/explanation, with regards to the sample of Tablet Calamox 625 mg, Batch No.210889, manufactured by us drawn from the premises of M/s. Main Medicine Store CEO (DHA) Office Attock being declared as Sub-Standard vide Test Report No, TRA/O1- 74002939/DTL, dated: 24/12/2021, by the Government Analyst, Drugs Testing Laboratory, Rawalpindi and NIH Islamabad vide test report No, 0145-P/2022 dated 29.08.2022

We base our contentions on the following facts and grounds;

i. That the test report of above batch purporting to declare the sample of drug as Sub-Standard is not reliable, valid or correct for the purposes of the legal requirements for a test report specified under the Drugs Act, 1976 and the Rules framed there under.
ii. That the test performed on Assay of Amoxicillin has been determined at 104.11 % within limits of 90 - 120%, and Assay of Clavulanic Acid has been determined at 100.52 % against limits of 90- 120% and respectively as mentioned in the DTL, Rawalpindi test report dated 24-12-2021.
iii. That for such reason, the declaration of the drug as substandard on the grounds of low and unbelievable dissolution of Clavulanic acid may be due to an error in the calculation of Clavulanic Acid because out of 6 tablets 04 tablets shows 95.66 to 99.85% results, as per DTL Rawalpindi Test report. Whereas Dissolution of Amoxicillin is complied with the specifications.
iv. That we have supplied the same Batch No, C210889 of Calamox Tablet 625 mg to THQ Hospital, Malakwal (Mandi Bahauddin) and CEO Office Layyah found results vide Test I Analysis Report No. 0000022592, dated: 04-08-2021 and Report No. 0000048652, dated 06- 08-2021 is of Standard Quality from Government Analyst Drug Testing Laboratory, Faisalabad and Drug Testing Laboratory, Multan
v. We are astonished here to see the Appellate Laboratory report i.e., NIH, Islamabad that the Assay of Amoxicillin and Clavulanic acid which is very they have not performed essential test. We would like to inform you here that the test of Dissolution of Amoxicillin is passed by Government Analyst DTL Rawalpindi, whereas in NIH report 2 tablets out of six deviated from the limit. Same in case of Clavulanic acid Dissolution DTL Rawalpindi showing 2 tablet out of limit having I8.76 % and 21.099%. But NIH report 3 tablet out of six is deviated from limit showing 0.859 &, 33.99% and 2.25% which may be due to human / instrument error.
vi. It is necessary to mention here that as per the report of the WHO for substandard and falsified medical products, it is mentioned that the medicines are degraded during transport or storage and can lose their potency because they were not stored at proper level of temperature and humidity and becomes the main reason for instability of the active ingredients of the medicines.
vii. It is also pertinent to mention here that have gone through the laboratory test on warrantor portion of the active ingredients of subject medicine i.e. amoxicillin and clavulanic acid and are completely satisfied with the result of both the components, which are as follows:

Assay of Amoxicillin:

%=103.51% (Limits: 90-120%)

Assay of Clavulanic acid:

%=105.16% (Limits: 90-120%)

We have also gone through the test of dissolution of Amoxicillin and Clavulanic acid and Are satisfied with its result as well.

viii. In the light of what has been stated above it is necessary to keep the medicine Calamox below 25 °C (degree Celsius) to get the desired result and if the same is not kept in a proper controlled room its potency will always be degraded. It will not be out of place to mention here that after handing over physical possession of medicine to the institutions, the storage of medicines in a controlled room temperature is the responsibility of the institutions and the hospitals and pharmacies are under a legal obligation to stock and store drugs in an area which is protected from sunlight and have proper temperature facilities, and in case if they are not following the prescribed rules and regulations the Drug Inspector is competent to initiate legal proceedings against the institution by cancelling their license or sealing the storage area under Section l8(1) (h) of the Drugs Act, 1976, but in such a case, the Drug Inspector cannot initiate proceedings against the manufacturer.

We request to the honourable Board to constitute a panel for product specific inspection (psi) of the drug under discussion. Because we have marketed Calamox tablet since 1998 in local market, government institutions as well as export in different countries.

ix. The company is always ready and willing to provide all kind of assistance for the betterment of proper storage facilities in accordance with the rules and regulations provided under the law to avoid degradation of medicines, which may create hardship for the patients. We once again request you to kindly withdraw your notice forthwith. Details of concerned persons, is attached herewith for your record.

4. Personal Hearing notice(s) issued to accused person(s) dated 18.05.2023.

Case is placed before the Board for decision.

Summary:

Manufacturing Date: 04-2021

Expiry Date: 03-2023

Sampling Date: 27-09-2021

Sent to DTL (Form 6): 27-09-2021

Date of receipt in DTL: 01-10-2021

DTL Report Date: 24-12-2021

Time Extension: granted in 236-M dated 15-12-2021

1ST DI Communication with firm on dated: 07-01-2022

Date of Retesting Request of Firm: -12-01-2022

Fate of Retesting Request: -Allowed in 244-M dated 31-05-2022

Investigation Report Dated: 20-10-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Request No. 8

DISTRICT DERA GHAZI KHAN

PQCB/R-443/2022

Tehsil Dera Ghazi Khan (Rural), District Dera Ghazi Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi, Pakistan** through its Chief Executive Officer/Managing Director Syed Muhammad Wajeehuddin 2. Syed Muhammad Wajeehuddin Chief Executive Officer/Managing Director 3. Rashid Mohammad Khan Production Incharge 4. Muhammad Farooq Quality Control Incharge/Warrantor of **M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi, Pakistan**.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Dera Ghazi Khan (Rural), District Dera Ghazi Khan reported that: -

i. He, on 31-10-2022 inspected main medicine store of CEO (DHA) Dera Ghazi Khan situated at multan road near RHC sarwar wali Dera Ghazi Khan, took subject sample of five different types of drugs on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum no. 147307 dated 03-11-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Vibramycin [Doxycycline hyclate equivalent to doxycycline 100mg] capsule. **Mfg. Date:** 06-2022 **Exp. Date:** 05-2025 **Regn. No:** 000456	GE8080	M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi, Pakistan	01-89007823/DTL dated 17-12-2022	**Result of test/ analysis with specifications applied:** USP 2022 **DESCRIPTION:** Yellow color powder filled in green colored hard gelatin capsules having cap printed with ''Pfizer'' & ''VBM 100'' on body of capsule packed in ALU-PVC blister of 06 units in a labeled outer hard carton. Each outer carton contains 20 blisters of 06 units i.e. 20*6=120 capsules. **Note**: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states, "All registration holders shall follow official pharmacopeial specifications for all such formulations for which official monographs of drug product is available in the most recent edition of such pharmacopoeia". Product specification of given sample is "Manufacturer's Specifications" and it is manufactured after the expiration of timeline to apply such specifications despite the availability Doxycycline Hyclate Capsules monograph in USP 2022, so the manufacturer's claim regarding product specification is in contradiction to DRAP circular and in violation to Drug Act 1976. **Mis-Branded(Does not comply)** **Uniformity of Dosage Unit (Weight Variation)** Max. AV=L1: 15% **(Complies)** **Identification:** Doxycycline Hyclate Identified. **ASSAY:** Stated: 100 mg/capsule Determined: 103.80 mg/capsule Percentage: 103.80% Limit: 90- 120% **(Complies)** **Dissolution Test:** **Limit:** NLT 80% (Q) of the labeled amount of Doxycycline dissolved in 30 minutes. **(Complies)** **RESULT:** The above mentioned sample is **Mis-Branded** as per Section 3 (s) (iv) of The Drugs Act, 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022.

iii. Storekeeper, main medicine store of CEO (DHA) Dera Ghazi Khan provided Invoice/Warranty No. 3037607544 date 22-09-2022 issued by M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi-Pakistan as proof of its purchase.

iv. Warrantor Portion of subject drug sample was sent to M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi-Pakistan.

v. Copy of Test/ Analysis reports was sent to M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi Pakistan 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 (as amended) / DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacture for sale/sale of the Misbranded drug**

b. **Issuance of false warranty**

3. Show cause Notice (s) issued to the accused person(s) Dated 04-05-2023.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023.

5. Case is placed before the Board for Decision

Summary	Warning to the subject Product	Warning to the firm in different Products
Dated	28-10-2021	First warning: 28-10-2021 Total warnings to firm: 10

PROCEEEDINGS & DECISION BY THE BOARD:

Request No. 9

PQCB R-121/2022

PSSHMC Hospital, Muzaffargarh

ATTENDANCE:

Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Arreta Pharmaceuticals Pvt. Ltd., Plot No. 13, Street No. N-5, RCCI Industrial Estate, Rawalpindi, Pakistan,** through its Chief Executive officer Sajjad Hussain 2. Sajjad Hussain — Chief Executive Officer 3. Arfa Benish — Quality Control Incharge 4. Zahoor Ilahi — Production Incharge/Warrantor of M/S **Arreta Pharmaceuticals Pvt. Ltd., Plot No. 13, Street No. N-5, RCCI Industrial Estate, Rawalpindi, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Punjab Social Security Health Management Company Hospital, Muzaffargarh reported that: -

i. He, on 13-11-2021, inspected the premises Central Medicine Store Punjab Social Security Health Management Company, Muzaffargarh, and took drug sample on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Multan.

ii. Following drug sample, sent vide memo no. 110862, dated 13-11-2021, after test/ analysis was declared as **Misbranded** by Government Analyst, Drug Testing laboratory **Multan** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Capsule Retafim 400mg (Each capsule contains: Cefixime trihydrate eqv. To Cefixime 400mg) **Mfg. date**: Nov-2021 **Exp. Date**; Nov-2023 **Regs. #** 099801	732	M/S Arreta Pharmaceuticals Pvt. Ltd., Plot No. 13, Street No. N-5, RCCI Industrial Estate, Rawalpindi, Pakistan	01-94000622/DTL dated: 15-01-2022	**Result of test/ analysis with specifications applied:** MS **DESCRIPTION**: White to Off-white to light yellow powder filled in hard gelatin capsules of orange cap & ivory body packed in ALU-ALU blister of 5 units in a labeled outer hard carton. Each outer carton contains 1 blister of 5 units i.e., 1*5=5 Capsules. The product claims JP Finished Drug Product Specifications and in JP the monograph for 50 & 100 mg Cefixime capsule is given while the label claim of the product is "Cefixime capsule 400mg" which is false & misleading. **(Misbranded) (Does Not Comply)** **WEIGHT VARIATION:** Average Weight 519.24mg Limit ±7.5% (NMT 2 capsules None deviate from ±15%) **(Complies)** **IDENTIFICATION USP:** Cefixime as Trihydrate identified **ASSAY:** Cefixime Stated 400 mg/capsule Determined 414.61 mg/capsule Percentage 103.65**%** Limit: 90-105% **(Complies)** **DISSOLUTION TEST:** **Acceptance Criteria**: NLT 80% of labeled amount of Cefixime is dissolved in 90 minutes. **(Complies)** **RESULT:** The sample is **Misbranded** as defined under clause (iv) of subsection (s) of section 3 of the Drug Act 1976.

iii. Store keeper of Central Medicine Store, Punjab Social Security Health Management Company Hospital, Muzaffargarh provided invoice/warranty No. 7682 dated 10-11-2021 issued by M/S Delta Enterprises, 4-B Aiwan.e. Mashriq, 7-Abbot Road, Lahore, Pakistan.

iv. Warrantor Portion was sent to M/S Delta Enterprises, 4-B Aiwan.e. Mashriq, 7-Abbot Road, Lahore, Pakistan with directions to provide the requisite information.

V. Copy of test/analysis report was sent to M/S Arreta Pharmaceuticals Pvt. Ltd., Plot No. 13, Street No. N-5, RCCI Industrial Estate, Rawalpindi, Pakistan, with directions to provide the requisite information and explain their position 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 Misbranded Drug**

b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 20-01-2023.

Personal Hearing notice(s) issued to accused person(s) on 18-05-2023.

Case is placed before the Board for Decision.

Summary	**Warning to the subject Product**	**Warning to the firm in different products**
	1st time	First warning: 247th meeting dated: 21-07-2022 Total warnings to firm: 01

PROCEEDINGS & DECISION BY THE COMMITTEE:

Request No. 10

PQCB R-386/2022

PSSHMC Hospital, Muzaffargarh

ATTENDANCE:

Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Albert Pharmaceuticals (Pvt) Ltd., 127-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan** through its Chief Executive Officer, Umar Habib 2. Umar Habib — Chief Executive Officer / Warrantor 3. Gull Muhammad — Production Incharge 4. Hafiz Muhammad Abid Rasool — Quality Control Manager of **M/s Albert Pharmaceuticals (Pvt) Ltd., 127-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Punjab Social Security Health Management Company Hospital, Muzaffargarh reported that: -

i. He, on 19-09-2022 inspected the Central Medical Store, Punjab Social Security Health Management Company Hospital, Muzaffargarh, Near Thal Jute Mills and took a drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan vide memo no. 140351 dated 19-09-2022.

ii. Following drug samples, after test/analysis was declared as **Misbranded** by Government Analyst, Drug Testing Laboratory, **Multan.** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Capsule Furid 100mg [each capsule contains: Immediate release pellets of Itraconazole… 100mg] **Mfg. Date**: 08-2022 **Exp. Date**: 08-2024 **Regn. No**: 089426	C-258	M/s Albert Pharmaceuticals (Pvt) Ltd., 127-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan	01-94006008/DTL dated: 30-12-2022	**Result of test/ analysis with specifications applied: USP 2022** **DESCRIPTION**: White to off-white colored pellets filled in hard gelatin capsules having blue color cap and white colored body packed in ALU_ALU blister of 04 units in a labelled outer hard carton. Each outer carton contains 01 blister of 04 units i.e., 01*= 04 Capsules. **Note**: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states that "**All registration holders shall follow official pharmacopeial specifications for all such formulation for which official monographs of drug product is available in the most recent edition of such pharmacopoeia**". Product specification of given sample is "**Manufacturer's specs"** and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "**Itraconazole Capsules"** monograph in **USP 2022**. So, the manufacturer's claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drug Act 1976.Therefore, **the product is Misbranded** **Uniformity of Dosage Unit (Weight Variation):** Max. AV=L1 15% **(Complies)** **IDENTIFICATION:** Itraconazole is identified **ASSAY:** Itraconazole **Stated**: 100mg/Capsule **Determined**: 96.46mg/Capsule **Percentage**: 93.46% **Limit**: 90-110% **(Complies)** **DISSOLUTION TEST:** Tolerance limit: NLT 80% (Q) of the labeled amount of Itraconazole is dissolved in 45mins. **RESULT:** The above-mentioned sample is **Misbranded** as per Section **3 (s) (iv)** of Drug Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022.

iii. Store keeper, Punjab Social Security Health Management Company Hospital, Muzaffargarh provided invoice/ warranty No. 2022-119-017, dated: 23-08-2022 issued by M/S MedWell Enterprises, 462, Block-A, Revenue Employees Cooperative Housing

Society, Lahore as a proof of purchase.

iv. Warrantor Portion of subject drug sample was sent to M/S MedWell Enterprises, 462, Block-A, Revenue Employees Cooperative Housing Society, Lahore.

v. M/S MedWell Enterprises, 462, Block-A, Revenue Employees Cooperative Housing Society, Lahore in turn provided invoice/ warranty No. 4099 dated 18-08-2022 issued by M/s Albert Pharmaceuticals (Pvt) Ltd., 127-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.

vi. A Copy of Test/ Analysis report was sent to M/s Albert Pharmaceuticals (Pvt) Ltd., 127-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan and they were directed to 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 Misbranded Drug**

b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 26-04-2023.

Reply to Show Cause Notice:
Firm has revised the artwork and submitted the rectified label.

Personal Hearing notice(s) issued to accused person(s) on 18-05-2023.

Case is placed before the Committee for Decision.

Summary	**Warning to the subject Product**	**Warning to the firm in different products**
	1st time	First warning: No waring before. Total warnings to firm: 0

PROCEEDINGS & DECISION BY THE COMMITTEE:

Request No. 11

Case No.

PQCB/R-246/2021

Tehsil Khiarpur Tamewali & District Bahawalpur

Misbranded & Sub-Standard (Assay and Physical Description

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan** through its Managing Director Farhat Qadeer Dar. 2. Farhat Qadeer Dar — Managing Director 3. Liaqat Ali — Production Manager 4. Tanveer Ali — Quality Control Manager 5. Muhammad Amjad — Warrantor 6. Tasaddaq Riaz — Marketing Incharge of **M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Khairpur Tamewali, District Bahawalpur reported that: -

i. He, on 30-12-2020, inspected the business premises of M/S United Medical Store, Aleemia Bazar Main Bahawalpur Road, Tehsil Khairpur Tamewali, District Bahawalpur and took four different types of drug samples on Form No. 04 for the purpose of test and analysis.

ii. Following drug sample, after test/ analysis, was declared **Substandard & Misbranded** 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~~
Suspension. Unidol [Paracetamol 120mg/5ml, 60ml Paediatric Suspension]	~~UD014~~	M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan	01-77002917/DTL Dated. 27-02-2021	**Analysis with specifications applied: USP 2020.** **Composition:** Each 5ml Contains: Paracetamol BP 120mg **Description:** Pink Color suspension containing **sedimental visible crystals which are not dispersed on shaking. (Observed upon Physical Inspection). (Does not comply with specifications).** **The label of the product does not bear the name of Pharmacopoeia or document according to which product is manufactured. (The product is misbranded).** **PH (USP):** **Limit 4.0-6.9** **Determined 5.470** **Identification (USP):** Paracetamol is identified. **Assay:** **Paracetamol:** Stated 120mg/5ml **Determined 87.30mg/5ml** **Percentage 72.75%** Limit 90.0-110.0% **(Does not comply with specifications) Result:** The sample is declared **Substandard**, on the basis of **Assay and Physical Description** test and **Misbranded** as defined under clause (vi) of Subsection (s) of section 3 of the Drugs Act 1976.

iii. M/S United Medical Store, Aleemia Bazar Main Bahawalpur Road, Tehsil Khairpur Tamewali, District Bahawalpur provided Invoice/warranty No R 202188 dated 30-10-2020 issued by M/S UK Pharma, House No. 93/11, Bahawal Colony, Bahawalpur who in turn provided invoice/warranty No. 672, dated 05-10-2020 issued by M/S Falkan Traders, Bilal Chowk,Samnabad, Faisalabad who in turn provided invoice/warranty No. 4624, Dated. 24-09-2020 issued by M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S UK Pharma, House No. 93/11, Bahawal Colony, Bahawalpur.

v. A copy of test/analysis report was sent to M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, 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 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. **Manufacturing for sale /Stocking/selling of Substandard & Misbranded drug**

b. **Issuance of false warranty**

3. Showcause was issued to accused person(s) vide dated 17-12-2021

Reply of Show Cause Notice:

M/S Unipharma stated that:

a. Product specifications are mentioned along with composition of product. But we will further elaborate it as per rule.
b. We will recall unidol Susp Batch No. UD-014 as early as possible to avoid any hazardous effects to patients and further improve the quality of product reviewing its manufacturing method and other parameters regarding raw material and formulation with process validations and will forward after complete stability studies.
c. Our company fully appreciate Government efforts to ensure quality of drugs and look forward to receive guidance to further improve the standard of our drugs.

4. Personnel Hearing notice(s) issued to accused person 12.09.2022

Case was placed before the Board for Decision

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its **250th** meeting held on **22-09-2022** under the chairmanship of Secretary Primary & Secondary Healthcare Department, Punjab. Mr. Attiq-ur-Rehman Secretary DQCB District Bahawalpur and Mr. Muhammad Ahmad Mehmood Drug Inspector Tehsil Khairpur Tamewali were present along with original record of the case. Drug Inspector Drug Inspector Tehsil Khairpur Tamewali briefed the Board about facts of the case and asked for permission for prosecution against the accused persons. No one among the nominated accused appeared before the Board on the behalf of **M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan.**

7. The Board after discussion decided to **adjourn** the case due to non-appearance of accused persons in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

8. Personnel Hearing notice(s) issued to accused person(s) dated 20-04-2023.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

9. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its **260th** meeting held on **04-05-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department, Punjab. Mr. Attiq Ur Rehman, Secretary DQCB, District Bahawalpur attended the meeting online via zoom link along with the original case record. No one among the nominated accused appeared before the Board on the behalf of M/s M/s Unipharma (Pvt.) Ltd, 4.5-Km Manga Raiwind Road, Lahore.

10. The Board after discussion decided to **adjourn** the case due to non-appearance of accused persons in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

Summary:

Manufacturing Date: 09-2020

Expiry Date: 08-2022

Sampling Date (Form 4): 30.12.2020

Sent to DTL (Form 6): 01.01.2021

Date of receipt in DTL: 02.01.2021

DTL Report Date (Form 7): 27.02.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 21.04.2021

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated:18.11.2021

11. Personnel Hearing notice(s) issued to accused person(s) dated 18-05-2023.

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Request No. 12

PQCB R-262/2022

Central Medical Store Depot, Pessi, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Frontier Dextrose LTD., Plot No. 18/3 Phase-1 Hattar Industrial Estate Haripur, Pakistan,** through its CEO/MD M. Ashar Khurram. 2. Muhammad Ashar Khurram CEO/Managing Director (MD) 3. Khalid Iqbal Production Incharge/ Warrantor 4. Saeed Ahmad Quality Control Manager of M/s Frontier Dextrose LTD., Plot No. 18/3 Phase-1 Hattar Industrial Estate Haripur, Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Central Medical Store Depot (CMSD), PESSI, Lahore reported that: -

i. He, on 27-09-2022 inspected the premises of Central Medical Store Depot (CMSD), PESSI, Lahore and took samples of 13 different types of drugs on Form No. 4 for the purpose of test/analysis 0000142003 dated 27-09-2022.

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
Injection Mini BC 50ml [Sodium Bicarbonate 84mg/ml, 50ml Mfg. date: 09-2022 Exp. Date: 08-2025 Regn. No.: 076880	009622	M/s Frontier Dextrose LTD., Plot No. 18/3 Phase-1 Hattar Industrial Estate Haripur, Pakistan.	01-10097000312/DTL dated: 17-11-2022	**Result of test/analysis with specifications applied:** BP 2022 **COMPOSITION:** Each ml contains: Sodium bicarbonate BP…….... 84mg **DESCRIPTION:** Colorless liquid in a transparent plastic sealed bottle for IV infusion. Stated Volume is 50ml. **EXTRACTABLE VOLUME (BP):** Determined: **48.0ml** Limit: NLT nominal Volume 50ml **Does not comply with specs** **STERILTY (BP):** The product is sterile **IDENTIFICATION (BP)**: Sodium bicarbonate is identified. **ASSAY (BP): Sodium Bicarbonate** Stated: 84mg/ml Determined: 86.10mg/ml Percentage: 102.5% Limit: 94.0 - 106.0%. **RESULT:** The sample is declared **Substandard**, on the basis of physical test i.e., **Extractable volume**.

iii. Store Incharge, CMSD, PESSI, Lahore provided Invoice/Warranty No. 14160 dated 26-09-2022 issued by M/s Frontier Dextrose LTD., Plot No. 18/3 Phase-1 Hattar Industrial Estate Haripur, Pakistan, as proof of purchase.

iv. Warrantor Portion of drug sample was sent to M/s Frontier Dextrose LTD., Plot No. 18/3 Phase-1 Hattar Industrial Estate Haripur, Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Frontier Dextrose LTD., Plot No. 18/3 Phase-1 Hattar Industrial Estate Haripur, Pakistan and they were directed to provide requisite information in this regard.

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

i. **Manufacture for sale / Sale of Substandard Drug**

ii. **Issuance of false warranty**

Summary:

Manufacturing Date: 09-2022

Expiry Date: 08-2025

Sampling Date: 27-09-2022

Sent to DTL (Form 6): 27-09-2022

Date of receipt in DTL: 28-09-2022

DTL Report Date: 17-11-2022

1ST DI Communication with firm on dated: 08-12-2022

Date of Retesting Request of Firm: No

Investigation Report Dated: 22-12-2022

3. Show cause notice(s) issued to the accused persons dated 04-01-2023

Firm submitted Written reply to show cause Notice vide letter ref no. DDL/MOH/233 dated 18-01-2023

Reference to your letter No. PQCB/R-262/2022, dated 04-01-2023, our sample Mini BC 50m Injection, B. No. 009622 has been declared as sub-standard by Government analyst drug testing laboratory Bahawalpur on the basis of physical test i.e., Extractable volume performed. (DTL Report No. TRA. 01-10097000312/DTL dated: 17-11-2022). In this connection, we would like to submit as under:

1. We received DTL report No. TRA. 01-10097000312/DTL Dated 17-11-22 with this letter where our product Mini BC Injection 50 mL (Sodium Bicarbonate 84 mg/mL, 50 mL) Batch No. 009622 declared substandard on the basis of a Physical Test, "Extractable Volume" filling of 2.0 mL less volume than labeled volume of 50 mL.

2. In the same DTL report TRA No. TRA. 01-10097000312/DTL by government analyst our product complies all Chemical and Microbiological tests as per product specifications.

3. We have already given new stock to hospital free of cost as replacement so that hospital and patient should not face any problem.

4. We have reviewed the Batch Manufacturing record and found no deviation from our standard manufacturing procedure.

5. we have rechecked the volume variation of retained samples of said product Mini BC Injection 50 mL, Batch No. 009622 and found average volume within the range.

We have world's best company filling machine, which has filling nozzles with pneumatic controlled GEMU valve which gives 100% accuracy in filling volume.

6. In our manufacturing process temperature of filling solution is about 40-55°C which slightly shows rise in volume during filling process but upon cooling of solution slightly condensed, once poured in measuring cylinder we observed that change in volume takes place. We normally keep the fill volume of product 5-10mL in excess than the stated volume. This time the variation may be due to human error to check the meniscus of cylinder and there was no malafide intention involved from the company side.

7. Now we have further started to check the volume variation by weight to avoid the effect of temperature. We have given the intensive training to our operators and QA staff and implemented the checking of volume variation by both weighing method as well as by measuring cylinder method. We assure you by the implementation of above practices such type of problem will never happen in future. Verified the names of accused.

Keeping in view all test results of DTL Report it is clear that product of Mini BC Injection 50 mL (Sodium Bicarbonate 84 mg/mL, 50 mL Batch No. 009622 complies all its chemical and microbiological tests and this 2ml volume variation has no bad impact on the quality of product as well as patient health.

We assure you that we will consistently improve our product quality especially in terms of filled volume, and will not give you a chance for any such objection raised against us in future. We hope you will look our request sympathetically and will give us a chance and close our case.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023

Case is placed before the Board for Decision

PROCEEDINGS & DECISION BY THE BOARD:

Request No. 13

DISTRICT JHANG

PQCB/R-399/2022

Tehsil & District Jhang

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi, Pakistan** through its Chief Executive Officer/Managing Director Syed Muhammad Wajeehuddin 2. Syed Muhammad Wajeehuddin Chief Executive Officer/Managing Director 3. Rashid Muhammad Khan Production Incharge 4. Muhammad Farooq Quality Control Incharge/Warrantor of **M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi, Pakistan.**

BRIEF FACTS OF THE CASE

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

i. She, on 14-10-2022 inspected medicine store office of Chief Executive Officer DHA Jhang, took subject sample of six different types of drugs on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 144463 dated 14-10-2022.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report</th><th>DTL Test Report Result</th></tr>
<tr><td>Capsule Vibramycin (Each capsule contains doxycycline hyclate…USP… equivalent to doxycycline… 100mg)

Mfg. Date: 06-2022
Exp. Date: 05-2025
Regn. No: 000456</td><td>GE8081</td><td>M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi, Pakistan</td><td>01-68019570/DTL dated
02-12-2022</td><td>
Result of test/ analysis with specifications applied: BP 2022

<u>DESCRIPTION:</u> Yellow powder free from visible contaminants, contained in dark green opaque body imprinted with ‘’VBM-100’’ and opaque dark green cap imprinted with ‘’pfizer’’ packed in ALU-PVC packing of 6 units.

Note: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states, “All registration holders shall follow official pharmacopeial specifications for all such formulations for which official monographs of drug product is available in the most recent edition of such pharmacopoeia”. Product specification of given sample is “Pfizer Specs” and it is manufactured after the expiration of timeline to apply such specifications despite the availability of its monograph in Pharmacopoiea (USP 2022 and BP 2022). So, the manufacturer’s claim regarding the product specifications is in contradiction to DRAP circular and also in violation to Drug Act 1976.

(Does not comply)

<u>Uniformity of Weight (Mass)</u> Comply the acceptance criteria of uniformity of weight as per BP 2022. (Average weight of contents of capsule: 307.385 mg)

<u>Tolerance limit:</u> ± 7.5% of average weight (BP 2022)

<u>Reference limit:</u> 284.3-330.4 mg

<u>Determined limit</u>: 298.6-316.6 mg <u>(Complies)</u>

<u>Identification:</u> Doxycycline hyclate is identified.

<u>ASSAY:</u>

Stated: 100mg doxycycline/cap

Determined: 100.927mg doxycycline/cap

Percentage: 100.927%

Limit: 95- 105% (BP 2022)

<u>Dissolution Test:</u>

Complies with the dissolution test as per BP 2022 as detailed below:-

Tolerance limit: Not less than 70% of the stated amount of doxycycline is dissolved in 30 minutes in 900 ml of 0.1 M hydrochloric acid using apparatus 1 at 100 rpm.

<table>
<tr><th>Level</th><th>Number tested</th><th colspan="6">Acceptance criteria</th><th>Remarks</th></tr>
<tr><td rowspan="3">1</td><td>6</td><td colspan="6">Each capsule is not less than 70% of the stated amount</td><td rowspan="3">Complies</td></tr>
<tr><td>Time</td><td>UNIT1</td><td>UNIT 2</td><td>UNIT 3</td><td>UNIT 4</td><td>UNIT 5</td><td>UNIT 6</td></tr>
<tr><td>30 minutes</td><td>105.0%</td><td>106.7%</td><td>104.6%</td><td>106.3%</td><td>104.3%</td><td>105.6%</td></tr>
</table>
<u>RESULT</u>: Given sample is <u>Misbranded</u> as per Section 3 (s) (iv) of The Drugs Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022.
</td></tr>
</table>

iii. Storekeeper, medicine store office of Chief Executive Officer DHA Jhang provided Invoice/Warranty No. 3037607751 date 26-09-2022 issued by M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi-Pakistan as proof of its purchase.

iv. Warrantor Portion of subject drug sample was sent to M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi-Pakistan.

v. Copy of Test/ Analysis reports was sent to M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi Pakistan 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 (as amended) / DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacture for sale/sale of the Misbranded drug**

b. **Issuance of false warranty**

3. Show cause Notice (s) issued to the accused person(s) Dated 04-05-2023.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023.

5. Case is placed before the Board for Decision

Summary	Warning to the subject Product	Warning to the firm in different Products
Dated	28-10-2021	First warning: 28-10-2021 Total warnings to firm: 10

PROCEEEDINGS & DECISION BY THE BOARD:

Request No. 14

PQCB R-429/2022

Mumtaz Abad Town, Multan

ATTENDANCE:

Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan** through its CEO/MD Syed Muhammad Wajeeh Uddin 2. Syed Muhammad Wajeeh Uddin CEO/MD 3. Rashid Mohammad Khan Production Incharge 4. Muhammad Farooq Quality Control Incharge/Warrantor of **M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Mumtazabad Town, District Multan, reported that: -

i. He, on 10-10-2022 inspected Main Medicine Store, O/o Chief Executive Officer, (DHA) Multan, and took 06 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. 144026 dated 11-10-2022, after test/ analysis was declared as **Misbranded** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Capsule Vibramycin [Doxycycline hyclate equi to Doxycycline 100mg] **Mfg. Date:** 06-2022 **Exp. Date:** 05-2025 **Reg. #** 000456	GF5138	M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi, Pakistan	01-89007362/DTL dated 01-12-2022	**Result of test/ analysis with specifications applied:** USP 2022 **DESCRIPTION:** Yellow color powder filled in green colored hard gelatin capsules having cap printed with "Pfizer" & "VBM 100" on body of capsule packed in ALU-PVC blister of 06 units in a labelled outer hard carton. Each outer carton contains 20 blisters of 06 units i.e., 20*06=120 capsules. **Note**: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states that "All registration holders shall follow official pharmacopeial specifications for all such formulation for which official monograph of drug product is available in the most recent edition of such pharmacopoeia". Product specification of given sample is "Manufacturer's Specification" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "**Doxycycline Hyclate capsules**" monograph in USP 2022. So, the manufacturer's claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drug Act 1976. **Misbranded (Does not comply)** **Uniformity of Dosage unit (Weight variation)** Max. AV=L1: 15% complies **IDENTIFICATION:** Doxycycline Hyclate identified. **ASSAY: Doxycycline** Stated: 100mg/cap Determined: 101.67mg/cap Percentage: 101.67% Limit: 90- 120% complies **Dissolution Test:** **Limit:** NLT 80% of the labelled amount of Doxycycline dissolved in 30mins. complies **RESULT:** The sample is **Misbranded** as per Section 3 (s) (iv) of Drug Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) Human import dated 7th February, 2022.

iii. Storekeeper, Main Medicine Store, O/o Chief Executive Officer, (DHA) Multan provided Invoice/Warranty No. 3037607282 date 12-09-2022 issued by M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi-Pakistan as proof of its purchase.

iv. Warrantor Portion of subject drug sample was sent to M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi-Pakistan.

V. Copy of Test/ Analysis reports was sent to M/s Pfizer Pakistan Ltd., B-2, S.I.T.E., Karachi Pakistan 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- 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 Misbranded Drug**

b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 26-04-2023.

Personal Hearing notice(s) issued to accused person(s) on 18-05-2023.

Case is placed before the Committee for Decision.

Summary	**Warning to the subject Product**	**Warning to the firm in different products**
	03 times, In 234th, 244th and 254th meeting.	First warning: 234th meeting dated: 28-10-2021. Total warnings to firm: 10

PROCEEDINGS & DECISION BY THE COMMITTEE:

Request No. 15

PQCB/ R-664/2021

Sir Ganga Ram Hospital, Lahore

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Bajwa Pharmaceuticals 36-Km off G.T. Road, Lahore-Pakistan** through its Chief Executive Officer Farhat Munawar Bajwa. 2. Farhat Munawar Bajwa Chief Executive Officer 3. Abdul Khaliq Production In-charge 4. Muhammad Rashid Iqbal Quality Control In-charge 5. Usman Aslam Warrantor Of M/s Bajwa Pharmaceuticals 36-Km off G.T. Road, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sir Ganga Ram Hospital, Lahore reported that: -

i. His predecessor, on 24-05-2021 inspected the premises of Medicine Store, Sir Ganga Ram Hospital, Lahore and took sample of Injection Baj-Prolol, Batch No. MP-0121, manufactured by M/s Bajwa Pharmaceuticals 36-Km off G.T. Road, Lahore-Pakistan on Form No. 4 for the purpose of test/ analysis and sent to Drug Testing Laboratory, Lahore vide memo no. 0000093432 dated 24-05-2021.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Injection Baj-Prolol [Metoprolol Tartarate USP 5mg/5ml] **Mfg Date:** 01-2021 **Exp Date:** 12-22 **Reg number:** 098164	MP-0121	M/s Bajwa Pharmaceuticals 36-Km off G.T. Road, Lahore-Pakistan	01-166001186/DTL dated: 08 July2021	**Result of test/ analysis with specifications applied:** USP 2021 **PHYSICAL DESCRIPTION:** Colourless liquid in sealed glass ampoule with label printed on it. Claimed volume=5ml **LABELLING:** **The label of the drug does not bear "Dosage and instructions in Urdu" on its immediate container (Misbranded)** **pH:** Stated: 5.0-8.0 Determined: 7.94 at 25.0C **IDENTIFICATION:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (Metoprolol Tartrate identified). **ASSAY OF METOPROLOL TARTARATE:** Stated: 5mg/5ml Determined: 4.58mg/5ml Percentage: 91.53% Limit: 90-110% of the stated amount. **STERILITY:** Must be sterile (complies) **RESULT: The above sample is "Misbranded" per the Drugs (Labeling & Packing) Rules, 1983[3{h(ii,iii)}]**

iii. The Store Keeper, Medicine Store, Sir Ganga Ram Hospital, Lahore provided invoice/warranty No. 4683 dated 18-05-2021 issued by M/s Bajwa Pharmaceuticals 36-Km off G.T. Road, Lahore-Pakistan

iv. Warrantor portion of drug sample was sent to M/s Bajwa Pharmaceuticals 36-Km off G.T. Road, Lahore-Pakistan

v. A copy of test/analysis report was sent to M/s Bajwa Pharmaceuticals 36-Km off G.T. Road, Lahore-Pakistan with directions to provide requisite information in this regard.

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: -

i. **Manufacturing for Sale /Selling of Misbranded drug**

ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s) dated 26.04.2023

Reply of the Firm to the Show Cause Notice:

Subject: Show Cause Notice
MISBRANDED, Baj-Prolol Injection 5ml (http://5.ml/) *(Metoprolol Tartrate USP 5mg/5ml) Batch# MP-0121)*
*With reference to letter No. PQCB/R-664/2021 dated: Lahore April 26, 2023 and received us on May 10, 2023, about misbrand injection Baj-Prolol 5mg/5.0ml (MP-0121).Root cause of misbrand is "**The label of the drug does not bear dosage and instructions in Urdu on its immediate container**" as declared by Drug Testing Laboratory report. Sir, we have rectified our label as per Labelling and Packing Rules 1986 [3{h (ii,iii}] and submitting specimen of rectified label and your requisites.*

4. Personal Hearing notice(s) issued to accused person(s) dated 18.05.2023.

Case is placed before the Board for decision.

Summary	Warning to the subject product	Warning to the firm (different products)
dated	-	First Warning: 26-11-2020 Total warnings to firm: 08

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Request No. 16

PQCB/R-625/2021

Punjab Institute of Neurosciences, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area Karachi, Pakistan** through its Chief Executive Officer/ Warrantor, Shaikh Mohiuddin Chawla 2. Shaikh Mohiuddin Chawla Chief Executive Officer/ Warrantor 3. Muhammad Ishaq Production Manager 4. Imtiaz Ahmed Quality Control Manager of M/s Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area Karachi, Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Punjab Institute of Neurosciences, District Lahore reported that: -

i. She, on 09-06-2021, inspected the premises of Main Medicine Store of Punjab Institute of Neurosciences, District 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. 96591 dated 10-06-2021.

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
Injection. Btrol [Tranexamic Acid BP …. 500mg/5ml] **Mfg Date** March 2021 **Expiry Date** Feb 2024 **Regn No.** 030791	BT210010	M/s Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area Karachi, Pakistan.	01-73008781/DTL dated 07-08-2021	**Analysis with specifications applied:** BP 2021 **PHYSICAL DESCRIPTION:** Colorless liquid in transparent glass ampoule with label printed on it. Claimed volume= 5mL **pH:** Limits: 6.5 – 8.0 Determined: 7.46 at 24.4 °C **IDENTIFICATION:** Tranexamic acid identified. **ASSAY OF TRANEXAMIC ACID:** Stated: 500 mg/ 5mL Determined: **567.9 mg/ 5mL** Percentage: **113.58%** Limit: 95-105% of the stated amount **STERILITY:** Sterile. **RESULT:** The above sample is **SUB-STANDARD**, on the basis of Assay performed as per BP.

iii. The storekeeper of the Main Medicine Store of Punjab Institute of Neurosciences, District Lahore provided delivery challan/warranty bearing No. IZ21-138 dated 28-05-2021 issued by

M/s Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area Karachi, Pakistan.

iv. Warrantor portion of the drug sample was sent to M/s Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area Karachi, Pakistan.

v. A copy of test/analysis report was sent to M/S Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi 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 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 Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area Karachi, Pakistan the retesting request of the subject drug sample was considered in the 240th Meeting of the Board held on 15-03-2022 and the subject drug sample was sent to NIH, Islamabad, from where the sample was declared **Sub-standard** as detailed below:

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>NIH Report No. & Dtae</th><th>NIH Test Report Result</th></tr>
<tr><td>Injection. Btrol 500mg/ 5ml</td><td>BT210010</td><td>M/s Bosch Pharmaceutical (Pvt) Ltd. 221-223, Sector 23, Korangi Industrial Area Karachi, Pakistan.</td><td>No. 069-P/2022 dated 13-06-2022</td><td>Analysis with specifications applied: British Pharmacopoeia 2017
<u>ASSAY:</u>
<table>
<tr><th>Assay</th><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td>Tranexamic acid</td><td>500mg/5ml</td><td>314.4mg/ 5ml</td><td>95-105%</td><td>62.88%</td></tr>
<tr><td colspan="5">Does not Comply with BP-2017</td></tr>
</table>
Conclusion: The sample is of <u>Sub-Standard</u> quality on the basis of the tests performed.</td></tr>
</table>

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 09-01-2023

<u>Firm replied to the show cause notice vide letter no. GMQO&RA/Bosch/210123/E dated 21-01-2023</u>

We base our contentions on the following facts and grounds;

i. *That the test report of above batch purporting to declare the sample of drug as Sub-Standard is not reliable, valid or correct for the purposes of the legal requirements for a test report specified under the Drugs Act, 1976 and the Rules framed there under.*

ii. *That the test performed on Assay of Tranexamic acid has been determined at 113.58 % against limits of 95 - 105% as mentioned in the DTL, Lahore test report TRA.01-7300878 1/DTL, Lahore dated: 07-08-2021.*

iii. *We have astonished here to see the Appellate Laboratory report i.e. NIH, Islamabad that they have performed the Assay of Tranexamic acid as per our Testing Request through PQCB, Lahore and is determined as 62.88%, which is very strange because Tranexamic acid is a stable salt and Suddenly **the drop of result from 113.58 % to 62.88 % just in Ten months which is unexpected**.*

iv. *That it is apparent that the Analyst has not performed the Assay test of Tranexamic acid as per procedure in the **B.P through Potentiometrically or applied the proper formula** for the calculations of the result of Assay as per the test protocol or follow the instructions.*

v. *That despite the above obvious shortcomings and invalidities of the test report of DTL, Lahore and NIH Islamabad, we have as an abundant precaution **rechecked and retested our reference laboratory sample, warrantor portion and have found the same to be of proper potency and of a Standard Quality**.*

vi. *That in view of the undeniable and established fact of the test reports of DTL Lahore & NIH Islamabad being **incompetent and inaccurate as regards to test performed**, there is no basis, justification or propriety in declaring the samples sub-standard.*

vii. *As per request of the institution and in good texture of the patient **<u>we have already replaced the stock approx. 4,500 ampoules lying in the Hospital</u>**.*

***<u>We request to the Honorable Board to kindly withdraw your notice forthwith</u>**.*

Furthermore, the firm verified the names of he accused nominated by the drug inspector.

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: March 2021

Expiry Date: Feb 2024

Sampling Date (Form 4): 09-06-2021

Sent to DTL (Form 6): 10-06-2021

Date of receipt in DTL: 11-06-2021

DTL Report Date (Form 7): 07-08-2021

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 02-09-2021

Retesting Request of Firm: Yes (14-09-2021)

Fate of Retesting Request: Allowed in 240-M dated 15-03-2022

NIH Report: 13-06-2022 (Substandard)

Investigation Report Dated: 07-09-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Request No. 17

DISTRICT LODHRAN

PQCB/R-395/2022

Tehsil & District Lodhran

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi-Pakistan** through its CEO/ Managing Director, Syed Muhammad Wajeehuddin 2. Syed Muhammad Wajeehuddin CEO/ Managing Director 3. Rashid Mohammad Khan Production In-charge 4. Muhammad Farooq Quality Control In-charge/ Warrantor

BRIEF FACTS OF THE CASE

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

i. He, on 22-10-2022, inspected the premises of Main Medicine Store, office of the PHFMC Lodhran took six 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 Multan vide memorandum no. 0000145374 dated 22-10-2022.

ii. The subject drug sample after test/analysis was declared as **Misbranded** by Government Analyst Drug Testing Laboratory **Multan**, as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report No. & Date	DTL Test Report Results
Vibramycin [Doxycycline Hyclate equivalent to Doxycycline 100mg] Capsule **Mfg Date:** June 2022 **Expiry Date:** May 2025 **Regn No.** 000456	GE8080	M/S Pfizer Pakistan Ltd., B-2, S.I.T.E Karachi, Pakistan.	01-89007537/DTL dated 17-12-2022	**Result of test/ analysis with specifications applied:** USP 2022 **DESCRIPTION:** Yellow color powder filled in green colored hard gelatin capsules having cap printed with ''Pfizer'' & ''VBM 100'' on body of capsule packed in ALU-PVC blister of 06 units in a labeled outer hard carton. Each outer carton contains 20 blisters of 06 units i.e. 20 * 06 = 120 Capsules. **Note:** As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states "**all registration holders shall follow official pharmacopeial specifications for all such formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia**". Product Specifications of the given sample is "Manufacturer's Specifications" and itis manufactured after the expiration timeline to apply such specifications despite the availability of Doxycycline Hyclate capsules monograph in USP 2022, so the manufacturer's claim regarding product specifications is in contradiction to DRAP circular and in violation to Drugs Act 1976. **Mis-Branded (Does not Comply)** **UNIFORMITY OF DOSGAE UNIT (Weight Variation):** Max. AV=L1: 15% **(Complies)** **Identification: Doxycyline Hyclate Identified.** **Assay:** Doxycycline Stated: 100mg/capsule; Determined: 101.81mg/capsule; Percentage: 101.81%; Limit: 90-120% **(Complies)** **Dissolution Test: Limit: NLT 80% (Q) of the labelled amount of Doxycycline dissolved in 30 minutes. (Complies)** **RESULT:** The above mentioned sample is **Mis-Branded** as defined under Section 3 (s) (iv) of The Drugs Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022

iii. Store Keeper Main Medicine Store, office of the PHFMC Lodhran provided invoice/warranty bearing No. 3037607263 dated 12-09-2022 issued by M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi-Pakistan .

iv. Warrantor portion of drug sample was sent to M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi-Pakistan.

V. A copy of test/analysis report was sent to M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi-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 Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacture for sale/sale of the Misbranded drug**

b. **Issuance of false warranty**

3. Show cause Notice (s) issued to the accused person(s) Dated 04-05-2023.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023.

5. Case is placed before the Board for Decision

Summary	**Warning to the subject Product**	**Warning to the firm in different Products**
Dated	28-10-2021	First warning: 28-10-2021 Total warnings to firm: 10

PROCEEEDINGS & DECISION BY THE BOARD:

Request No. 18

PQCB/R-623/2021

Tandlianwala Town, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Star Laboratories (Pvt.) Ltd., 23-Km, Multan Road, Lahore-Pakistan** through its Chief Executive Officer, Muhammad Israr H. Malik 2. Muhammad Israr H. Malik Chief Executive Officer 3. Ubaid Mahmood Khan Production Incharge 4. Mohsin Gull Aziz Quality Control Manager 5. Sameer Ishfaq Warrantor of M/s Star Laboratories (Pvt.) Ltd., 23-Km, Multan Road, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tandlianwala Town, District Faisalabad reported that: -

i. His predecessor, on 01-10-2021, inspected the business premises of M/s Amin Medical Store situated at Maridwala Road, Near RHC Mamukanjan, Tehsil Tandlianwala, 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 memorandum no. 108294 dated 02-10-2021.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr>
<td>Aerosol Spray. Oxycort 150ml [Each 150ml contains: Oxytetracycline HCL (USP) …. 750mg and Hydrocortisone (BP) …. 240mg]

Mfg Date:
Sep 2021

Expiry Date:
Sep 2023

Regn No. 014143</td>
<td>VG.1211</td>
<td>M/s Star Laboratories (Pvt.) Ltd., 23-Km, Multan Road, Lahore-Pakistan.</td>
<td>01-68012255/DTL dated: 01-12- 2021</td>
<td>Analysis with specifications applied: MS

<u>DESCRIPTION:</u> Greenish brown colored liquid, filled in printed tin can with plastic actuator and covered with red cap.

NOTE: Manufacturer claims <u>Orange to Reddish orange color</u> alcoholic liquid while in case of given sample the color of liquid is observed to be greenish brown. (Does Not Comply)

<u>IDENTIFICATION:</u> Oxytetracycline HCl and Hydrocortisone Identified.

<u>ASSAY:</u>

<u>Oxytetracycline HCl</u>
<table>
<tr><td>Stated:</td><td>750 mg / 150ml</td></tr>
<tr><td>Determined:</td><td>408.6825 mg / 150ml</td></tr>
<tr><td>Percentage:</td><td>54.491% (Does Not Comply)</td></tr>
<tr><td>Limit:</td><td>90–110% (Manufacturer’s Specifications)</td></tr>
</table>
<u>Hydrocortisone</u>
<table>
<tr><td>Stated:</td><td>240 mg / 150ml</td></tr>
<tr><td>Determined:</td><td>240.077 mg / 150ml</td></tr>
<tr><td>Percentage:</td><td>100.032% (Complies)</td></tr>
<tr><td>Limit:</td><td>90–110% (Manufacturer’s Specifications)</td></tr>
</table>
<u>RESULT:</u> <u>Given sample is Sub-Standard with regards to Assay (of Oxytetracycline HCl) and description (physical characteristics) of liquid.</u></td>
</tr>
</table>

iii. M/s Amin Medical Store situated at Maridwala Road, Near RHC Mamukanjan, Tehsil Tandlianwala, District Faisalabad provided invoice/ warranty bearing No. 25819 dated 30-09-2021 & 25661 dated 16-09-2021 issued by M/s Muzammal Drug House Distributors, 1st Floor, 6 Moon Plaza, Chiniot Bazar, Faisalabad.

iv. Warrantor portion of drug sample was sent to M/s Muzammal Drug House Distributors, 1st Floor, 6 Moon Plaza, Chiniot Bazar, Faisalabad who provided invoice/ warranty bearing No. 168079 dated 11-09-2021 issued by M/s Naveed Taders Chiniot Bazar, Faisalabad as aproof of its purchase.

v. M/s Naveed Taders Chiniot Bazar, Faisalabad finally provided invoice/ warranty bearing No. 2122001374 dated 07-09-2021 issued by M/s Star Laboratories (Pvt.) Ltd., 23-Km, Multan Road, Lahore-Pakistan

vi. A copy of test/analysis report was sent to M/s Star Laboratories (Pvt.) Ltd., 23-Km, Multan 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 request, the Provincial Quality Control Board in its 244th meeting held on 31-05-2022, **allowed** to send the sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>NIH Test Report No.</th><th>NIH Test Report Result</th></tr>
<tr><td>Oxycort Aerosol Spray 150ml (Vet)</td><td>VG.1211</td><td>M/s Star Laboratories (Pvt.) Ltd., (Animal Health Care Division) 23-Km, Multan Road, Lahore-Pakistan.</td><td>0163-P/2022 dated 09-09-2022</td><td>Analysis with specifications applied: Manufacturer Specification

<u>DESCRIPTION:</u> Dark brown coloured alcoholic Liquid filled in printed tin cane with plastic actuator & covered with red coloured cap. (Does not comply with manufacturer specification which states that yellow to brown colored alcoholic liquid free from extraneous matter, filled in printed tin can plastic actuator & covered with red color cap.)

<u>ASSAY:</u>
<table>
<tr><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td colspan="4">Oxytetracycline HCl</td></tr>
<tr><td>750 mg/ 150ml</td><td>78.05 mg/ 150ml</td><td>90-110%</td><td>23.74%</td></tr>
<tr><td colspan="4">Hydrocortisone</td></tr>
<tr><td>240 mg/150ml</td><td>182.26mg/ 150ml</td><td>90-110%</td><td>75.94 %</td></tr>
</table>
Does not comply with manufacturer specification.

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

viii. A copy of NIH test/analysis report was sent to M/s Star Laboratories (Pvt.) Ltd., 23-Km, Multan Road, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 21-12-2022

<u>Firm replied to the show cause notice vide letter dated 02-01-2023</u>

Oxycort Aerosol Spray is a VETERINERY product for external use only. The sample of the said batch of Oxycort Aerosol Spray was taken by Drug Inspector Tandlianwala Town from "Muzammal Drug house" and sent to DTL Faisalabad for testing. The sample was declared sub-standard by DTL Faisalabad report No. TRA-01-68012255 dated 01.12.2021.

Upon receiving the DTL report we tested our Retained sample for physical appearance and assay for Oxytetracycline HCI and Hydrocortisone. ***The results were found well within the specifications.*** *We requested the board for retesting. Our request was entertained by the board and sample was sent to NIH for retesting. The sample declared sub-standard by NIH test report No. 0163-P/2022 dated 09.09.2022.*

Our technical team thoroughly investigated the matter as to why the sample failed. The sample was analyzed on 02.09.2022 after about one year from the date of manufacturing and during this period ***samples were placed in different conditions may be at high temperature in store (Muzammal drug house), PQCB sample store as well as NIH****. Whereas* ***<u>in case of Aerosol the temperature is very important</u>*** *and can affect the quality and appearance of product. The only reason might be the storage condition as It is mentioned on the can "Store below 25°C, protect from direct heat and sunlight" and* ***<u>it should be used or tested after shaking well.</u>***

So kindly consider our above claim that may be the reasons of low assay.

<u>Furthermore, firm verified the names of the accused persons nominated by the drug inspector in the subject case.</u>

4. Personal hearing notice(s) issued to accused person(s)

<u>Previous Proceedings & Decision By The Board:</u>

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **257th meeting** held on **07-02-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Ms. Rubina Akhtar, Secretary DQCB, District Faisalabad and Dr. Haroon Arshad, Drug Inspector Tandlianwala Town, District Faisalabad was present along with the original case record. No one among the nominated accused persons of M/s Star Laboratories (Pvt.) Ltd., 23-Km, Multan Road, Lahore-Pakistan appeared before the Board.

6. Secretary Provincial Quality Control Board apprised the Board that firm has submitted written request for adjournment vide letter dated 06-02-2023 stating that the firm's relevant technical person is unavailable due to unavoidable circumstances. The Board, after due deliberation and detailed discussion, unanimously decided to **adjourn the case** of **M/s Star Laboratories (Pvt.) Ltd., 23-Km, Multan Road, Lahore-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 18-05-2023

8. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 09-2021

Expiry Date: 09-2023

Sampling Date (Form 4): 01-10-2021

Sent to DTL (Form 6): 02-10-2021

Date of receipt in DTL: 07-10-2021

DTL Report Date (Form 7): 01-12-2021

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 26-01-2022

Retesting Request of Firm: Yes (31-01-2022)

Fate of Retesting Request: Allowed in 244th Meeting Dated 31-05-2022

Sample Received at NIH: 09-06-2022

NIH Report: 09-09-2022

Investigation Report Dated: 03-11-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Request No. 19

Case No.

PQCB/R-575/2021

Tehsil Chichawatni District Sahiwal

Sub-Standard (Dissolution Test

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Atco Laboratories Limited, B-18, S.I.T.E, Karachi-Pakistan** through its Chairman/ Managing Director Khalid Ahmad Asghar S/O Muhammad Asghar. 2. Khalid Ahmad Asghar Chairman/ Managing Director 3. Muhammad Giasuddin Siddiqui Production Incharge 4. Saeema Shahid Quality Control Incharge/Warrantor **of M/S Atco Laboratories Limited, B-18, S.I.T.E, Karachi-Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Chichawatni, District Sahiwal reported that: -

i. His Predecessor, on 14-09-2021, inspected the business premises of M/S Al-Abbas Medical Store, College Road Chichawatni, District Sahiwal 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 Memo. No.0000107285, dated. 14-09-2021.

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
Enteric Coated Tablet. Ascard-75 [Acetylsalicylic Acid 75mg] **Mfg Date:** Aug-2020 **Exp Date:** Aug-2022 **Registration No.** 057508	AR022G	M/S Atco Laboratories Limited, B-18, S.I.T.E, Karachi-Pakistan	01-85000122/DTL Dated. 20-11-2021

DTL Test Report Result

Analysis with specifications applied: **BP 2020.**

Composition:

Each enteric coated tablet contains:

Acetylsalicylic acid……75mg

Description (MS):

Pink colored round biconvex tablet, plain on both sides. Packed in Alu-Alu blister pack of 10 tablets.

Identification:

Aspirin is identified.

Assay (BP):

Aspirin:

Stated	75mg/Tab
Determined	78.46mg/Tab
Percentage	104.57%
Limit	95.0-105.0%

Dissolution Test (USP):

Tolerance Limit of Acid Stage: Drug Release of each unit should be less than 5% dissolved.

Stage (Acid)	Number Tested	Acceptance Criteria						Average	Remarks
A1	06	Drug Release of each unit should be less than 5% dissolved.						11.72%	Does not comply with the specifications.
	Asprin	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
		0.61%	20.52%	11.99%	1.22%	10.57%	25.40%		

Result: 04 out 06 units are more than 5%. Average drug release is 11.72%.

Tolerance Limit of Buffer Stage: Drug release of each unit should be more than 70% dissolved.

Stage (Buffer)	Number Tested	Acceptance Criteria						Average	Remarks
B1	06	Drug Release of each unit should be more than 70% dissolved.						95.84%	Comply with the specifications.
	Asprin	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
		108.51%	82.53%	95.52%	110.04%	93.99%	84.44%		

Result: The above sample is declared **Substandard** on the basis of Dissolution.

iii. M/S Al-Abbas Medical Store, College Road Chichawatni, District Sahiwal provided Invoice/warranty No SOB-0063988, dated 09-09-2021 issued by M/S Aamir Medicose, 18-B Small Industrial Estate, Sahiwal who in turn provided invoice/warranty No. 21-22-00412-LAB, dated. 14-07-2021 isuued by M/S Atco Laboratories Limited, B-18, S.I.T.E, Karachi-Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Aamir Medicose, 18-B Small Industrial Estate, Sahiwal and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Atco Laboratories Limited, B-18, S.I.T.E, Karachi-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 245th Meeting dated 16-06-2022 and Board after unanimous decision decided to turn down the said retesting request.

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 drug.**

b. **Issuance of false warranty**

3. Show-cause was issued to accused person(s) vide dated 26.01.2022

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. 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. Ahmad Awais, Secretary DQCB, District Sahiwal and Mr. Irfan Munir, Drug Inspector, Tehsil Chichawatni District Sahiwal were present along with the original case record. No one among the nominated accused persons was present, however, counsel of the firm, Dr. Khawaja Tahir Mehmood (Advocate) was present on behalf of **M/S Atco Laboratories Limited, B-18, S.I.T.E, Karachi-Pakistan.** Secretary PQCB apprised the Board that the firm has submitted written request for adjournment. 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/ final opportunity of personal hearing to the accused persons.

Summary:

Manufacturing Date: 04.2021

Expiry Date: 04.2023

Sampling Date (Form 4): 14.09.2021

Sent to DTL (Form 6): 20.09.2021

Date of receipt in DTL: 23.09.2021

DTL Report Date (Form 7): 20.11.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 18.12.2021

Date of Retesting Request of Firm: 24.12.2021

Fate of Retesting Request: Turn Down in 245th meeting dated16.06.2022

Investigation Report Dated: 26.08.2022

6. Personnel Hearing notice(s) issued to accused person 18.05.2023

Case is placed before the Board for Decision**.**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Request No. 20

PQCB/ R-642/2021

Tehsil and District Jhelum

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Wilshire Laboratoies (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore-Paksitan** through its Managing Director, Ghazanfar Ali Jawa. 2. Ghazanfar Ali Jawa Managing Director 3. Syeda Anita Marium Rizvi Production Incharge 4. Akhtar Hussain Quality Control Incharge 5. Irfan Ahmed Warrantor Of M/s Wilshire Laboratories (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore-Pakistan

BRIEF FACTS OF THE CASE

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

i. He, on 30-08-2021 inspected the premises of Main Medicine Store, Office of CEO/DHO DHA, Jhelum, took samples of six different drugs, including Tablet Zivus 200 mcg, Batch No. 026 manufactured by M/s Wilshire Laboratories (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore-Pakistan on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo No. 0000105013 Dated 01-09-2021.

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
Tablet Zivus [Misoprostol 200mcg] **Mfg. Date**: 03-2021 **Exp. Date**: 03-2023 **Reg** # 063170	026	M/s Wilshire Laboratories (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore-Pakistan	01-74002673/ DTL dated: 28 Dec 2021	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION:** White Coloured, round shaped, biconvex, tablets, plain from one side and engraved with "WILSHIRE" on other side. Packed in Alu/Alu blister of 1*10's, further packed in labelled outer carton. **WEIGHT VARIATION:** Results: All 20 units comply with the Test. Limit: ±5% **DISINTEGRATION TEST:** Results: All units comply the disintegration Test. Limit: NMT 30min **IDENTIFICATION:** Misoprostol identified **ASSAY:** Stated: 200mcg/tab **Determined**: 135.729mcg/tab **Percentage**: 67.86% **(Does not comply)** Limit: 90-110% **RESULT:** **The above sample is SUB-STANDARD with respect to Assay test performed.**

iii. The Store Keeper of Main Medicine Store, CEO DHA Office, Jhelum provided warranty/invoice bearing No. 196526 dated 08-04-2021 issued by M/S Wilshire Laboratories (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore.

iv. The Store Keeper of Main Medicine Store CEO DHA Office, Jhelum was asked **not to dispose of** the stock of the said substandard drug on Form 3.

V. Warrantor Portion as well as a copy of Test/ Analysis reports was sent to M/S Wilshire Laboratories (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore and they were asked to provide requisite information in this regard.

vi. The firm requested for re-testing of the sample from the Appellate Laboratory, National Institute of Health (NIH), Islamabad. The firm's re testing request was forwarded to The Secretary, Provincial Quality Control Board on 15-01-2022.

vii. Provincial Quality Control Board allowed the re-testing of the sample in its 244th meeting on 31-05-2022.

viii. Pursuant to the retesting request of the firm, sample was sent to Appellate Laboratory, National Institute of Health (NIH), Islamabad from where the sample was declared substandard.

<table>
<tr><th>ame of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>Test Report No.</th><th>Details of Result of Test/analysis
(With protocols of test applied)</th></tr>
<tr><td>ablet Zivus 200mcg</td><td>026</td><td>M/S Wilshire Laboratories (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore</td><td>0140-P/2022 dated: 19th September 2022</td><td>Reference: MS
<table>
<tr><th>Assay:</th><th>Stated:</th><th>Found:</th><th>Limit:</th><th>Percentage:</th></tr>
<tr><td>Misoprostol</td><td>200mcg/Tablet</td><td>115.94mcg/Tablet</td><td>90-110%</td><td>57.97%</td></tr>
</table>
(DOES NOT COMPLY WITH MANUFACTURERS' SPECIFICATIONS)
RESULT:
The above sample is SUB-STANDARD on the basis of test performed.</td></tr>
</table>

The Drug Inspector directed not to dispose of stock of the said batch, quantity of 44,000 Tablets on Form 3 dated 03.01.2022

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: -

i. **Manufacturing for Sale /Selling of Substandard drug**
ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s) dated 23.01.2023

Reply of the Firm to the Show Cause Notice:

RE: SHOW CAUSE NOTICE
Reference your letter no. PQCB/R-642/2021 dated 23-01-2023 received on 31-02-2023 regarding the subject mentioned above, please note following:-

- Your above letter shows that DTL Rawalpindi declared our product Zivus (Misoprostol) 200mcg Tablet, Batch No. 026 as substandard on the basis of Assay which was found as 67.86% vide DTL report no. 01-74002673/DTL dated 28-12-2021.
- Upon our retesting request, our product sample was tested by NIH and declared our product as Substandard on the basis of Assay which was found as 57.97% vide its Test Report No. 0140-P/2022 dated 19-09-2022.
- We supplied Zivus 200mcg Tablet, Batch No. 026 to CEO, DHA, Jhelum on 08-04-2021 and sample was picked by Drug Inspector on 30-08-2021 from The Main Medicine Store, Office of CEO, DHA, Jhelum (i.e. after 143 days of supply).
- We received sample portion along with above mentioned letter on 04-01-2022 which is after 271 days viz. more than 9 months of picking the samples which is violation of Section 19 (3) of The Drug Act 1976 which is reproduced as under:
  "The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same within seven days as follows "
  "(iv) the fourth, where taken, he shall send to the person purporting to be its manufacturer or importer, as the case may be.
- DTL Report says that they received sample from Drug Inspector on 02-09-2021 while report was issued on 28-12-2021 (appx. after 117 days) which is contravention of Drug Act 1976 which states that,
  Section 22(2) of The Drug Act 1976,
  The Government Analyst, as far as may be, shall submit the report referred to in sub- section (l) within sixty days of the receipt by him.
- As the Drugs Act 1976 was not followed it has renedered the entire proceedings illegal and null and void in the eyes of the law.
- If we count days from supply to testing then it took 264 days i.e. appx. 9 months to test the product. During that period, the sample remained in storage or transit during hot and humid days of summer and monsoon and we are not sure about storage conditions whether sample remained in suitable storage conditions or not as no such storage conditions mentioned in DTL report.
- According to Manual of Quality Assured MNCH Commodities with respect to Misoprostol Product published by USAID Module III.

  "Misoprostol Tablet are stable at room temperature and don't require cold chain storage. However, exposure to moisture and high humidity has been shown to be the PRINCIPAL DRIVER in degradation of MISOPROSTOL in tablet into three main inactive degradation products named Type A. Type B and 8-epimer."
  These degradation processes are catalysed by moisture. The rate of degradation increases as moisture content increase. Keeping all these aspects we are using extensive precaution during formulation selection and processes involved in Misoprostol Tablet manufacturing and storage. Such as proceeding its manufacturing and storage in low humidity with maximum exclusion of water, keeping temperature not more than 25 degree Celsius and Relative humidity 30% to 50% as per the standard recommendations to ensure product stability.

- The above said supply was the 12th supply to government institutions with same batch i.e. batch no. 026. All other supplies were tested by different DTLs including DTL Rawalpindi which also tested the said batch twice earlier and declared our product as standard. Detail is provided as below:-

DC Date	Institution	DTL Sampling Date	DTL Name	Report Date	Result
17-May-21	DHA Jhang	28-May-21	Faisalabad	3-Aug-21	pass
17-May-21	DHA Faislabad	2-Jun-21	Faisalabad	3-Aug-21	pass
04-May-21	DHA Mandi Bahauddin	2-Jun-21	Faisalabad	3-Aug-21	pass
15-Jun-21	DHA Gunjranwala	30-Jun-21	Faisalabad	3-Aug-21	pass
27-April-21	DHA Bahawalpur	2-Jun-21	Bahawalpur	19-Jun-21	pass
27-April-21	DHA Sahiwal	7-May-21	Bahawalpur	18-Jun-21	pass
08-Apr-21	DHA Okara	20-May-21	Bahawalpur	18-Jun-21	pass
03-Jun-21	DHA Dera Ghazi Khan	14-Jun-21	Multan	30-Jun-21	pass
02-Jun-21	DHA KHanewal	11-Jun-21	Multan	28-Jun-21	pass
21-Apr-21	DHA Rawalpindi	26-May-21	Rawalpindi	18-Jul-21	pass
06-Apr-21	DHA Chakwal	19-Apr-21	Rawalpindi	3-Jul-21	pass
08-Apr-21	DHA Jhelum	4-Sep-21	Rawalpindi	28-Dec-21	Substandard

- Looking at above detail, it is evident that 10 supplies were made later than the product being discussed and all were tested earlier than the said product. Four DTLs (including DTL Rawalpindi) declared our same product with same batch no. as of standard quality (DCs

& DTL Reports are enclosed).

- There is also possibility that product was stored in inappropriate storage conditions and due to which, it could have been degraded.

So, we request you to please withdraw your show cause notice and oblige.

Your required information is also provided as below: -

Name of CEO (Dr. Syed Aqil Hasnain).
Name of Production Incharge (Ms. Syeda Anita Marium Rizvi).

Name of Quality Control Incharge (Mr. Akhtar Hussain).

The Board of Directors neither had any knowledge nor granted their consent to any illegality or violation of the law.

4. Personal Hearing notice(s) issued to accused person(s) dated 18.05.2023.

Case is placed before the Board for decision.

Summary:

Manufacturing Date: 03-2021

Expiry Date: 03-2023

Sampling Date: 30-08-2021

Sent to DTL (Form 6): 01-09-2021

Date of receipt in DTL: 02-09-2021

DTL Report Date: 28-12-2021

Time Extension: granted in 235-M dated 30-11-2021

1ST DI Communication with firm on dated: 03-01-2022

Date of Retesting Request of Firm: -10-01-2022

Fate of Retesting Request: -Allowed in 244-m dated 31-05-2022

Investigation Report Dated: 26-11-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Request No. 21

DISTRICT JHANG

PQCB/R-211,235/2022

Tehsil & District Jhang

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi-Pakistan** through its Managing Director Syed Nophil Rizvi 2. Syed Nophil Rizvi — Managing Director 3. Kamran Awan — Production Incharge 4. Muhammad Fakhir Khaleeq — Quality Control Incharge/ Warrantor Of **M/s AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi-Pakistan.**

BRIEF FACTS OF THE CASE

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

i. She, on 29-06-2022, inspected the premises of Medicine Store, office of Chief Executive Officer (District Health Authority), Jhang, took sample of four different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug samples to Drug Testing Laboratory, Faisalabad vide memorandum no. 0000131793 & 0000131794 dated 29-06-2022.

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

iii. The drug inspector seized the stock of subject drug samples on Form 5 dated 15-09-2022.

iv. Store Keeper, Medicine Store, office of Chief Executive Officer (District Health Authority), Jhang submitted Invoice/warranty No. 0000005719 dated 16-06-2022 issued by M/s AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi-Pakistan as a proof of its purchase of the said drug.

v. Warrantor Portion of the drug sample was sent to M/s AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi-Pakistan and they were asked to provide requisite information in this regard.

vi. A copy of test report of the subject drug sample was sent to M/s AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi-Pakistan and they were asked to provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug samples from Appellate Laboratory, National Institute of Health, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its 251th meeting held on 20-10-2022 & 252nd meeting held on 01-11-2022, after due deliberation and discussion unanimously decided to accept the firm's appeal for **withdrawal** of retesting requests of subject drug samples and the Board further directed the Drug Inspector of concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

<table>
<tr><th>Sr. No.</th><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>1.</td><td>Powder for Reconstitution Macrobac 15 ml (Each 5 ml reconstituted suspension contains: Azithromycin dihydrate (USP) equivalent to Azithromycin …200mg).
Mfg.date:
Apr-2022
Exp. date:
Apr-2024
Regn No.
082215</td><td>S0541</td><td>M/s AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi-Pakistan</td><td>TRA No. 01-68016727/DTL
Dated:-12-08-2022</td><td><u>Result of Test/ Analysis with specifications applied:</u>
USP 2022
<u>Description</u>:
White powder contained in white plastic bottle with child resistance cap packed in outer hard carton along with leaflet and measuring device. After reconstitution, it forms light pink color suspension.
<u>Identification</u>: Azithromycin is identified.
<u>Assay:</u>
<table><tr><td>Stated</td><td>Determined</td><td>Percentage</td><td>Limit</td></tr><tr><td>200mg/ 5 ml</td><td>188.926mg/ 5 ml</td><td>94.436 % (Complies)</td><td>90-110% (USP 2022)</td></tr></table><u>PH:</u>
Stated: 8.5-11 (USP 2022)
Determined: 8.40 (Does Not Comply)
<u>Deliverable Volume:</u>
Stated: 15 ml (USP 2022)
Determined: 15.3 ml (Avg. of 10 bottles) (Complies)
<u>Result:</u> <u>Given sample is Sub-Standard with regards to PH Test.</u></td></tr>
<tr><td>2.</td><td>Powder for Reconstitution Macrobac 15 ml (Each 5 ml reconstituted suspension contains: Azithromycin dihydrate (USP) equivalent to Azithromycin …200mg).
Mfg.date:
Apr-2022
Exp. date:
Apr-2024
Regn No.
082215</td><td>S0546</td><td>M/s AsianContinental (Pvt.) Ltd. D-32, S.I.T.E II, Super Highway, Karachi-Pakistan</td><td>TRA No. 01-68016726/DTL
Dated:-12-08-2022</td><td><u>Result of Test/ Analysis with specifications applied:</u>
USP 2022
<u>Description</u>:
White powder contained in white plastic bottle with child resistance cap packed in outer hard carton along with leaflet and measuring device. After reconstitution, it forms light pink color suspension.
<u>Identification</u>: Azithromycin is identified.
<u>Assay:</u>
<table><tr><td>Stated</td><td>Determined</td><td>Percentage</td><td>Limit</td></tr><tr><td>200mg/ 5 ml</td><td>185.787mg/ 5 ml</td><td>92.894 % (Complies)</td><td>90-110% (USP 2022)</td></tr></table><u>PH:</u>
Stated: 8.5-11 (USP 2022)
Determined: 8.34 (Does Not Comply)
<u>Deliverable Volume:</u>
Stated: 15 ml (USP 2022)
Determined: 15.35 ml (Avg. of 10 bottles) (Complies)
<u>Result:</u> <u>Given sample is Sub-Standard with regards to PH Test.</u></td></tr>
</table>

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

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

b. **Issuance of false warranty**

3. Show cause Notice (s) issued to the accused person(s) Dated 05-01-2023.

REPLY OF THE FIRM TO SHOW CAUSE NOTICE DATED 25-01-2023

Your letter no. PQCB/R-211,235 /2022-dated 05th January 2023 that has been receivedby us on dated 21ST January 2023.

Whereas, you have stated in that letter with test report number TRA: 01-68016727 of DTL, dated 12 August, 2022 and test report number TRA:01-68016726 of DTL Faisalabad which has been declared the Macrobac Dry Suspension Batch # S0541 & #50546 Registration #082215 are substandard with regards to tests performed of physical test, identifications, pH determination test, Assay and Deliverable Volume.
Along with documents, you have required us to explain our position for manufacturing, stocking selling of substandard drugs and you have also required from us to verify the names of accused persons and also requested to submit the attested documents for board consideration.
In response thereto, we state as follow:
That first letter from Provincial Inspector of Drugs, Tehsil Jhang was received to us on dated 02-09-2022 and same was replied on dated 05-09-2022 within targeted information with required information and documentations and confirmed that questioned product after cross checked of all quality parameters is of standard quality
(Copy of reply letter enclosed with this letter.) Annex-I.
With regards to above said show cause notice, our justifications and clarifications are as followed:
Please note that we have received the Warrantor Portion Sample of our product Macrobac 200 mg/5 ml. Suspension on the same day dated 02/09/2022 along with Letter No. 584/85 dated 31-08-2022; however, we have analyzed the Warrantor Portion Sample of Batch No's. S0541 & S0546 along with the retention samples of the same batches and found that our product is of STANDARD QUALITY with respect to prescribed parameters of physical characteristics, assay, and pH.

It is pertinent to mention here that the product in question is dry powder suspension of Azithromycin as Dihydrate, which is reconstituted with water to form liquid suspension dosage form. The pH of the suspension is dependent upon proper reconstitution of the formulation with water. In case the dry powder is not properly mixed in water, it may sediment and alter the pH value, which is evident from the reports of DTL Faisalabad s the pH value of both batches is slightly lower than the specified limits. If the Govt. Analyst properly reconstitute the suspension and took the pH after removal of air bubbles the desired value of pH may be attained.

Even though we totally unaccepting the DTL Faisalabad Testing reports we are not requesting for the retest of the batches in question and going to replace both batches with the fresh stock as an act of curtesy and grace.

Based on above facts it is evident that this is the borderline case, therefore, it is humbly requested to take a kind decision and the case may please be closed amicably and fairly with formal warning to us.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023.

5. Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 04-2022**
- **Expiry Date: 04-2024**
- **Sampling Date (Form 4): 29-06-2022**
- **Sent to DTL (Form 6): 29-06-2022**
- **Date of receipt in DTL: 01-07-2022**
- **DTL Report Date (Form 7): 12-08-2022**
- **Time Extension: NA**
- **1ST DI Communication with firm on dated: 31-08-2022**
- **Date of Retesting Request of Firm: 05-09-2022**
- **Fate of Retesting: Board decided to accept the firm's appeal for withdrawal of retesting requests in its 251th meeting held on 20-10-2022 & 252nd meeting held on 01-11-2022**
- **Investigation Report Dated: 23-11-2022**

PROCEEEDINGS & DECISION BY THE BOARD:

Request No. 22

DISTRICT DERA GHAZI KHAN

PQCB/R-442/2022

Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi, Pakistan** through its Chief Executive Officer/Managing Director Syed Muhammad Wajeehuddin 2. Syed Muhammad Wajeehuddin Chief Executive Officer/Managing Director 3. Rashid Mohammad Khan Production Incharge 4. Muhammad Farooq Quality Control Incharge/Warrantor of M/s Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi, Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan reported that: -

i. He, on 28-10-2022 inspected the premises of Medicine Store, Punjab Health Facilities Management Company, House No. 2143 College Chowk Block No. 18, Dera Ghazi Khan, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan vide memorandum no. 146335 dated 28-10-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Vibramycin [Doxycycline hyclate equivalent to doxycycline 100mg] capsule. **Mfg. Date:** 06-2022 **Exp. Date:** 05-2025 **Regn. No:** 000456	GF5138	M/s Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi, Pakistan	01-89007750/DTL dated 17-12-2022	**Result of test/ analysis with specifications applied:** USP 2022 **DESCRIPTION:** Yellow color powder filled in green colored hard gelatin capsules having cap printed with ''Pfizer'' & ''VBM 100'' on body of capsule packed in ALU-PVC blister of 06 units in a labeled outer hard carton. Each outer carton contains 20 blisters of 06 units i.e. 20*6=120 capsules. **Note**: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states, "All registration holders shall follow official pharmacopeial specifications for all such formulations for which official monographs of drug product is available in the most recent edition of such pharmacopoeia". Product specification of given sample is "Manufacturer's Specifications" and it is manufactured after the expiration of timeline to apply such specifications despite the availability **Doxycycline Hyclate Capsules** monograph in USP 2022, so the manufacturer's claim regarding product specification is in contradiction to DRAP circular and in violation to Drug Act 1976. **Mis-Branded(Does not comply)** **Uniformity of Dosage Unit (Weight Variation)** Max. AV=L1: 15% **(Complies)** **Identification:** Doxycycline Hyclate Identified. **ASSAY:** Stated: 100 mg/capsule Determined: 99.41 mg/capsule Percentage: 99.41% Limit: 90- 120% **(Complies)** **Dissolution Test:** **Limit:** NLT 80% (Q) of the labeled amount of Doxycycline dissolved in 30 minutes. **(Complies)** **RESULT:** The above mentioned sample is **Mis-Branded** as per Section 3 (s) (iv) of The Drugs Act, 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022.

iii. Storekeeper, Punjab Health Facilities Management Company, House No. 2143 College Chowk Block No. 18, Dera Ghazi Khan provided Invoice/Warranty No. 3037607554 date 22-09-2022 issued by M/s Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi-Pakistan as proof of its purchase.

iv. Warrantor Portion of subject drug sample was sent to M/s Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi-Pakistan.

v. Copy of Test/ Analysis reports was sent to M/s Pfizer Pakistan Ltd. B-2, S.I.T.E., Karachi Pakistan 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 (as amended) / DRAP Act 2012 and Rules framed there under by the way of: -

a. **Manufacture for sale/sale of the Misbranded drug**

b. **Issuance of false warranty**

3. Show cause Notice (s) issued to the accused person(s) Dated 04-05-2023.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023.

5. Case is placed before the Board for Decision

Summary	Warning to the subject Product	Warning to the firm in different Products
Dated	28-10-2021	First warning: 28-10-2021 Total warnings to firm: 10

PROCEEEDINGS & DECISION BY THE BOARD:

ITEM No. 4

SUBSTANDARD

Issue # 1

COURT CASE

M/s Amson Vaccines and Pharma (Pvt) Ltd. Versus Province Quality Control Board and Others.

Tehsil and District Sahiwal

PQCB/R-546/2019

Tehsil and District Sahiwal

Substandard (Dissolution Test)

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 Industrial Triangle Kahuta Road, Islamabad, Pakistan** through its managing director Syed Saleem Asghar 2. Syed Saleem Asghar Managing Director 3. Sajjad Hussain Production Incharge/Warrantor 4. Muhammad Mudassir Quality Control Incharge Of **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 Industrial Triangle Kahuta Road, Islamabad, Pakistan.**

The firm filed **Writ Petition** No. 10009 of 2022 and Lahore High Court, Lahore Orders dated 09-02-2023, received in the office of PQCB on 21-02-2023.

ORDER SHEET

IN THE LAHORE HIGH COURT, LAHORE.

JUDICIAL DEPARTMENT W.P. No. 10009 of 2022

M/s Amson Vaccines and Pharma (Pvt) Ltd. Versus Province Quality Control Board and Others.

09.02.2023

Presence same as in W.P. No.54146 of 2021

For the reason recorded in my detailed order of even date passed in connected petition W.P.No. 54146 of 2021, the instant petition is ***allowed.***

BRIEF FACTS OF THE CASE

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

i. She, on 11-10-2019, inspected the business premises of M/s Matloob Medical Store, 99/6- R Adda Bootipal Tehsil & District Sahiwal and took sample of below-mentioned drug on Form-4 for the purpose of test/analysis, drug sample, after test/ analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

<table>
<tr><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>DTL Report TRA</th><th>DTL Test Report Results</th></tr>
<tr><td>Film-coated tablet, Famotid [Famotidine 20mg]</td><td>037</td><td>M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle Islamabad</td><td>TRA No. 01-2500458 0/DTL dated:10-12-2019</td><td>
Analysis with specifications applied:
USP 2018
<u>COMPOSITION</u>: Each Film Coated tablet contains:
Famotidine USP……...…….20mg
<u>DESCRIPTION (MS)</u> yellow color, round, biconvex tablet which is plain on both sides and packed in a blister pack of 10 tablets.
<u>IDENTIFICATION (USP)</u> Famotidine is identified.
<u>ASSAY (USP)</u> <u>Stated</u> <u>Determine</u> <u>Percentage</u>
Famotidine 20 mg/Tab. 19.70 mg/Tab. 98.52% LIMIT: 90-110%
<u>DISSOLUTION TEST (USP)</u>: Does not Comply with the specifications of USP as detailed below:
Tolerance Limit: Not less than 75% (Q) of the labeled amount of Famotidine.
<table>
<tr><th>STAGE</th><th>NUMBER TESTED</th><th colspan="6">ACCEPTANCE CRITERIA</th><th>AVERAGE</th><th>REMARKS</th></tr>
<tr><td rowspan="2">S1</td><td rowspan="2">06</td><td colspan="6">Each unit is not less than Q+5% and not more than 2 units are less than Q-15% and no unit is less than Q-25%.</td><td rowspan="2">S1</td><td rowspan="2">Does Not Comply with specification</td></tr>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit 5</td><td>Unit 6</td></tr>
<tr><td>Stage 1</td><td>Famotidine</td><td>35.55%</td><td>42.28%</td><td>55.30%</td><td>40.81%</td><td>49.45%</td><td>43.30%</td><td>44.45%</td></tr>
</table>
<u>Note</u>: All Six units are less than Q-15%, moreover Five out of Six Units (i.e., unit no. 01, 02, 04, 05 & 06) are less than Q-25%.
<u>RESULT</u>: The sample is declared <u>SUB-STANDARD</u> on the basis of DISSOLUTION TEST.
</td></tr>
</table>

ii. M/s Matloob Medical Store, 99/6-R Adda Bootipal Tehsil & District Sahiwal provided invoice/ warranty no. 60207 dated 22-09-2019 issu by M/s Ghazi Pharma, building Peshawary Nan Shop Karbala Road Sahiwal as a proof of its purchase.

iii. Warrantor portion of the drug sample was sent to M/s Ghazi Pharma, building Peshawary Nan Shop Karbala Road Sahiwal.

iv. A copy of test report was sent to M/s Ghazi Pharma, building Peshawary Nan Shop Karbala Road Sahiwal with directions to explain th position and provide requisite information in this regard, who in-turn provided invoice/ warranty no. 69516 dated 29-07- 2019 issued by M Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad.

v. A copy of test report was sent to M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad with directions to expl 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 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/ Selling of Substandard Drug**

   b. **Issuance of false warranty.**

3. Show-cause notice(s) issued to accused person on dated 23.06.2020

REPLY OF THE FIRM TO THE DRUG INSPECTOR:

2. M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad submitted written reply stating that:

Reference to your letter No. PQCB/R-546/2019 dated 23rd June 2020; received at AMSON on dated 29-6-2020 through UMS-Pakistan Post. The letter states that our product Famotid Tablets (Famotidine 20mg) Batch No 037 is found substandard on the basis of Dissolution Test by Drug Testing Laboratory, Bahawalpur.

In this regard following documents to justify our product quality standard on technical ground:

1. Test report of other Drug Testing Laboratories (attached)
2. Test report done at Amson with chromatograms (attached)
3. Valid Drug Manufacturing and valid drug product registration certificates (attached)
4. Appointment letters of technical staff, copy of job certificate and national identity card (attached)
5. Respected sir, on the basis of above-mentioned technical facts it can be confirmed that our product Famotid Tablets (Famotidine 20mg) Batch No. 037 is declared standard quality by DTL Karachi as well as internal testing results.
6. So, we humbly request you to withdraw the show-cause notice against us or send samples of our product to Appellate Laboratory for retest as per procedure.

4. Personal hearing notice served earlier for 229th Meeting on dated 20-01-2021.

Case was placed before the Board for Decision.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board (PQCB), Punjab under section 11 of the Drugs Act 1976 in its **229th meeting held on 02-02-2021.** Ms. Atia Nawaz Secretary DQCB District Sahiwal and Mr. M. Irfan Munir Drug Inspector Tehsil & District Sahiwal were present. Among nominated accused persons Muhammad Muddassir (Quality Control Incharge) of M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad was present along-with representative from the firm Tahir Hameed Gill. They submitted their grievance on the report of Government Analyst Drug Testing Laboratory, Bahawalpur. They stated that the Specifications supposed to be applied was of U.S.P. 19, whereas, Government Analyst has applied the specifications of U.S.P 2018. The Columns and flow rate are different in both U.S.P.'s. They also requested to send their sample to Appellate Laboratory, National Institute of Health Sciences, Islamabad for retest/ analysis.

6. The Board after keen perusal of the Report of Government Analyst, Drug Testing Laboratory, Bahawalpur, reply of the firm submitted in response to show-cause notice issued to them and the arguments of the accused persons observed that the Product Film-coated tablet Famotidine was declared Substandard from Drug Testing Laboratory, Bahawalpur on the basis of dissolution test. All the six units tested were out of the specified range. Dissolution testing measures the extent and rate of solution formation from a dosage form. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. The product failed to comply the dissolution test would result in lesser bioavailable drug and would not be able to provide optimal therapeutic response. Furthermore, the Board also observed that the request of re-testing of the drug sample was not made within the stipulated time. The firm requested for retesting of the drug sample in response to the show-cause notice issued to them. Hence, the report of Government Analyst Drug Testing Laboratory, Bahawalpur is considered as the conclusive evidence of the facts stated therein.

7. keeping in view the facts of the case, the Board after due deliberation and detailed discussion unanimously decided to grant **permission for prosecution** against the following accused persons in the Drug Court:

1. **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad**

through its Managing Director Syed Saleem Asghar

2. Syed Saleem Asghar Managing Director
3. Sajjad Hussain Production Incharge/ Warrantor
4. Muhammad Muddassir Quality Control Incharge

Of **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad.**

For the offences of:

a) **Manufacturing/ Stocking/ Selling of Substandard Drug**

b) **Issuance of false warranty.**

REVIEW PETITION

The firm filed review petition in PQCB against the prosecution orders of PQCB dated 02.02.2021s, received in the office of PQCB on 06.05.2021, stated that;

Grounds

1. That the Honorable Board in the impugned order dated,2/2/21, failed to consider the additional grounds of the Petitioner.

2. That no warrantor portion was sent to the Petitioner Company by the Drug Inspector, hence this was a mandatory for the Drug Inspector to send collected sample to the Petitioner Company, hence failure goes to the roots of the case, a valid ground for the review of order dated,2/2/21.

3. That Honorable Board did not consider the ground that the Drug Testing Laboratory Karachi Declared the same batch of medicine standard quality, which rise the question on the credibility of Drug Testing Laboratory Bahawalpur and investigation conducted by that Drug Inspector.

4. That the Honorable Board failed to consider establish principle of law, when law required a thing to be done in a particular manner then it should be done in such particular manner, if it is not followed then the proceedings become invalid and illegal.

5. That the Honorable Board turned down the retesting request by not providing opportunity to the Petitioner to prove its innocence.

6. That Honorable Board even discussed one of the contentions raised by the Petitioner in its Additional grounds while the other grounds were not even considered which is also error floating on the record.

7.That the Govt Analyst Report was not of with protocol hence liable to be rejected.

8. That no Govt Analyst laboratory report was sent to Petitioner Company which was mandatory and obligatory on the part of Drug Inspector or The Prosecution and failure to fulfill this mandatory provision of law provides opportunity to this Honorable Board to review its decision dated, 2/2/21 and drop the proceeding against the Petitioner.

9. That the dissolution test conducted by the Govt Analyst is not required by the law. Hence not acceptable and liable to be rejected.

Under the submission above it is requested that by accepting the instant review petition case against company may please be dropped.

08. Personal Hearing notice(s) issued to accused person(s) dated 27-04-2023.

PREVIOUS PROCEEEDINGS & DECISION BY THE BOARD:

09. Case was considered by the Provincial Quality Control Board in compliance to the Orders of Honourable Lahore High Court, Lahore dated 09.02.2023 in writ petition no. 10009/2022, Under Section 11 of the Drug Act 1976 in its **260th meeting held on 04-05-2023** under the chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab/ Chairperson, Provincial Quality Control Board, Punjab. Mr. Ahmad Awais Secretary DQCB District Sahiwal attended the meeting online via Zoom Link. No one appeared before the Board on behalf of M/s Amson Vaccines and Pharma (Pvt) Ltd. However, counsel for the firm submitted written request for adjournment, received in the office of the Secretary, Provincial Quality Control Board, Punjab on dated 02-05-2023.

10. The Board after due deliberation and discussion unanimously accepted the firm's request for adjournment and decided to **adjourn** the case till next meeting in best interest of justice. The board further decided to provide another but final opportunity of personal hearing to the accused persons.

Summary:

- **Manufacturing Date: 07.2019**
- **Expiry Date: 06.2022**
- **Sampling Date (Form 4): 11.10.2019**
- **Sent to DTL (Form 6): 12.10.2019**
- **Date of receipt in DTL: 15.10.2019**
- **DTL Report Date (Form 7): 10.12.2019**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 07.01.2020**
- **Date of Retesting Request of Firm: N/A**
- **Fate of Retesting: N/A**
- **Investigation Report Dated: 10.06.2020**
- **Prosecution granted against firm: 229st meeting dated 02-02-2021**
- **Review Petition submitted by firm: Dated 06.05.2021.**
- **Status of Review Petition: Pending**

11. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023.

Case is placed before the board for decision.

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Issue # 2

PQCB/R-348/2022

Lyallpur Town, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan** through its Chief Executive Officer, Syed Nophil Rizvi 2. Syed Nophil Rizvi — Chief Executive Officer 3. Kamran Awan — Production Incharge 4. Mohammad Fakhir Khaleeq — Quality Control Incharge/ Warrantor of M/s Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan.

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 30-06-2022, inspected the premises of Main Medicine Store, of the Chief Executive Officer, District Health Authority District Faisalabad, took thirteen different types of drug samples on Form No. 04 for the purpose of test and analysis and sent the subject drug sample to Government Analyst Drug Testing Laboratory, Faisalabad vide memorandum no. 131993 dated 30-06-2022

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report No. & Date</th><th>DTL Test Report Result</th></tr>
<tr>
<td>Powder for Reconstitution. Macrobac 15ml [Each 5mL reconstituted suspension contains: Azithromycin Dihydrate (USP) equivalent to Azithromycin ….. 200mg]

Mfg Date
Apr 2022
Expiry Date
Apr 2024
Regn No.
082215</td>
<td>S0546</td>
<td>M/s Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan.</td>
<td>01-68016813/ DTL
Dated
12-08-2022</td>
<td><u>Analysis with specifications applied:</u> USP 2022

<u>DESCRIPTION</u>: White powder contained in white plastic bottle with child resistance cap packed in outer hard carton along with leaflet and measuring device. After reconstitution, it forms light pink color suspension.

<u>IDENTIFICATION:</u> Azithromycin is identified

<u>ASSAY:</u>
<table>
<tr><td>Stated</td><td>200mg / 5ml</td></tr>
<tr><td>Determined</td><td>183.575 mg / 5ml</td></tr>
<tr><td>Percentage</td><td>91.788 % (Complies)</td></tr>
<tr><td>Limit</td><td>90–110% (USP 2022)</td></tr>
</table>
<u>pH:</u>
Stated: 8.5 – 11 (USP 2022)
Determined: 8.40 (Does Not Comply)

<u>DELIVERABLE VOLUME:</u>
Stated: 15ml (USP 2022)
Determined: 15.25ml (Avg. of 10 bottles) (Complies)

<u>RESULT:</u> <u>Given sample is Sub-Standard with regards to pH Test.</u></td>
</tr>
</table>

iii. Storekeeper of the Main Medicine Store, of the Chief Executive Officer, District Health Authority District Faisalabad provided Invoice/Warranty bearing number 0000005835 dated 21-06-2022 issued by M/s Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan, as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi Pakistan.

i. A copy of test/analysis report was sent to M/S Asian Continental (Pvt) Ltd. D-32 S.I.T.E. II Super Highway Karachi 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.

ii. Pursuant to firm's request, the Provincial Quality Control Board in its 253rd meeting held on 29-11-2022, after due deliberation and discussion unanimously decided to accept the firm's request for withdrawal of the retesting request of the subject drug sample.

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

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

<u>Firm replied to the show cause notice vide letter dated 08-03-2023</u>

This is with reference to your letter No. PQCB/R-348/2022 dated 17-02-2023 received at our office on 02-03-2023 regarding the subject captioned above.

As per your letter, it has been informed that the subject drug sample withdrawn has been declared as "SUBSTANDARD" by Government Analyst, DTL Faisalabad vide Report No. TRA 01-68016813 dated 12-08-2022 B.NO. SO546.

Along with documents, you have required us to explain our position for manufacturing, stocking selling of substandard drugs and you have also required us to verify the names of accused persons and also requested to submit the attested documents for board consideration.

In response thereto, we state as follow:

- *That First letter from Provincial Inspector of Drugs, Lyallpur Town Faisalabad was received to us on dated 20-09-2022 and same was replied on dated 26-09-2022 with required information and documentations and confirmed that questioned product after cross checked of all quality parameters is of standard quality.*
- *With regards to above said show cause notice, our justifications and clarifications are as followed:*
- *Please note that we have received the Warrantor Portion Sample of our product Macrobac 200 mg/ 5 ml. Suspension on the same day dated 20-09-2022 along with the letter No. F-49/2022/279/DC/LT dated 15-09-2022; however, we have analyzed the Warrantor Portion Sample of Batch No. S0546 along with the retention sample of the same batch and found that our product is of STANDARD QUALITY with respect to prescribed parameters of physical characteristics, assay, and pH.*
- *It is pertinent to mention here that the product in question is dry powder suspension of Azithromycin as Dihydrate, which is reconstituted with water to form liquid suspension dosage form. The **pH of the suspension is dependent upon proper reconstitution of the formulation** with water. In case the dry powder is not properly mixed in water, it may sediment and alter the pH value, which is evident from the report of DTL Faisalabad as the pH value of a batch is slightly lower than the specified limits. If the Govt. Analyst properly reconstitute the suspension and took the pH after removal of air bubbles the desired value of pH may be attained.*
- *Even though we totally unaccepting the DTL Faisalabad Testing report we are not requesting for the retest of the batch in question and **going to replace batch with the fresh stock** as an act of curtesy and grace.*

Based on above facts it is evident that this is the borderline case, therefore, it is humbly requested to take a kind decision and the case may please be closed amicably and fairly with formal

4. Personal hearing notice(s) issued to accused person(s) dated 18-05-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: Apr-2022

Expiry Date: Apr-2024

Sampling Date (Form 4): 30-06-2022

Sent to DTL (Form 6): 05-07-2022

Date of receipt in DTL: 05-07-2022

DTL Report Date (Form 7): 12-08-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 15-09-2022

Retesting Request of Firm: Yes

Fate of Retesting Request of Firm: Withdrawal accepted in 253-M dated 29-11-2022

Investigation Report Dated: 30-01-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Issue # 3

PQCB/ R-198/2021

Punjab Institute of Neurosciences, Lahore

(Court Direction Case)

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 COO/Managing Director, Dr. Zamir-ul-Hassan 2. Dr. Zamir-ul-Hassan COO/Managing Director 3. Umair Ahmed Production Manager 4. Muhammad Ibrahim Quality Control Manager 5. Waheed Shah Warrantor of M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan.

Order dated 09-02-2023 in W.P. No. 55855/2022

For the reasons recorded in my detailed order of even date passed in connected petition W.P. No. 54146 of 2021, the instant petition is ***allowed.***

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Punjab Institute of Neurosciences, Lahore reported that: -

i. She, on 23-06-2021, inspected the Main Medicine Store of Punjab Institute of Neurosciences, Lahore and took sample of following drug on Form No.04 for the purpose of test/analysis.
ii. The drug sample after test/analysis was declared as **Misbranded** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report
TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Powder for Injection. Merem 1g [Meropenem USP….1g/ Vial)</td><td>21E098</td><td>M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan</td><td>01-156001510/DTL
dated
26-08-2021</td><td>
Analysis with specifications applied: USP 2021

<u>PHYSICAL DESCRIPTION:</u> White coloured powder for injection in transparent glass vial with rubber stopper, aluminium seal and brown flip off cover.

<u>Observation:</u> Out of 25 units received, 07 units are found with label claim of “Merem 500mg (Meropenem) USP” on outer carton, whereas label on immediate container, i.e., vial of these 07 units bear “Merem 1g (Meropenem) USP”.

The inner and outer label of these 07 units are different in label claim strength.

(MISBRANDED DRUG)

<u>pH:</u>

Limit: 7.3 – 8.3

Determined: 8.08 at 23.6 °C

<u>IDENTIFICATION:</u> The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (MEROPENEM identified)

<u>ASSAY OF MEROPENEM:</u>

(On basis of immediate label claim on vial)
<table>
<tr><td>Stated</td><td>1 g/ Vial</td></tr>
<tr><td>Determined</td><td>1.1 g/ Vial</td></tr>
<tr><td>Percentage</td><td>110.0%</td></tr>
<tr><td>Limit</td><td>90% - 120% of the labelled amount</td></tr>
</table>
<u>STERILITY:</u> The product is sterile.

<u>RESULT:</u> The above sample is <u>MISBRANDED</u>, on the basis of THE DRUGS ACT 1976 3{s (iv)}
</td></tr>
</table>

iii. Storekeeper of Punjab Institute of Neurosciences, Lahore provided warranty bearing No. 6203811 dated 21-06-2021 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. Warrantor portion of drug sample was sent to M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan.

v. 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.

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. **Manufacturing/ Stocking /Selling of Misbranded drug**

b. **Issuance of false warranty**

3. Showcause was issued to accused person(s) dated 09-11-2021

Reply of the Firm to the Show Cause Notice:

We did complete investigation, and we are assure on the basis of investigation ***there may be only 20-30 cartons mixed from the Printer (Supplier) in the consignment,*** *which if you allow, can be sorted out to remedied the consignment supplied to Punjab Institute of Neurosciences, Lahore.*

Reply of the Firm to the Drug Inspector:

- *We checked all the documents including BMR, QC testing reports of all components including Packaging material testing reports and also inspect the Packaging material store to sort out the root cause of this discrepancy. During inspection of packaging material store,* ***we observed that this mixing of Unit Carton of Merem Inj 500mg in Unit Carton of Merem Inj 1gm was by mistake done at the Supplier end****; we could not observe this issue during testing and sampling of the said lot due to very low percentage (only 20-30 cartons) in whole lot.*
- *The investigation reveal that* ***only 1-2 sheets of Merem 500mg containing 20-30 cartons may be mixed with Merem 1gm carton.***
- *So we assure on the basis of investigation there may be only 20-30 cartons in the consignment, which if you allow, can be sorted out to remedied the consignment supplied to Punjab Institute of Neurosciences, Lahore.*
- ***We took a strict action against the supplier, also performed detailed audit of the said printing press, they have proper system and they are following the system including line clearance before starting the printing of any lot.*** *Supplier committed that in future they must sort and verify the quality of the supply before sending to Global Pharma.*
- *Moreover, we have revised our system for ordering of packaging material and instructed the procurement department to follow the below mentioned advices*
- ***If any product range have same dimension for two different strengths, then order of both strengths will be given to two different suppliers.*** *This will make zero chance of mixing of the packaging material of two different strength of the same product.*
- *QA and Production staff will also check more vigilantly the packaging components during packaging process.*

4. Personal Hearing notice(s) issued to accused person(s) dated 22-11-2021

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

235th meeting held on 30-11-2021

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **235th meeting** held on **30-11-2021** under the Chairmanship of Secretary Primary & Secondary Healthcare Department Punjab. Mr. Hassan Saeed, Secretary DQCB, District Lahore was present along with the original case record. Among the nominated accused persons, Dr. Zamir-ul-Hassan (COO/Managing Director) along with Sohail Aslam, Representative of M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan appeared before the Board. Representatives of the firm pleaded their case on following arguments:

i. We checked all the documents including BMR, QC testing reports of all components including Packaging material testing reports and also inspected the Packaging material store to sort out the root cause of this discrepancy. During inspection of packaging material store, we observed that this mixing of Unit Carton of Merem Inj 500mg in Unit Carton of Merem Inj 1gm was by mistake done at the Supplier end as we could not observe this issue during testing and sampling of the said lot due to very low percentage (only 20-30 cartons) in whole lot.

ii. So, our investigation reveals that there may be only 20-30 cartons which may be mixed with Merem 1gm carton from the Printer (Supplier) in the consignment.

iii. We took a strict action against the supplier, also performed detailed audit of the said printing press.

iv. Moreover, we have revised our system for ordering of packaging material. If any product range have same dimension for two different strengths, then order of both strengths will be given to two different suppliers. This will make zero chance of mixing of the packaging material of two different strength of the same product.

6. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample has been declared Misbranded by the Drug Testing Laboratory, Lahore as per The Drugs Act 1976 3 (s) (iv) on the basis that out of 25 units received, 07 units were found with label claim of “Merem 500mg (Meropenem) USP” on outer carton, whereas label on immediate container, i.e., vial of these 07 units bear “Merem 1g (Meropenem) USP” which means that the inner and outer label of these 07 units are different in their label claim strength.

7. The Board was highly perturbed on this gross negligence on part of firm as it could result in serious consequences. The Board was of the view that the batch was supplied to Punjab Institute of Neurosciences Lahore and if this error was unnoticed as the firm admitted that 20-30 cartons were mixed with Injection Merem 1gm, it could have led to wrong administration of dose to already debilitated and ailing patients.

8. Considering the facts of the case, the Board after due deliberation and discussion, unanimously decided to grant **permission for prosecution** against the following accused persons **M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan** in the drug court due to this major lapse of non-compliance to GMP by the firm:

1. **M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan** through its COO/Managing Director, Dr. Zamir-ul-Hassan
2. Dr. Zamir-ul-Hassan — COO/Managing Director
3. Umair Ahmed — Production Manager
4. Muhammad Ibrahim — Quality Control Manager
5. Waheed Shah — Warrantor

of M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan.

For the offences of:

a. **Manufacturing/ Stocking/ Selling of Misbranded drug**

b. **Issuance of false warranty**

9. The Board further directed to initiate a **regulatory recall** of batch 21E098 of Powder for Injection. Merem 1g [Meropenem USP….1g/ Vial) manufactured by M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan, through Chief Drug Controller Office may be done under The Drugs Act 1976 and rules framed thereunder in order to safeguard the public from potential adverse effects of this mixing. The Board further directed that:

i. Recall will be conducted at Level 2 i.e. from market, distributors, hospitals and retailers.

ii. Provincial Government may advertise Public Awareness Notice through newspaper regarding recall of above-mentioned batch of the drugs.

Furthermore, firm will recall the drug in intimation to Chief Drug Controller Office and also carry out the comprehensive investigation in the subject case and submit root cause analysis report.

10. Firm **submitted Review Petition** against the above mentioned orders in the office of the PQCB on 10-01-2022 which was **referred back to the firm** on 14-01-2022, in compliance to the Drug Court Lahore directions dated 25-08-2021.

Firm **re-submitted the subject review petition** in the office of the PQCB on 02-02-2022 and then filed a **writ petition No. 55855/2022 in Lahore High Court** in which the Honorable Lahore High Court passed above mentioned orders.

Subject: Review petition against the orders no. POCB/R-1982021 dated 30-11-2021 in case of Misbranded powder Injection Merem lgm (Meropenem USP 1gm) Batch No. 21E098

Respectfully submitted as under,

a. *That Drug inspector of Punjab Institute of Neurosciences (PINS) Lahore took the sample of subject Drug from main Medicine store of Punjab Institute of Neurosciences, Lahore on form 4 for the purpose of test/analysis.*
b. *That the drug sample after test analysis was declared as MISBRANDED by the Government Analyst DTL, Lahore vide test report # TRA 01-156001510 dated 26-8-202 1 and the reason of Misbranded mentioned on the test report are "out of 25 units received, 07 units are found with label claim of "Merem 500mg (Meropenem) USP" on outer carton, whereas label on immediate container, i.e., vial of these 07 units bear Merem lgm (Meropenem) USP".* ***The inner and outer labels of these 07 units are different in label claim strength."***
c. *That after the receipt of test report from Drug inspector, we submitted our reply vide letter no. REF/GP/065/DTLI21 dated 27-9-202, wherein* ***we guaranteed you that such type human error will be strictly prohibited in future****. However, the* ***product meets the Pharmacopoeial limit (90 - 120.0%) of active ingredient along with other parameters****, hence inference is that the drug is effective and safe for use on patients.*
d. *That in response to your show cause notice no. PQCB/R-198/2021 dated 08-11-2021. We submitted our reply vide letter no. REF/GP/073/DTL/21 dated 20-11-202.*
e. *That in response to personnel hearing notice no. POCB/R-198/2021 dated 22-11-202 1; we attended the 235th meeting of the Board held on 30-11-2021.*
f. *That PQCB, Punjab* ***granted permission for prosecution*** *against us vide order no. PQCB/R198/2021 dated 30-11-2021 in its 235th mecting held on 30-11-2021 received in Global Pharmaceuticals on 10-01-2022.*

We intend to submit;

g. *That the drug sample had been declared as Misbranded* ***due to mixing of outer carton of different strength, whereas the label on immediate container/vial was of correct strength in bold letter****. This happened due to* ***un-intended human error at the part of printer****. The gravity of mixing is up to 20-30 units in 3538 packs.*
h. *That whole batch of said drug sample was supplied to Punjab Institute of Neurosciences, Lahore and* ***not a single unit of the injection had been used by the institution****. All supplied injections are lying in the main Medicine store of Punjab Institute of Neurosciences, Lahore.*
a. *That* ***not a single unit of said drug has been supplied in the market****.*
j. *That the drug in question is of* ***standard quality with regards to assay, sterility test****, and other physical parameters and thus there is no risk on the use of drug for patients.*
k. *That the offence of* ***Misbrand is a rectifiable offence*** *as per section 18(t) of the Drug Act 1976 and it is a generalized policy of the DRAP/Board that the Misbranded offences, being rectifiable, are not prosecuted.*
ax. *That the* ***said test report (issued after 63 days) is time barred****, illegal and in violation of section 22(2) of the Drug Act 1976 and rules framed there under. Hence the same is not admissible evidence in the eye of Law.*

Reliance 1984 Pcr LJ 1580

1985 Pcr LJ 281

PRAY

That in the light of above submissions, you are ***requested to review the prosecution dated 30-11-2021 and set aside the case*** *in the best interest of justice, by exercising the powers orders of review under the Drug Act 1976 and rules frame there under.*

It is further prayed that ***the concerned Drug Inspector may very kindly be directed not to put up the case before the concerned Drug Court*** *till the final disposal of the review petition in hand.*

11. Personal Hearing Notice issued to accused dated 26-04-2023.

Previous Proceedings and Decision by The Board:

12. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **260th meeting** held on **04-05-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Mr. Hassan Saeed, Secretary DQCB, District Lahore was present along with the original case record. No one among the nominated accused persons of M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan was present.

13. Secretary Provincial Quality Control Board apprised the Board that firm has submitted written request for adjournment vide letter no. Ref/GP/050/DTL/23 dated 28-04-2023 stating that the firm's counsel is not available being busy in Supreme Court of Pakistan, Islamabad. The Board, after due deliberation and detailed discussion, unanimously decided to **adjourn the case** of **M/s Global Pharmaceuticals, (Pvt.) Ltd.,** Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan and to provide another yet final opportunity of personal hearing in the best interest of justice

14. Personal Hearing Notice issued to accused dated 26-04-2023.

15. Case is placed before the Board for decision.

Summary:

Manufacturing Date: May-2021

Expiry Date: Jan-2024

Sampling Date (Form 4): 23-06-2021

Sent to DTL (Form 6): 24-06-2021

Date of receipt in DTL: 25-06-2021

DTL Report Date (Form 7): 26-08-2021

Time Extension: Granted in 18th Committee Meeting dated 13-09-2021

1ST DI Communication with firm on dated: 16-09-2021

Retesting Request of Firm: NA

Investigation Report Dated: 15-10-2021

Previous Decision of Case: Prosecuted in 235th meeting dated 30-11-2021

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Issue # 4

COURT CASE

M/s Amson Vaccines and Pharma (Pvt) Ltd. Versus Province Quality Control Board and Others.

Tehsil and District Sahiwal

PQCB/R-40/2020

Tehsil and District Sahiwal

Substandard (Dissolution Test)

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 Industrial Triangle Kahuta Road, Islamabad, Pakistan** through its managing director Syed Saleem Asghar 2. Syed Saleem Asghar Managing Director 3. Sajjad Hussain Production Incharge/Warrantor 4. Muhammad Mudassir Quality Control Incharge Of **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 Industrial Triangle Kahuta Road, Islamabad, Pakistan.**

The firm filed **Writ Petition** No. 10009 of 2022 and Lahore High Court, Lahore Orders dated 09-02-2023, received in the office of PQCB on 21-02-2023.

ORDER SHEET

IN THE LAHORE HIGH COURT, LAHORE.

JUDICIAL DEPARTMENT W.P. No. 10009 of 2022

M/s Amson Vaccines and Pharma (Pvt) Ltd. Versus Province Quality Control Board and Others.

09.02.2023

Presence same as in W.P. No.54146 of 2021

For the reason recorded in my detailed order of even date passed in connected petition W.P.No. 54146 of 2021, the instant petition is ***allowed.***

BRIEF FACTS OF THE CASE

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

i. She, on 09-11-2019, inspected the business premises of M/s Rashid Pharmacy, 30-W Scheme No. 2, Farid Town, Tehsil & District Sahiwal and took sample of four different types of drugs on Form-4 for the purpose of test/analysis.

ii. One out of fore drug samples, after test/ analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

<table>
<tr><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>Film- coated tablet, Famotid [Famotidine 20mg]</td><td>035</td><td>M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad.</td><td>TRA No. 01-2500466 2/DTL dated:14-01-2020</td><td>
Analysis with specifications applied:
USP 2018
<u>Description:</u>
Yellow colour, round, biconvex tablet plain on both side packed in a blister pack of 10 tablets.
Assay (Famotidine):
Complies
Dissolution Test:
Does not comply with the specifications of USP as detailed below: Tolerance limit: Not less than 75% (Q) of the labelled amount of Famotidine
<table>
<tr><th>Stage</th><th>No. tested</th><th colspan="6">Acceptance criteria</th><th>Average</th><th>Remarks</th></tr>
<tr><td rowspan="2">S1</td><td rowspan="2">06</td><td colspan="6">Each unit is not less than Q +5% and not more than 2 units are less than Q -15% and no unit is less than Q-25%</td><td>S1</td><td rowspan="2">Does not comply with the specifications</td></tr>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit 5</td><td>Unit 6</td><td></td></tr>
<tr><td>Stage 1</td><td>famotidine</td><td>58.69%</td><td>53.17%</td><td>62.76%</td><td>44.74%</td><td>43.73%</td><td>61.16%</td><td>54.04%</td><td></td></tr>
</table>
Note: Four units (Unit No. 01, 02, 04 & 05) are less than Q-15% moreover among those four units two units (Unit no. 04 & 05) are less than Q-25%.
Result: The sample is declared Substandard, on the basis of dissolution test.
</td></tr>
</table>

iii. M/s Rashid Pharmacy, 30-W Scheme No. 2, Farid Town, Tehsil & District Sahiwal provided invoice/ warranty no. 67879/1 dated 29-04-2019 issued by M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent to M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad.

v. A copy of test report was sent to M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad 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 Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of:

   a. **Manufacturing/ Stocking/ Selling of Substandard Drug**

   b. **Issuance of false warranty.**

3. Show-cause notice(s) issued to accused person on dated 23.06.2020

REPLY OF THE FIRM TO THE DRUG INSPECTOR:

4. M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad submitted written reply stating that:

Reference to your letter No. PQCB/R-40/2020 dated 23rd June 2020; received at AMSON on dated 29-6-2020 through UMS-Pakistan Post. The letter states that our product Famotid Tablets (Famotidine 20mg) Batch No 035 is found substandard on the basis of Dissolution Test by Drug Testing Laboratory, Bahawalpur.

In this regard following documents to justify our product quality standard on technical ground:

1. Test report of other Drug Testing Laboratories (attached)
2. Test report done at Amson with chromatograms (attached)
3. Valid Drug Manufacturing and valid drug product registration certificates (attached)
4. Appointment letters of technical staff, copy of job certificate and national identity card (attached)
5. Respected sir, on the basis of above-mentioned technical facts it can be confirmed that our product Famotid Tablets (Famotidine 20mg) Batch No. 035 is declared standard quality by DTL Faisalabad as well as internal testing results.
6. So, we humbly request you to withdraw the show-cause notice against us or send samples of our product to Appellate Laboratory for retest as per procedure.

4. Personal hearing notice served earlier for 229th Meeting on dated 25-01-2021.

Case was placed before the Board for Decision.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board (PQCB), Punjab under section 11 of the Drugs Act 1976 in its **229th meeting held on 02-02-2021.** Ms. Atia Nawaz Secretary DQCB District Sahiwal and Mr. M. Irfan Munir Drug Inspector Tehsil & District Sahiwal were present. Among nominated accused persons Muhammad Muddassir (Quality Control Incharge) of M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad was present along-with representative from the firm Tahir Hameed Gill. They submitted their grievance on the report of Government Analyst Drug Testing Laboratory, Bahawalpur. They stated that the Specifications supposed to be applied was of U.S.P. 19, whereas, Government Analyst has applied the specifications of U.S.P 2018. The Columns and flow rate are different in both U.S.P.'s. They also requested to send their sample to Appellate Laboratory, National Institute of Health Sciences, Islamabad for retest/ analysis.

6. The Board after keen perusal of the Report of Government Analyst, Drug Testing Laboratory, Bahawalpur, reply of the firm submitted in response to show-cause notice issued to them and the arguments of the accused persons observed that the Product Film-coated tablet Famotidine was declared Substandard from Drug Testing Laboratory, Bahawalpur on the basis of dissolution test. Four among the six tested units were out of the specified range. Dissolution testing measures the extent and rate of solution formation from a dosage form. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. The product failed to comply the dissolution test would result in lesser bioavailable drug and would not be able to provide optimal therapeutic response. Furthermore, the Board also observed that the request of re-testing of the drug sample was not made within the stipulated time. The firm requested for retesting of the drug sample in response to the show- cause notice issued to them. Hence, the report of Government Analyst Drug Testing Laboratory, Bahawalpur is considered as the conclusive evidence of the facts stated therein.

7. keeping in view the facts of the case, the Board after due deliberation and detailed discussion unanimously decided to grant **permission for prosecution** against the following accused persons in the Drug Court:

   1. **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad**

      through its Managing Director Syed Saleem Asghar

   2. Syed Saleem Asghar — Managing Director
   3. Sajjad Hussain — Production Incharge/ W arrantor
   4. Muhammad Muddassir — Quality Control Incharge

Of **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad.**

For the offences of:

a. **Manufacturing/ Stocking/ Selling of Substandard Drug**

b. **Issuance of false warranty.**

REVIEW PETITION

The firm filed review petition in PQCB against the prosecution orders of PQCB dated 02.02.2021s, received in the office of PQCB on 03.05.2021, stated that;

Grounds

1. That the Honorable Board in the impugned order dated,2/2/21, failed to consider the additional grounds of the Petitioner.
2. That the report of the Govt analyst is time barred which is not considered by the Honorable Board as

   the impugned order is silent in respect of any extension taken by Govt analyst from the board hence the strong presumption is in favor of Petitioner Company that the Govt analyst has not taken any permission for extension from the Board, hence, it is error floating on the record, confirming that the report of the Govt analyst is time barred, thus on this solely ground proceedings are to be dropped or quashed.
3. That Honorable Board did not consider the ground that the Drug Testing Laboratory Faisalabad Declared the same batch of medicine standard quality, which rise the question on the credibility of Drug Testing Laboratory Bahawalpur and investigation conducted by that Drug Inspector.
4. That the Honorable Board failed to consider establish principle of law, when law required a thing to be done in a particular manner then it should be done in such particular manner, if it is not followed then the proceedings become invalid and illegal.
5. That the Honorable Board on the one hand turned down the request for retesting on the ground of time barred and other hand did not turn down the time barred Govt analyst report, hence committed the error floating on the record.
6. That Honorable Board even discussed one of the contentions raised by the Petitioner in its Additional grounds while the other grounds were not even considered which is also error floating on the record.
7. That the Govt Analyst Report was not of with protocol hence liable to be rejected.
8. That even the Govt Analyst Report is manifested that there is no extension is sought by the Govt Analyst for the extension of time hence it is liable to be rejected.
9. That the dissolution test conducted by the Govt Analyst is not required by the law. Hence not acceptable and liable to be rejected.

Under the submission above it is requested that by accepting the instant review petition case against company may please be dropped.

08. Personal Hearing notice(s) issued to accused person(s) dated 27-04-2023.

PREVIOUS PROCEEEDINGS & DECISION BY THE BOARD:

09. Case was considered by the Provincial Quality Control Board in compliance to the Orders of Honourable Lahore High Court, Lahore dated 09.02.2023 in writ petition no. 10009/2022, Under Section 11 of the Drug Act 1976 in its **260th meeting held on 04-05-2023** under the chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab/ Chairperson, Provincial Quality Control Board, Punjab. Mr. Ahmad Awais Secretary DQCB District Sahiwal attended the meeting online via Zoom Link. No one appeared before the Board on behalf of M/s Amson Vaccines and Pharma (Pvt) Ltd. However, counsel for the firm submitted written request for adjournment, received in the office of the Secretary, Provincial Quality Control Board, Punjab on dated 02-05-2023.

10. The Board after due deliberation and discussion unanimously accepted the firm's request for adjournment and decided to **adjourn** the case till next meeting in best interest of justice. The board further decided to provide another but final opportunity of personal hearing to the accused persons.

Summary:

- **Manufacturing Date: 01.2019**
- **Expiry Date: 12.2021**
- **Sampling Date (Form 4): 09.11.2019**
- **Sent to DTL (Form 6): 11.11.2019**
- **Date of receipt in DTL: 13.11.2019**
- **DTL Report Date (Form 7): 14.01.2020**
- **Time Extension: Granted in 218th Meeting**
- **1ST DI Communication with firm on dated: 07.02.2020**
- **Date of Retesting Request of Firm: N/A**
- **Fate of Retesting: N/A**
- **Investigation Report Dated: 10.06.2020**
- **Prosecution granted against firm: 229st meeting dated 02-02-2021**
- **Review Petition submitted by firm: Dated 03.05.2021.**
- **Status of Review Petition: Pending**

11. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023.

Case is placed before the board for decision

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Issue # 5

PQCB/ R-600/2020

Benazir Bhutto Hospital, Rawalpindi

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan** through its Chief Executive Officer, M. Shams Mehmood Sadana. 2. M.Shams Mehmood Sadana Chief Executive Officer 3. Sajjad Hussain Qureshi Production Manager 4. Zakir Hussain Quality Control Manager/Warrantor 5. Muhammad Adnan Khan Quality Assurance Manager Of M/s Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Benazir Bhutto Hospital, Rawalpindi, reported that: -

i. He, on 04-12-2019 inspected the premises of Main Medical Store, Benazir Bhutto Hospital Rawalpindi and took drug samples of the subject drug on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Rawalpindi.

ii. The following 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	DTL Report	DTL Test Report Result
Syrup Matilda-D 120ml [Calcium Phosphate (tribasic) 210mg/5ml; Vitamin-D_3 350 IU/5ml] **Mfg.date** 11-2019 **Exp date** 10-2021 **Reg No**. 044789	L19L060	M/s Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan	01-67000478/DTL dated: 11.02.2020	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION** Pink coloured, liquid preparation, having medicinal odour, filled in labelled multi dose amber coloured plastic bottle, sealed with white coloured plastic screw cap, further packed in labelled unit carton. The sample is not a stable preparation, as after shaking it immediately separates into two layers. **(DOES NOT COMPLY)** **pH (MS) :** Determined: 6.696 Limit: 4.5-7.0 (MS) **Assay (MS):** Calcium Phosphate (Tribasic): Stated: 210mg/5ml Determined: 224.517mg/5ml Percentage: 106.91% Limit: 90-110% Vitamin-D_3: Stated: 350 IU/5ml Determined: 390.4256 IU/5ml Percentage: 111.55% Limit: 90-120% **Result:** The above sample is **Substandard** on the basis of Physical Characteristics observed.

iii. Store Keeper, Main Medical Store, Benazir Bhutto Hospital Rawalpindi, provided Warranty bearing No. BBH-1002 dated 04-12-2019 issued by M/s Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore as proof of their purchase.

iv. Warrantor Portion of drug sample was sent to M/s Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan

v. 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 and they were directed to provide requisite information in this regard. In response, the firm challenged the report and requested to re-test the above mentioned drug sample from Appellate Laboratory NIH, Islamabad.

vi. 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 Result
Matilda-D Syrup120ml	L19L060	M/s Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan	0237-P/2021 dated: 20.09.2021	**DETAILS OF RESULT OF TEST AND AMALYSIS** (With Protocols of test applied): MS **PHYSICAL DESCRIPTION** Off white suspension contained in amber coloured labelled plastic bottle **(DOES NOT COMPLY with manufacturer specification which states that pink coloured suspension contained in an amber coloured labelled plastic bottle. Moreover, it also does not comply with manufacturer specification which states that Matilda-D is a suspension whereas on immediate pack as well as on the outer carton of Matilda-D is printed as syrup)** **IDENTIFICATION:** Tri calcium Phosphate identified. **pH:** Determined: 7.0 Limit: 4.5-7.0 Complies with manufacturer specification. **VOLUME**: Determined: 120ml Limit:120ml Complies with manufacturer specification. **ASSAY:** Calcium Phosphate (Tribasic): Stated: 210mg/5ml Determined: 237.38mg/5ml Percentage: 113.04% Limit: 90-120% Complies with manufacturer specification. **Result:** The above sample is of **Substandard** quality on the basis of tests performed..

vii. Copies of NIH test reports of drug samples were sent to M/S Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan with directions to provide the requisite information and to explain their position in this regard.

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: -

i. **Manufacturing for Sale /Selling of Substandard drug**

ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s) dated 30.12.2021

Reply of the Firm to the Show Cause Notice:

Subject: Show cause Notice regarding Matilda-D syrup B# L19L060
Sir, Reference to your letter no. PQCB/R-600/2020 dated 30/12/2021 received on 11/1/2022 our product Matilda-D syrup has been registered by DRAP in 2007 as syrup registration no, 044789 dated 18/1/2007. Technically the active ingredient Calcium Tribasic phosphate is heavier than water for which the syrup separates in two layers after standing still for long time but upon vigorous shaking it becomes homogeneous syrup with complete specs.
As per registration letter product name is Matilda-D syrup as mentioned on label and unit carton which we use till 2019 for all commercial and government supplies of standard quality declaration.
After 2019 our product declared substandard on physical condition basis for which we apply for dosage form correction as oral suspension from oral syrup as per registration letter dated 22/6/21
PQCB vide letter # PQCB 10802/2020 dated 13/9/21 asked us to stop production until decision of DRAP.
Sir, as per DTL reports the active ingredient is up to standard, technical separation is due to nature of active ingredient Calcium tribasic phosphate so please we request you deal the case on compassionate grounds as we assure you the standard quality of product in future as well after DRAP approval decision receipt.

4. Personal Hearing notice(s) issued to accused person(s) dated 18.05.2023.

Case is placed before the Board for decision.

Summary:

Manufacturing Date: 11-2019

Expiry Date: 10-2021

Sampling Date: 04-12-2019

Sent to DTL (Form 6): 04-12-2019

Date of receipt in DTL: 05-12-2019

DTL Report Date: 11-02-2020

Time Extension: granted in 218-M

1ST DI Communication with firm on dated: 04-12-2019

Date of Retesting Request of Firm: -04-06-2020

Fate of Retesting Request: -Allowed in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 29-11-2021

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

PQCB/ R-601/2020

Benazir Bhutto Hospital, Rawalpindi

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan** through its Chief Executive Officer, M. Shams Mehmood Sadana. 2. M.Shams Mehmood Sadana Chief Executive Officer 3. Sajjad Hussain Qureshi Production Manager 4. Zakir Hussain Quality Control Manager/Warrantor 5. Muhammad Adnan Khan Quality Assurance Manager Of M/s Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Benazir Bhutto Hospital, Rawalpindi, reported that: -

i. He, on 04-12-2019 inspected the premises of Main Medical Store, Benazir Bhutto Hospital Rawalpindi and took drug samples of the subject drug on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Rawalpindi.

ii. The following 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	DTL Report	DTL Test Report Result
Syrup Matilda-D 120ml [Calcium Phosphate (tribasic) 210mg/5ml; Vitamin-D_3 350 IU/5ml] **Mfg.date** 11-2019 **Exp date** 10-2021 **Reg No**. 044789	L19L058	M/s Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan	01-67000477/DTL dated: 12.02.2020	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION** Pink coloured, liquid preparation, having medicinal odour, filled in labelled multi dose amber coloured plastic bottle, sealed with white coloured plastic screw cap, further packed in labelled unit carton. The sample is not a stable preparation, as after shaking it immediately separates into two layers. **(DOES NOT COMPLY)** **pH (MS) :** Determined: 6.581 Limit: 4.5-7.0 (MS) **Assay (MS):** Calcium Phosphate (Tribasic): Stated: 210mg/5ml Determined: 224.517mg/5ml Percentage: 106.91% Limit: 90-110% Vitamin-D_3: Stated: 350 IU/5ml Determined: 377.8313 IU/5ml Percentage: 107.95% Limit: 90-120% **Result:** The above sample is **Substandard** on the basis of Physical Characteristics observed.

iii. Store Keeper, Main Medical Store, Benazir Bhutto Hospital Rawalpindi, provided Warranty bearing No. BBH-1001 dated 04-12-2019 issued by M/s Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore as proof of their purchase.

iv. Warrantor Portion of drug sample was sent to M/s Synchro pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore-Pakistan

v. 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 and they were directed to provide requisite information in this regard. In response, the firm challenged the report and requested to re-test the above mentioned drug sample from Appellate Laboratory NIH, Islamabad which was turned down by the committee of provincial quality control board in its 18th meeting held on 13-09-2021.

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: -

i. **Manufacturing for Sale /Selling of Substandard drug**

ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s) dated 30.12.2021

Reply of the Firm to the Show Cause Notice:

Subject: Show cause Notice regarding Matilda-D syrup B# L19L058
Sir, Reference to your letter no. PQCB/R-601/2020 dated 30/12/2021 received on 11/1/2022 our product Matilda-D syrup has been registered by DRAP in 2007 as syrup registration no, 044789 dated 18/1/2007. Technically the active ingredient Calcium Tribasic phosphate is heavier than water for which the syrup separates in two layers after standing still for long time but upon vigorous shaking it becomes homogeneous syrup with complete specs.
As per registration letter product name is Matilda-D syrup as mentioned on label and unit carton which we use till 2019 for all commercial and government supplies of standard quality declaration.
After 2019 our product declared substandard on physical condition basis for which we apply for dosage form correction as oral suspension from oral syrup as per registration letter dated 22/6/21
PQCB vide letter # PQCB 10802/2020 dated 13/9/21 asked us to stop production until decision of DRAP.
Sir, as per DTL reports the active ingredient is up to standard, technical separation is due to nature of active ingredient Calcium tribasic phosphate so please we request you deal the case on compassionate grounds as we assure you the standard quality of product in future as well after DRAP approval decision receipt.

4. Personal Hearing notice(s) issued to accused person(s) dated 18.05.2023.

Case is placed before the Board for decision.

Summary:

Manufacturing Date: 11-2019

Expiry Date: 10-2021

Sampling Date: 04-12-2019

Sent to DTL (Form 6): 04-12-2019

Date of receipt in DTL: 05-12-2019

DTL Report Date: 11-02-2020

Time Extension: granted in 218-M

1ST DI Communication with firm on dated: 04-12-2019

Date of Retesting Request of Firm: -25-03-2020

Fate of Retesting Request: -Turned down in 18th Committee Meeting dated 13-09-2020

Investigation Report Dated: 29-11-2021

CURRENT PROCEEDINGS AND DECISION OF THE BOARD: