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

258 PQCB Meeting cases

Date: 05-04-2023

Time: 10:30 AM

Venue

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

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ITEM No. 1
COURT MATTERS

Case No. 1

COURT CASE

M/s Renacon Pharma Limited Versus Province of Punjab, etc.

DISTRICT LAHORE

PQCB/R-136/2022

Jinnah Hospital, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Renacon Pharma Ltd., 18 Km, Ferozepur Road, Lahore-Pakistan** through its Chief Executive Officer Dr. Salman Shakoh 2. Dr. Salman Shakoh — Chief Executive Officer 3. Fareed Ahmad — Quality Control Manager 4. Salman Idrees — Production Manager/ Warrantor Of **M/s Renacon Pharma Ltd., 18 Km, Ferozepur Road, Lahore-Pakistan**.

The firm filed **Writ Petition** No. 11419 of 2023 and Lahore High Court, Lahore Orders dated 20-02-2023, received in the office of PQCB on 24-02-2023.

ORDER SHEET

IN THE LAHORE HIGH COURT, LAHORE.

JUDICIAL DEPARTMENT

W.P. No. 11419 of 2023

M/s Renacon PHARMA Limited Versus Province of Punjab, etc.

20.02.2023

The Petitioner/M/s. Renacon Pharma Limited (the"Petitioner") through this writ Petition under Article 199 of the Constitution of Islamic Republic of Pakistan, 1973 (the"Constitution") has impugned the order dated 05.07.2022 and the impugned prosecution order dated 13.12.2022, passed by the Respondent No.2/Provincial Quality Control Board and also sought direction to the Respondent No.2 to adjudicate upon its pending review Petitions dated 03.10.2022 and 10.02.2023.

2. Dr. Imran Mehmood Chaudhry, Advocate submitted that the Petitioner filed review Petitions before the Respondent No.2/Provincial Quality Control Board, which are still pending and have not been decided till date. Added that now the Respondents are going to take coercive measures against the Petitioner under the garb of aforesaid impugned orders, due to which fundamental rights of trade and business guaranteed under Article 18 of the Constitution have been infringed.

3. Learned Law Officer at the outset objected to the maintainability of this Petition being premature.

4. In response thereof, learned counsel for the Petitioner submitted that under the Doctrine of Ripeness, the matter before the competent Authority has not been ripened but the Respondents are bent upon to take measures against the Petitioner under the garb of impugned orders. He added this Court has already rendered a detailed judgment reported in *"SHAHEEN MERCHANT Versus FEDERATION OF PAKISTAN etc"* **(2021 PTD 2126 Lahore)** in which this Court has developed the doctrine of time bound legislation with its mandate to decide the matter as per time frame given under a statute while discussing the anatomy of authority/regulator, jurisprudential anthology regarding the duty of the State to provide expeditious justice under Article 37-D of the "Constitution". He added that though the Respondent No.4/ Provincial Quality Control Board has been established under Section 11 of the Drugs Act, 1976 (the "Act") but no specific time frame to decide the matter by the Board has been provided in the Act. He further relied on the recent judgment of this Court cited as *"Pakistan Tehreek-e-Insaaf through its General Secretary Asad Umar v. Governor of Punjab and another"* **(2023 LHC 395)** wherein it has been held that under Article 37-D of the "Constitution" the State is duty bound to give the expeditious justice.

5. He further argued that Article 4 of the Constitution clearly states that it is his inalienable right to be treated in accordance with law by the Respondents and no action detrimental to the reputation, life, and liberty shall be taken except as per law and in the case in hand the relevant law is tax rules and regulations. He maintains that Article 10-A of the Constitution provides right of fair trial and due process for determination of rights and obligations therefore, during the pendency of matter before the Respondent, if any action is taken under the garb of impugned order, the Petitioner will suffer an irreparable loss and injury.

6. Heard.

7. It is noted with great dismay that though the Respondent No.4/Provincial Quality Control Board has been established under Section 11 of the Drugs Act, 1976 (the "Act") but no specific time frame to decide the matter by the Board has been provided in the Act, thus, increasing miseries of the persons concerned/litigants and offending the mandate of Article 37(d) of the Constitution. Therefore, in view of the law laid down in aforesaid judgments, the Respondent No.4 is directed to decide the pending review Petitions of the Petitioner within a period of one (01) month positively in accordance with law. Compliance report be submitted to the Deputy Registrar (Judicial) of this Court. However, keeping in view the law laid down by this Court in the judgments reported as *Shell Pakistan Limited versus Government of Punjab etc*. **(2020 PTD 1607)** and *Shaheen Merchant* (mentioned supra) as a stopgap measure, till the decision of aforesaid review Petitions by the Respondent No.4, no coercive measure shall be taken against the Petitioner.

BRIEF FACTS OF THE CASE

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

i. She on, on 29-12-2021, inspected the Main Medicine Store A of Jinnah Hospital, Lahore and took samples of seven different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Lahore vide memorandum no. 0000113992 dated 29-12-2021.

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

iii. The drug inspector directed Store Keeper of Main Medicine Store A of Jinnah Hospital, Lahore not to dispose of stock in his possession vide Form 3 dated 14-03-2022.

iv. Store Keeper of Main Medicine Store A of Jinnah Hospital, Lahore submitted warranty no. 203524 dated 08-12-2021 issued by M/s Renacon Pharma Ltd., 18 Km, Ferozepur Road, Lahore-Pakistan as a proof of its purchase of the said drug.

v. Warrantor portion of the drug sample and a copy of test/analysis report were sent to M/s Renacon Pharma Ltd., 18 Km, Ferozepur Road, Lahore-Pakistan and they were asked to provide the requisite information in this regard. In response, the firm requested for retesting of the drug sample and the subject request for retesting of the drug sample was placed before the Provincial Quality Control Board (PQCB) in its 246th meeting held on 05-07-2022 where the board unanimously decided to Turn Down request for re-testing of the subject drug sample.

<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>Renacarb (RBR) Haemodialysis Concentrate (Part A (Solution 4.0L For Bicarbonate Haemodialysis), Part B (Sodium Bicarbonate) (36.83X) Large Volume Solutions
Mfg.date:
Dec-2021
Exp. date:
Dec-2023
Regn No.
069481</td>
<td>213568</td>
<td>M/s Renacon Pharma Ltd., 18 Km, Ferozepur Road, Lahore-Pakistan</td>
<td>TRA No. 01-171000341/DTL
Dated:-25-02-2022</td>
<td>
<u>Analysis with specifications applied:</u>
Ph. Eur. 10.0
<u>Physical Description:</u>
Colorless liquid filled in an opaque white plastic bottle sealed with a red colored plastic screw cap, attached with a green colored plastic bag having white powder.
<u>Assay of Chlorides:</u>
<table>
<tr><td>Stated Potency</td><td>108.0 mmol/L</td></tr>
<tr><td>Determined Potency</td><td>105.81 mmol/L</td></tr>
<tr><td>Percentage</td><td>97.97%</td></tr>
<tr><td>Limit</td><td>95-105% of Label claim</td></tr>
</table>
<u>Assay of Anhydrous glucose:</u>
<table>
<tr><td>Stated Potency</td><td>5.50 mmol/L</td></tr>
<tr><td>Determined Potency</td><td>5.665 mmol/L</td></tr>
<tr><td>Percentage</td><td>103.00%</td></tr>
<tr><td>Limit</td><td>95-105% of Label claim</td></tr>
</table>
<u>Assay of Acetic Acid:</u>
<table>
<tr><td>Stated Potency</td><td>5.0 mmol/L</td></tr>
<tr><td>Determined Potency</td><td>4.90 mmol/L</td></tr>
<tr><td>Percentage</td><td>98.06%</td></tr>
<tr><td>Limit</td><td>95-105% of Label claim</td></tr>
</table>
<u>Assay of Sodium Bicarbonate:</u>
<table>
<tr><td>Percentage</td><td>101.39%</td></tr>
<tr><td>Limit</td><td>95-105%</td></tr>
</table>
<u>Assay of Potassium:</u>
<table>
<tr><td>Stated Potency</td><td>2.0 mmol/L</td></tr>
<tr><td>Determined Potency</td><td>1.92 mmol/L</td></tr>
<tr><td>Percentage</td><td>96.02%</td></tr>
<tr><td>Limit</td><td>95-105% of Label claim</td></tr>
</table>
<u>Assay of Sodium:</u>
<table>
<tr><td>Stated Potency</td><td>102.0 mmol/L</td></tr>
<tr><td>Determined Potency</td><td>95.03 mmol/L</td></tr>
<tr><td>Percentage</td><td>93.17%</td></tr>
<tr><td>Limit</td><td>97.5%-102.5% of Label claim</td></tr>
</table>
(DOES NOT COMPLY)
<u>Result:</u>
The above sample is <u>SUB-STANDARD</u>, on the basis of ASSAY test of Sodium performed as per European Pharmacopoeia.
</td>
</tr>
</table>

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 issued to accused person(s) dated 15-11-2022.

Reply of the firm to show cause notice dated 21-11-2022:

1. **We have already replaced the product in the hospital while the questionable product was never used anywhere.**
2. **Stoichiometric calculation of 'Cl' as per DTL result in a batch do not match with 'Cl' result given by DTL-a difference of 3-5 mmol/l** which is not scientifically possible also indicates that low 'Na' by DTL was an erroneous result.

TRA No. 01-171000341/DTL Batch: 213568

Assay performed by DTL, Lahore	**DTL reported mmol/L**	**Results**
Chloride, Acetate, Potassium, Bicarbonate and Dextrose		**Complies**
Sodium	**95.03%**	**Not Complies**
Chloride	**105.81%**	**Complies**

In response to the test analysis report, our technical experts who includes chemists and Pharmacists trained at level of M.Phil and Ph.D., submitted their view point to the management which is as under:

The technical staff explained that Stoichiometrically the concentration of one ion like Sodium (Na) ion is always calculated in conjunction with its attached ion. **The DTL, Lahore has detected less ''Na" ion than that of the Chloride ion content in the dialysis concentrate**. The result revealed to us shows a difference of 3-5 mmol/Liter in the calculation of **'Cl' ion content. This is scientifically not possible.**

The following ionic situation was explained by the QC and QA Incharge:

Total Chloride content in the dialysis concentrate is	**As per above DTL report results**
Chlorides from Na, K = **96.95** Chlorides from Ca = **4.0** Total Chlorides = **100.95**	Total Chlorides = **105.81%**

3. The technical experts are of the view that, may be the 'Na'' ion was not properly extracted or the equipment or the method used by the operator was erroneous and inaccurate. It is stated that the main purpose of the PQCB, Lahore to provide standard drug to the public at large could be achieved, if the sample could have to be retested by an independent laboratory, instead of making decision on the basis of inadvertently wrong test report.
4. **During a recent PSI inspection of our company, an official of DTL himself discussed in length with our technical staff that they are analyzing 'Na ion' on Atomic Absorption spectrophotometer.**

Our Staff argued that this is not recommended by BP/EP, because it is most likely to give falsely low results for 'Na ion' which can be proved, rather 'Emission spectroscopy' be used such as 'Flame Emission Spectroscopy' which contains a monochromator. If 'Na ion' is analyzed by Atomic Absorption Spectrophotometer, it give results in PPM and 'Na ion' level in Hemodialysis concentrate is 82,915 ppm. This is also be done after the sample is diluted to 10,000 times then reverse calculation gives wrong result owing to Bear Lambart's law.

5. **As informed by an official of DTL during inspection of our facility that they performed 'Na' level on Atomic Absorption spectrophotometer** which is not recommended in BP/EP because it is most likely to give falsely low results for 'Na' which can be proved, rather 'Emisision Spectroscopy' be used such as 'Flame Emission Spectroscopy' which contains a monochromator. Because in case of Atomic Absorption Spectrophotometer it checks in PPM and Na level in Hemodialysis concentrate is 82,915 ppm and after sample is diluted to 10,000 times then reverse calculation gives wrong result owing to Beer Lambart's law.
6. **Hemodialysis Concentrate monograph is NOT mentioned in USP as contrary to narrated in your letter.**
7. **HPLC is not advised anywhere in case of Hemodialysis concentrate assay in BP/EP nor it is used by use suggested in your letter.**
8. **We did not used UV Spectroscopy to test Na rather** we used 'Flame Emission Spectroscopy' through Flame photometer. But it is mentioned in our letter. Moreover it is not recommended.
9. **Flame Photometer is a type of 'Atomic Emission Spectroscopy'**, a general term with several types. In Eur.Ph. 10'Atomic Emission Spectroscopy' is recommended for checking Na level which indicated 'atomization n flame' with apparatus having a 'monochromater' which is a part of Flame photometer (Annex 2).
10. **In 'Vogels' Chemistry' book which is considered as a bible of chemistry 'Flame Photometer' is described as a type of 'Flame Emission Spectroscopy' (Annex 3).**
11. Lastly, actually it was also mentioned in your previous letter (PQCB/P-200-2-2022) that Mr. Tariq Mahmood, representative Renacon Pharma Ltd., appeared before PQCB and **in point 11, it was mentioned that the firm failed to appear before the board while Dr. Salman Shakoh, MD., Renacon Pharma, and Dr. Mahmood Ahmed (Ph.d., Chemistry) appeared before the Board** in contradiction to the stance in PQCB letter (PQCB/P-200-2/2022).
12. It is not out of place to mention that all the inorganic salts and Active Pharmaceutical ingredients (API) were mostly imported and lot of hard money of Government of Pakistan have been incurred on its import. And millions of local and foreign money was used in research for the development of its formulations. That batch should not be wasted on the basis of erroneous reporting.
13. In view of above it is humbly submitted that the Sodium assay performed by DTL is scientifically incorrect and **samples should have been sent to appellate laboratory** for retesting.
14. In view of above technical facts on record, it is requested to **kindly withdraw the show cause notice**.

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

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 **254th meeting** held on **13-12-2022** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Hassan Saeed, Secretary DQCB, District Lahore and Miss Sumaira Maqbool, Drug Inspector, Jinnah Hospital, Lahore were present along with the original case record. Among the nominated accused persons, Dr. Salman Shakoh, Chief Executive Officer of **M/s Renacon Pharma Ltd., 18 Km, Ferozepur Road, Lahore-Pakistan** appeared before the Board along with representatives of the firm, Mehmood Ahmed and Tariq Mehmood and submitted that sodium content have been tested by the Government Analyst, Drug Testing Laboratory (DTL), Lahore on Atomic Absorption Spectrophotometer rather than Atomic Emission Spectrophotometer, due to which low sodium content has been observed in the test/analysis report of DTL, Lahore.

6. The Government Analyst, DTL, Lahore appraised the Board that the tests performed are in accordance with the testing protocols provided in European Pharmacopoeia pertaining to the subject drug sample and the technique of Atomic Emission Spectrophotometry was applied for testing which is a valid and reliable technique to conduct analysis of the subject drug sample.

7. The Board observed that Government Analyst has provided all relevant raw data to ascertain validity of the test performed and comply all requirements of testing protocol as described in the monograph of European Pharmacopoeia specifications, as per label claim. The Board was of considered opinion that subject drug sample was declared Substandard on the basis of assay of the Sodium which was determined to be 93.17% while the permissible limit was 97.5%-102.5% of Label claim. An imbalance in sodium content of haemodialysis concentrate can lead to intradialytic symptoms such as muscle cramps, headache, nausea, fatigue and may also lead to hypotensive episodes among the patients.

8. 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 who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under:

1. **M/s Renacon Pharma Ltd., 18 Km, Ferozepur Road, Lahore-Pakistan** through its Chief Executive Officer, Dr. Salman Shakoh
2. Dr. Salman Shakoh Chief Executive Officer
3. Fareed Ahmad Quality Control Manager
4. Salman Idrees Production Manager/ Warrantor

Of **M/s Renacon Pharma Ltd., 18 Km, Ferozepur Road, Lahore-Pakistan**

For the offences of:

i. **Manufacture for sale /sale of Substandard drug**
ii. **Issuance of false warranty**

9. The Board further directed the concerned Provincial Inspector of Drugs to launch the complaint in the concerned Honourable Drug Court.

REVIEW PETITION

The firm filed review petition No. 1002/2023 against the prosecution orders of PQCB dated 10-02-2023, received in the office of PQCB on 13-02-2023, stated that;

Grounds

A. That the order passed by this Honourable Board is not only against the principles of natural justice but also against the law and the constitution of Pakistan thus is liable to be set aside.
B. That the learned Board failed to scrutinize the lacunas prevailing in the report of government analyst DTL Lahore which were duly pointed out by the petitioner vide its letters dated 03-10-2022 and 21-11-2022 and also agitated by the petitioner before the board during personal hearing as follows:
i. That the product sampled Renacarb Haemodialysis Concentrate Solution is a **"non drug"** item i.e. medical device as per its registration issued by the competent authority.
Copy of registration letter of the product sampled is attached herewith as ***Annexure K***.
The government analyst of DTL Lahore was not authorized to analyze the sample Renacarb Haemodialysis Concentrate Solution being medical device. Since as per Medical Device Rules 2017, only those laboratories can test and analyze medical device which are notified by DRAP in this regard. Whereas none laboratory including
DTL Lahore has ever been notified by DRAP for testing the product sampled. Thus the testing of the product sampled by DTL Lahore being CORAM NON JUDICE is without lawful authority and Jurisdiction.
ii. That it is also imperative to discuss here that declaration of the sampled Medical Device as substandard by Government Analyst DTL Lahore on form-7 is also illegal as form-7 is meant ONLY for "DRUGS" as per Rule 11 read with form-7 of Punjab Drug Rules 2007.
iii. That the learned Board also failed to scrutinize the case on technical aspects. It is imperative to mention here that the assay content of Active Pharmaceutical Ingredients i.e. Sodium, Potassium, Magnesium, Calcium and Chloride etc. of the product sampled is determined on molarity basis i.e. in mmol/L. Chloride content (Cl-) determined by DTL Lahore was 97.97%. i.e. 105.81 mmol/L. While Chloride (Cl-) content in the product comes from Sodium Choride (NaCl), Potassium Choride (KCI), Magnesium
Chloride ($MgCl_2$) and Calcium Chloride ($CaCl_2$) API of the product sampled.
If we do stoichiometric calculation of chloride (Cl-) content from its sources in the product sampled, we get following results:
Potassium Choride (KCI):
As per stoichiometric chemistry, the ion content ratio or mole ratio of Potassium (K+) and Chloride (CI) on dissociation of KCI into Potassium (K+) and Chloride (CI) is 1:1 respectively. And as per DTL report, Potassium (K+) was found 1.92mmol/L. So as per 1:1 mole ratio, (Cl-) content contribution from Potassium Choride in the product is also **1.92mmol/L.---(A)**
Calcium Chloride ($CaCl_2$):
As per stoichiometric chemistry, the ion content ratio or mole ratio of Calcium (Ca+2) and Chloride (CI) on dissociation of $CaCl_2$ into Calcium (Ca+2) and Chloride (CI) is 1:2 respectively.
As per label claim of the product sampled, Calcium (Ca+2) content is 1.25 mmol/L.
So as per 1:2 mole ratio, (Cl-) content contribution from Calcium
Chloride in the product is **2.50mmol/L.----(B)**
Magnesium Chloride ($MgCl_2$):
As per stoichiometric chemistry, the ion content ratio or mole ratio of Magnesium (Mg+2) and Chloride (CI) on dissociation of $MgCl_2$ into Magnesium (Mg+2) and Chloride (Cl-) is 1:2 respectively.
As per label claim of the product sampled, Magnesium (Mg+2) content is 0.75 mmol/L.
So as per 1:2 mole ratio, (Cl-) content contribution from Magnesium
Chloride in the product is **1.50mmol/L.----(C)**
if we sum up Chloride (Cl-) content contribution from Potassium Chloride (A), Calcium Chloride (B) and Magnesium Chloride (C) i.e. A+B+C (1.92+2.50+1.50) we get total 5.92 mmol/L of Chloride (CI) content from three of them. While DTL determined 105.81 mmol/L of Choride content, it means, rest of Choride content
i.e. 99.89 mmol/L (105.81 -5.92 = 99.89 mmol/L) was contributed by Sodium Chloride (NaCl).
NOW IF WE LOOK AT SODIUM CHORIDE (NaCl) STOICHIOMETRIC CALCULATIONS:
As per stoichiometric chemistry, the ion content ratio or mole ratio between Sodium (Na) and Chloride (CI) on dissociation of NaCl into Sodium (Na+) and Chloride (CI) is 1:1 respectively.Whereas as per DTL report, Choride content contribution from Sodium Chloride as discussed above is 99.89mmol/L.
So keeping in view 1:1 mole ratio, Sodium (Na*) concentration in the product sampled also comes out to be 99.89mmol/L. while the DTL determined 95.03mmol/L which is scientifically not possible and is against the principles of stoichiometry chemistry. This clearly indicates that government analyst didn't
perform Sodium concentration accurately and erroneously declared our product as substandard.
C. That the learned Board also failed to scrutinize/appreciate that it has erroneously turned down the retesting request of the petitioner on the basis that the data submitted by the firm regarding the product sampled was not according to the protocol of the assay test as given in the USP. While as a matter of fact, the product sampled i.e. Haemodialysis Concentrate is not available as monograph in USP.
D. That the Board also didn't scrutinize/appreciate that it has erroneously turned down the retesting request of the petitioner on the basis that the petitioner didn't perform the assay test using HPLC technique. While as a matter of fact, assay determination of Haemodialysis Concentrate by HPLC is not advised anywhere in BP/EP.
E. That the Board badly failed to scrutinize/appreciate the available record of
the case that the flame photometer used by the petitioner for the test analysis of assay of Sodium in Haemodialysis Concentrate is based on Atmoic Emission Spectroscopy not Atomic Absorption Spectroscopy. But the Board erroneously turned down the retesting request of the petitioner on this reason.
F. That the Board passed the impugned prosecution order ignoring the fact that the review petition dated 03-10-2022 of the petitioner regarding its retesting request was still pending for adjudication before the Board. But the Board arbitrarily without deciding the said review petition dated 03-10-2022 passed the impugned order dated 13-12-2022.
G. That the Board also didn't scrutinize the case on the aspect that manufacturing department of the petitioner got issued and mixed the prescribed standard quantity of Sodium Chloride as transpired by the manufacturing order and mixing sheet. Further quality control department of the petitioner when tested the finished product, Sodium content was well within the prescribed range i.e. 102mmol/L. So the product sampled is of standard quality meeting all its specifications.
H. That the learned Board failed to scrutinize that the Drug Inspector didn't send the warrantor portion to the petitioner which is sheer violation of schedule V, clause 3 of the DRAP Act 2012. Even the Board in the paragraph no. V of impugned order dated 13-12-2022 averred that warrantor portion was provided to the petitioner along with the DTL report which is entirely contrary to actual facts. The letter sent by the Drug
Inspector letter dated 11-03-2022 clearly transpires that only DTL report was provided to the petitioner. As a matter of fact the drug inspector Jinnah hospital Lahore didn't send any portion of the said sample to the petitioner till now. So, non provision of warrantor portion to the petitioner makes the whole sampling transaction illegal and unlawful and entire action taken in this regard is void ab initio and all proceedings based on such illegal foundation are unlawful and liable to be set aside.

Reliance 2009 SCMR 339.

Furthermore recently, the learned Board has already 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.**

I. That it is the duty and obligation of the public functionaries to act justly fairly, equitably, reasonably without any element of discrimination and squarely within the parameters of law as is envisaged by Article 4 of the Constitution.
J. That in addition to above, the Petitioner Company reserves its right to submit further assistance to this honorable forum during the arguments of the instant Petition.

Prayer

In view of the foregoing, it is most respectfully and humbly submitted that this Honorable Board may be pleased to:

Accept the Instant Review Petition and set aside the Impugned Order dated 13-12-2022 being passed without proper examination of available record;
Suspend the Impugned Order till the decision of the instant review petition.

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

Case is placed before the Board for decision.

Summary:

- **Manufacturing Date: 12-2021**
- **Expiry Date: 12-2023**
- **Sampling Date (Form 4): 29-12-2021**
- **Sent to DTL (Form 6): 29-12-2021**
- **Date of receipt in DTL: 31-12-2021**
- **DTL Report Date (Form 7): 25-02-2022**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 11-03-2022**
- **Date of Retesting Request of Firm: 30-03-2022**
- **Fate of Retesting: Turn Down (246th meeting dated 05-07-2022)**
- **Investigation Report Dated: 07-10-2022**
- **Prosecution granted against firm: 254th meeting dated 13-12-2022**
- **Review Petition submitted by firm: Dated 10-02-2023 (Received in the office of PQCB dated 13-02-2023.**
- **Status of Review Petition: Pending**
- **Writ Petition filed by firm No. 11419 of 2023 and Lahore High Court, Lahore Orders dated 20-02-2023, received in the office of PQCB on 24-02-2023.**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 2

PQCB/R-405/2018

Tehsil & District Sialkot

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan** through its Managing Director Abdul Hameed Malik 2. Abdul Hameed Malik — Managing Director 3. Dr. Muhammad Zahid — Quality Assurance Manager 4. Atiq-ur-Rehman — Production Incharge 5. Aamir Faheem — Quality Control Incharge/Warrantor of M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan.

The firm filed **Writ Petition** No. 1668 of 2023 and Lahore High Court, Lahore Orders dated 08-03-2023, issued on 13-03-2023, received in office of PQCB on 15-03-2023, in which the Honorable Court directed the board to decide the review petition of the Petitioner Firm.

Order Sheet

In Lahore High Court, Lahore

Judicial Department

M/s Jinnah Pharmaceuticals (Pvt) Ltd., v/s Province of Punjab

The petitioner filed a review application pursuant to Notification No. PQCB/DEV/2001 dated 03.05.2002 calling into question order dated 02.2.2021 of the respondent Board which was adversely decided vide order dated 24.06.2021. Grievance of the petitioner is that petitioner was not heard before passing order dated 24.06.2021 declining the Review application and directing prosecution, and that the non-appearance was neither deliberate nor intentional but because of absence of service of notice of hearing. Reference was made to tracking report of the Postal Service at page 38 which supports the petitioners stance , that the notice which was purportedly issued on 18-06-2021 for hearing on 24.06.2021 was not delivered much later on 14.1.2022 by which time the impunged order dated 24.06.2021 had already been passed. Adds that petitioner thereafter filed an application bringing non-receipt of notice to the attention of the respondents with a request for opportunity of hearing was not attended as yet and that petitioners inalienable right to due process and hearing was negated in the instant case.

2. Learned Law Officer also the Departmental representative present in court where confronted with the stance based on the tracking report of the Postal Service that shows receipt of notice on 14.01.2022 much after the date of hearing 24.06.2121 corroborating that the petitioner never received the notice of hearing in time and, as such non-appearance did not seem intentional on part of the petitioner; they were unable to defend this aspect. This being so, it will be appropriate that the petitioner may be given an opportunity of fair hearing and and ordre be passed on its Review Application thereafter afresh so as to ensure due process while holding the impugned order in abeyane.

3. An authorized representative of the petitioner shall accordingly attend the office of **Respondent No. 2** on **16.03.2023** at **11:00A.M**. to enable the process of hearing to be streamlined. It is expected that a **fresh order on the Review Application of the petitioner will be passed within 30 days** of the date herein above mentioned in accordance with law after ensuring one clear opportunity of the fair hearing to the petitioner. **Disposed of.**

BRIEF FACTS OF THE CASE

The Provincial Inspector of Drugs, Tehsil & District Sialkot reported that:

i. She, on 13-08-2018, inspected the business premises of M/S AIMS Pharma, Hunter Pura Near Bara Pathar School, Sialkot and took sample of a drugs on form No. 4 for the purpose of test/analysis, which after test/analysis was declared **Substandard** by the Govt. Analyst Drug Testing Laboratory Punjab, Faisalabad as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Tablet Diabnil [Each tablet contains: Glimepiride (BP)… 2mg]	773	M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan.	TRA.No: 01-63000770/DTL Dated: 15-09-2018	**ANALYSIS WITH SPECIFICATIONS APPLIED:** MS/BP 2018 **DESCRIPTION:** Round shaped, greenish colored, flat-faced tablets, engraved with "JP" on one side and plain from other side, packed in Alu-Alu 1 X 10's blister. **IDENTIFICATION:** GLIMEPIRIDE IDENTIFIED **ASSAY**: **Stated: 2 mg/TABLET** **Determined: 1.7133 mg/ TABLET** **Percentage: 85.66% (Does Not Comply MS)** **Limit: 90-110%** **DISINTEGRATION TEST:** Stated: Not more than 15 minutes. (MS) Determined: All six units disintegrated within 09 minutes. **UNIFORMITY OF WEIGHT:** **Does not comply with BP 2018 specifications as detailed below:** **Tolerance Limit:** Out of 20 units, not more than two of the individual masses deviate from the average mass more than ±5% for tablets with average mass more than 250mg and none deviate by more than twice of that percentage (i.e. ±10%) **Determined:** Five (05) units deviate ±5% uniformity of weight limit and one (01) unit deviate twice of that limit (i.e. ±10%) **(Does Not Comply BP 2018)** **RESULT:** The above sample is **Sub-Standard** on the basis of Uniformity of Weight and Assay.

ii. M/S AIMS Pharma, Hunter Pura, Near Bara Pathar School, Sialkot provided invoice/ warranty No. 16132 dated 14-12-2017 issued by M/S Haris Traders, SE-6, Officer Colony, Bosan Road, Multan who in turn provided invoice/ warranty No. 32 dated 19-10-2017 issued by M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan, as a proof of its purchase of the said drug, whereas the Drug Inspector accepted the above-mentioned bill/warranty.

iii. Whereas, warrantor portion and a copy of test report was sent to M/S Haris Traders, SE-6, Officer Colony, Bosan Road, Multan.

iv. Whereas, a copy of test report of drug sample was sent to M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan and they were asked to explain their position and provide requisite information in this regard.

Reply of the firm to Drug Inspector:

M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan replied that:

"we believe in manufacturing and selling of perfectly standard quality drugs according to cGMP including Diabnil 2mg Tablets. DTL tested this batch as per BP specification, but this batch was manufacturer specifications."

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/ Selling of Substandard Drug**

b. **Issuance of false warranty.**

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB 215TH MEETING DATED 14-12-2019:

4. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **215th** meeting held on 14-12-2019. Ms. Farah Majeed Secretary DQCB Sialkot and Ms. Naila Rafique Drug Inspector Tehsil & District Sialkot were present along with original record of the case. Among accused persons**,** Abdul Hameed Malik (Managing Director) and Aamir Faheem (Quality Control manager) of M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan were present. The Managing Director of the firm submitted before the Board that they received personal hearing of this case 2 days before the meeting date and they didn't have time to prepare the case and requested for adjournment. The Board after 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.

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 (PQCB) Punjab under section 11 of the Drugs Act 1976 in its **229th meeting held on 02-02-2021.** Mr. Hafiz Muhammad Faisal Secretary DQCB District Sialkot and Mr. Amaad Ashraf Drug Inspector Tehsil Sambrial District Sialkot were present along-with original case record. Among nominated accused persons Aamir Faheem (Quality Control In-charge/Warrantor) of **M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan** was present along-with counsel person of the firm Rana Maqsood Afzal Khan. They submitted before the Board that they have retested their product, all the tests performed lies within official limits. Assay of the product was found to be 98% and the product also complied with content uniformity and weight variation tests. These tests were performed after expiry of the product still result lies within official limits. They requested for lenient view.

6. The Board after keen perusal of the case record, report of Government Analyst, Drug Testing Laboratory, Faisalabad and statement of accused persons observed that the product Tablet Diabnil was declared substandard from Drug Testing Laboratory, Faisalabad on the basis of assay i.e 85.66%, lesser than the permissible limit of 90-110% and also on the basis of uniformity of weight. The product having lesser amount of chemical content would not be able to produce desired clinical response. Furthermore, the product also does not comply with the uniformity of weight, which indicates that the manufacturing process was uncontrolled. Results of these tests indicate that the product Tablet Diabnil Batch No. 773, Manufactured by M/s Jinnah Pharmaceuticals Multan was of compromised quality, hence, would have lesser therapeutic effectiveness.

7. Considering the facts of the case, the Board after due deliberation and detail discussion, unanimously decided to grant **permission for prosecution** against the following accused persons in the Drug Court:

1. **M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan** through its Managing Director Abdul Hameed Malik
2. Abdul Hameed Malik Managing Director
3. Dr. Muhammad Zahid Quality Assurance Manager
4. Atiq-ur-Rehman Production Incharge
5. Aamir Faheem Quality Control Incharge/Warrantor

of M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan.

For the offences of:

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

b. **Issuance of false warranty.**

REVIEW PETITION

8. The firm has submitted review petition against the orders of PQCB stating that:

1. The Provincial Inspector of Drugs Tehsil and District Sialkot, on 13-08-2018, inspected the business premises of M/S AIMS Pharma, Hunter Pura Near Bara Pathar School, Sialkot and took sample of Tablet Diabnil (Glimepiride BP) 2mg batch no. 773 manufactured by M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan drugs on form No. 4 for the purpose of test/analysis, which after test/analysis was declared Substandard by the Govt. Analyst Drug Testing Laboratory Punjab, Faisalabad vide TRA. No: 01-63000770/DTL Dated 15-09-2018.
2. That quality control manager of the frim along with counsel of the firm has appeared before this Honorable Court 02-02-2021 and adduce their evidence but despite of evidence Honorable Board has passed the impugned order which resulted in grave miscarriage of justice. The order has passed in hasty and slipshod manner.
3. That the above review petition is directed against the above unjust and unlawful order of Honorable Board of prosecution against the petitioner issued vide order dated 02-02-2021 .The decision of the prosecution by the Honorable Board is based on test and analysis Report TRA No. 01-633000770/DTL dated 15-09-2018 issued by the Govt Analyst of the Drug Testing Laboratory Faisalabad. It is appropriate to point out that our product Tab. Diabnil complies with the specifications, whereas the result of the test report has been prepared on the basis of MS/BP 2018 specifications are applied, which is contradictory to the product specification as mentioned on the immediate label and outer carton. It is not possible to apply two specification simultaneously , therefore the test report in question is ambiguous, unauthentic and unlawful and could not not presented as conclusive evidence in the court of law.In the light of above discussion the report of DTL has no value in the eyes of law. This point has not been considered by the Board while passing the impugned order.
4. That the review petition is well within time.
5. It is therefore, respectfully prayed that by accepting this Review Petition, order dated 02-02-2021 passed by the PQCB may very kindly be set aside by exercising power of review jurisdiction,
6. It is further prayed that the concerned DI 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. Personal hearing Notice(s) issued to the accused persons

PROCEEDINGS & DECISION BY THE BOARD:

10. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **232nd meeting** held on **24-06-2021**. Mr. Hafiz Faisal Secretary DQCB District Sialkot was present**.** No-one appeared before the Board on behalf of M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan. Secretary PQCB apprised the Board that no request for adjournment has been received from the firm.

11. The Board after careful perusal of the case record and the grounds of review petition observed that the case has already been discussed at length in PQCB 229th meeting dated 02-02-2020 and the firm has not provided any new ground in its review petition. The product Tablet Diabnil was declared substandard on the basis of Assay of the product which was 85.66%, whereas the permissible limit was 90-110%, and on the basis of uniformity of weight, from Drug Testing Laboratory Faisalabad. Lesser quantity of active ingredient is sub-therapeutic and is not able to produce optimum response. According to Section 22(4) of the Drugs Act, 1976, the Report of Drug Testing Laboratory, Faisalabad is the conclusive evidence of the facts stated therein. Moreover, the firm neither appeard in the proceedings of personal hearing before the Board nor any request for adjournment has been received from the firm. Keeping in view the facts of the case, the Board after due deliberation and detailed discussion unanimously decided to uphold its previous decision taken in PQCB 229th meeting dated 02-02-201 for the grant of permission for prosecution against the following accused persons in the Drug Court:

1. **M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan** through its Managing Director Abdul Hameed Malik
2. Abdul Hameed Malik Managing Director
3. Dr. Muhammad Zahid Quality Assurance Manager
4. Atiq-ur-Rehman Production Incharge
5. Aamir Faheem Quality Control Incharge/Warrantor

of M/S Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km, Lahore Road, Multan, Pakistan.

For the offences of:

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

b. **Issuance of false warranty.**

M/s Jinnah Pharmaceuticals submitted the Review petition no. nil dated nil received in the office of Provincial Quality Control Board dated 21-12-2022. The grounds of the review petition is as under:

1. That the petitioner Pharmaceutical company with the name and style of M/s Jinnah Pharmaceuticals (Pvt.) Ltd. , 13-km Lahore Road, Multan, manufacturer of vast range of drug of standard quality.
2. That the facts of the case are that on 13/08/2018 Respondent, Provincial Drug Inspector took the sample of Diablin 2 mg, Batch No. 773 manufactured by M/s Jinnah Pharmaceuticals, 13-km Lahore Road, Multan on Form 4 from the premises of M/s AIMS Pharma, Sialkot for test and analysis.
3. That the Drug Inspector sent the sample to the Drug Testing Laboratory who vide Test Report declared the subject sample as substandard vide test report dated 15/09/2018.
4. That the matter was referred to the PQCB who issued a show cause Notice to the petitioners under section 11 of the Drugs Act, 1976 and Rule 5 of the Punjab Drug Rules, 2007.
5. That the case was placed in the meeting of PQCB held on 02.02.2021 the petitioner along with others appeared before the PQCB at Lahore and the case was decided whereby the petitioners were ordered to be prosecuted.
6. That the IMPUGNED ORDER dated 02-02-2021 passed by the PQCB was without proper hearing the petitioners as the points argued had not been adverted to in the order of prosecution and as such was illegal because the same was in violation of the Rule 5(3) of the Punjab Drug Rules, 2007, therefore, the Review petition was filed.
7. That on 26-11-2022 the petitioner asked for fixation of the review petition but this learned informed the petitioner that the said petition was already decided vide impugned order dated 24-06-2021, hence this petition.
8. That the impugned orders of prosecution, without giving hearing to the petitioners as no notice of hearing was received by the petitioner, therefore, was illegal and without lawful authority because the same was in violation of the Rule 5(3) of the Punjab Drug Rules, 2007 and as such was corum non-judice.
9. That this learned Board having failed to act within the parameters of section 24-A of the General Clauses Act by not giving reasons for prosecution had not acted in accordance with law in view of the Article 4 of the Constitution. Reliance in this regard was placed on 2005 MLD 599.
10. That the Govt., Analyst did not mention the full protocols of the tests applied, therefore, the reports were not to be relied upon being not admissible in evidence. Reliance was placed on PLD 2003 Lahore 115.
11. That the no notice of reliance upon the warranty was received by the petitioner therefore the plea of warranty was not available to the person from whom the product was recovered.

PRAYER:

Under the circumstances explained above, it is, therefore, respectfully prayed that this review petition/ application for re-hearing may kindly be accepted and the impugned orders of prosecution passed in a meeting held on 02-02-2021 & 24-06-2021 may kindly be set aside and the case against the petitioner may kindly be dropped for the reasons mentioned above.

Any other relief deemed fit in the circumstances of the case may also be granted.

Summary:

- **Manufacturing Date: 09-2017**
- **Expiry Date: 08-2020**
- **Sampling Date (Form 4): 13-08-2018**
- **Sent to DTL (Form 6): 15-08-2018**
- **Date of receipt in DTL: 18-08-2018**
- **DTL Report Date (Form 7): 15-09-2018**
- **Time Extension: not applicable**
- **1ST DI Communication with firm on dated: 21-01-2019**
- **Date of Retesting Request of Firm: No**
- **Fate of Retesting: N/A**
- **Investigation Report Dated: 06-11-2019**
- **Prosecution granted against firm: 229th meeting dated 02-02-2021**
- **Review Petition submitted by firm: 17-05-2021**
- **Status of Review Petition: Decision upheld 232nd meeting dated 24-06-2021**
- **Review filed: 21-12-2022**
- **Writ Petition filed by firm No. 1668 of 2023 and Lahore High Court, Lahore Orders dated 08-03-2023, received in the office of PQCB on 15-03-2023**

PROCEEDINGS AND DECISION BY THE BOARD:

ITEM No. 2
REGULAR CASES

MISBRANDED CASES

Case No. 1

PQCB R-144/2020

DHQ Hospital, Attock

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi** through its Managing Director, Erum Shakir Rahim 2. Erum Shakir Rahim — Managing Director 3. Saqib Azmat — Production Manager 4. Khurram Ahmed — Quality Control Manager 5. Nasir Aleem — Warrantor Of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Isfandyar Bukhari District Headquarter Hospital, Attock reported that:-

i. He, on 04-06-2020 inspected Main Medicine Store, Isfandyar Bukhari District Headquarter Hospital, Attock, took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo No. 0000067517 Dated 06-06-2020.

ii. The following drug sample, after test/analysis was declared as **Substandard and Misbranded** 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
Suspension. Zentel 10mL Suspension [Albendazole…200mg/5mL] Mfg. Date: 04-2020 Exp. Date: 04-2023 Reg # 006730	YU5P	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi.	01-72001186/ DTL dated: 15 Aug 2020	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION:** White to off-white coloured viscous suspension having characteristic odour, filled in single dose amber coloured glass bottle with affixed label, sealed with golden coloured Aluminum screw cap imprinted with "GSK", further packed in labelled unit carton. **Manufacturer specifies "USP Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in labelling that "Label it to indicate that it is for veterinary use only" whereas manufacturer prescribes given sample for human use. (Does not comply)** **pH** Limit: 4.5-5.5 Determined: **6.743 at 25C (Does not comply)** **IDENTIFICATION** Albendazole identified **ASSAY:** Stated: 200mg/5mL Determined: 195.374/5mL Percentage 97.69% Limit: 90-110% **RESULT:** **The above sample is "Sub-standard" on the basis of pH performed and "Misbranded" as defined under clause (iv) of sub-section (s) of section 3 of The Drugs Act 1976**

iii. The Pharmacy Manager, provided warranty/invoice No. 20015195/20016271 dated 18-05-2020-28-05-20202, issued by M/s GlaxoSmithKline Pakistan Limited F/268, S.I.T.E. Karachi,

iv. Warrantor Portion was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi.

v. A copy of Test/ Analysis reports was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi and they were directed to explain their position and provide requisite information in this regard

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

i. **Manufacture for Sale/Sale of Substandard Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 08-02-2023.

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

Summary:

Manufacturing Date: 04-2020

Expiry Date: 04-2023

Sampling Date: 04-06-2020

Sent to DTL (Form 6): 06-06-2020

Date of receipt in DTL: 04-06-2020

DTL Report Date: 16-06-2020

Time Extension: N/A

1ST DI Communication with firm on dated: 25-08-2020

Date of Retesting Request of Firm: -N/A

Fate of Retesting Request: -N/A

Investigation Report Dated: 24-01-2023

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 2

PQCB/R-615, R-616/2020

Tehsil & District Bahawalpur

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan** through its Managing Director Iram Shakir. 2. Iram Shakir — Managing Director 3. Imtiaz Hussain — Production Manager 4. Khalid Mehmood Sheikh — Quality Operation Head 5. Nasir Aleem Qureshi — Warrantor of M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan.

BRIEF FACTS OF THE CASE

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

i. He, on 03-08-2020, inspected the premises of M/S Medicine Store office of Chief Executive Officer [DHA] Bahawalpur and took twelve different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur.

ii. Following Drug sample after test/analysis was declared as **Misbranded & 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 Result</th></tr>
<tr><td>Suspension Zental [Albendazole 200mg/5ml, 10ml]</td><td>L25Y</td><td>M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan</td><td>01-77002208/DTL
Dated. 06-11-2020</td><td>
<u>Analysis with specifications applied:</u> MS.

<u>Composition:</u>

Each 5ml contains:

Albendazole USP……..200mg

<u>Description:</u>

White to off white suspension with an orange odour contained in amber glass bottle, sealed and caped with aluminium cap, packed in outer hard carton. (Stated volume:10ml).

Note: Manufacturer specifies “USP Specifications” on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in Labelling that “Label it to indicate that it is for veterinary use only” whereas manufacturer prescribe given sample for human use. Therefore, manufacturer’s claim of USP Specification is false/misleading which is in violation to Drugs Act 1976, and is declared misbranded. (Does not comply)

<u>PH (MS):</u>

<table>
<tr><td>Limit</td><td>4.5-5.5</td></tr>
<tr><td>Determined</td><td>6.685</td></tr>
</table>

Does not comply with specifications.

<u>Identification (MS):</u>

Albendazole is identified.

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

Albendazole:

<table>
<tr><td>Stated</td><td>200mg/5ml</td></tr>
<tr><td>Determined</td><td>199.94mg/5ml</td></tr>
<tr><td>Percentage</td><td>99.97%</td></tr>
<tr><td>Limit</td><td>90.0-110.0%</td></tr>
</table>

<u>Result:</u>

The above sample is “Substandard” on the basis of PH test and is “Misbranded” as defined under clause (vi) of subsection (s) of section 3 of the Drug Act 1976..
</td></tr>
</table>

<table>
<tr>
<td>Suspension Zental [Albendazole 200mg/5ml, 10ml]</td>
<td>L26A</td>
<td>M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan</td>
<td>01-77002207/DTL

Dated. 06-11-2020</td>
<td>
<u>Analysis with specifications applied:</u> MS.

<u>Composition:</u>

Each 5ml contains:

Albendazole USP……..200mg

<u>Description:</u>

A White to off white suspension with an orange odour contained in amber glass bottle, sealed and caped with aluminium cap, packed in outer hard carton. (Stated volume:10ml).

Note: Manufacturer specifies “USP Specifications” on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in Labelling that “Label it to indicate that it is for veterinary use only” whereas manufacturer prescribe given sample for human use. Therefore, manufacturer’s claim of USP Specification is false/misleading which is in violation to Drugs Act 1976, and is declared misbranded. (Does not comply)

<u>PH (MS):</u>

<table>
<tr><td>Limit</td><td>4.5-5.5</td></tr>
<tr><td>Determined</td><td>6.684</td></tr>
</table>

Does not comply with specifications.

<u>Identification (MS):</u>

Albendazole is identified.

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

Albendazole:

<table>
<tr><td>Stated</td><td>200mg/5ml</td></tr>
<tr><td>Determined</td><td>199.46mg/5ml</td></tr>
<tr><td>Percentage</td><td>99.73%</td></tr>
<tr><td>Limit</td><td>90.0-110.0%</td></tr>
</table>

<u>Result:</u>

The sample is declared “Substandard” on the basis of PH test and is “Misbranded” as defined under clause (vi) of subsection (s) of section 3 of the Drug Act 1976..
</td>
</tr>
</table>

iii. Store Keeper of M/S Medicine Store office of Chief Executive Officer [DHA] Bahawalpur provided Invoice/warranty No 20022891/20022510/20022511/20022900, dated 30-07-2020, 27-07-2020, 27-07-2020,30-07-2020 issued by M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan 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-74000, Pakistan and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan and they were asked to provide the requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 07-03-2022

4. Personal hearing notice(s) issued to accused person(s) dated 29-03-2023

5. Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 3

PQCB R-613/2020

Tehsil and District Bhakkar

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan** through its Managing Director, Iram Shakir. 2. Iram Shakir Managing Director 3. Imtiaz Hussain Production Manager 4. Khalid Mehmood Sheikh Quality Operation Head 5. Nasir Aleem Qureshi Warrantor Of M/s GlaxoSmithKline Pakistan Limited, **GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000**

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 29-05-2020 inspected Main Medicine Store of Chief Executive Officer (DHA) Bhakkar and took three different types of drug samples on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Rawalpindi.

ii. following drug sample, after test/analysis was declared as **Substandard and Misbranded** 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. Zentel 10mL Suspension [Albendazole…200mg/5mL]	VS7F	M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan	01-71000762/ DTL dated: 23 Aug 2020	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION:** White to off-white coloured viscous suspension having characteristic odour, filled in single dose amber coloured glass bottle with affixed label, sealed with golden coloured Aluminum screw cap imprinted with "GSK", further packed in labelled unit carton. **Manufacturer specifies "USP Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in labelling that "Label it to indicate that it is for veterinary use only" whereas manufacturer prescribes given sample for human use. (Does not comply)** **pH** **Observed: 6.648 (does not comply)** **Limit: 4.5-5.5** **IDENTIFICATION** Albendazole identified **ASSAY:** **Stated: 200mg/5ml** **Determined: 210.453mg/5ml** **Percentage: 105.23%** **Limit: 90-110%** **RESULT:** The above sample is "Sub-standard" on the basis of pH performed and "Misbranded" as defined under clause (iv) of sub-section (s) of section 3 of The Drugs Act 1976

iii. Store Keeper of Medicine Store, Office of Chief executive Officer (DHA) Bhakkar provided warranty/invoice No. 20015043/20015048 dated 16-05-2020, issued by M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000,Pakistan as a proof of its purchase.

iv. Warrantor Portion was sent to M/s GlaxoSmithKline Pakistan Limited 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan and they were asked to explain their position in this regard.

v. A copy of Test/ Analysis reports was sent to M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, 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/DRAP Act 2012 and Rules framed there under by the way of: -

i. **Manufacture for Sale/Sale of Substandard and misbranded Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 07-03-2022.

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

Summary:

Manufacturing Date: 03-2020

Expiry Date: 03-2023

Sampling Date: 29-05-2020

Sent to DTL (Form 6): 30-05-2020

Date of receipt in DTL: 04-06-2020

DTL Report Date: 03-08-2020

Time Extension: -

1ST DI Communication with firm on dated: 02-10-2021

Date of Retesting Request of Firm: -N/A

Fate of Retesting Request: -N/A

Investigation Report Dated: 07-01-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 4

DISTRICT BAHAWALNAGAR

PQCB/R-612/2020

Tehsil Fortabbas District Bahawalnagar

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E, Karachi** through its Director Maheen Rehman. 2. Iram Shakir — Managing Director 3. Imtiaz Hussain — Production Manager 4. Khalid Mehmood Sheikh — Quality Operation Head 5. Nasir Aleem Qureshi — Warrantor **of M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E, Karachi**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Fort Abbas & District Bahawalnager reported that: -

i. His Predecessor, on 25-08-2020, inspected the business premises of M/S Ahmad Medical Store Committee Chowk Tehsil Fort Abbas, District Bahawalnager, and took three different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Suspension. Zental [Albendazole 200mg/5ml, 10ml]	F43C	M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E, Karachi	01-77002275/DTL Dated. 21-10-2020	**Analysis with specifications applied: MS.** **Composition:** Each 5ml contains: Albendazole USP…….200mg **Description:** A white to off white suspension with an orange odour contained in amber glass bottle, sea and caped with aluminum cap, packed in outer hard carton. (Stated Volume:10ml). Note: **Manufacturer specifies "USP Specifications" on the label of immediate contai as well as on outer unit carton. But in USP 2019, Monograph of Albendazole O suspension clearly mention in Labelling that "Label it to indicate that it is for veterin use only" whereas manufacturer prescribe given sample for human use. Therefo manufacturer claim of USP specification is false/misleading which is in violation Drugs Act 1976, and is declared misbranded. (Does not comply).** **PH (MS):** **Limit: 4.5-5.5** **Determined: 7.045** **Does not comply with specifications.** **Identification (MS):** Albendazole is identified. **Assay (MS):** Stated: 200mg/5ml Determined: 180.06mg/5ml Percentage: 90.03% Limit: 90.0-110.0% **Result:** The sample is declared **Substandard** on the basis of PH Test and is **Misbranded** as defi under clause (vi) of subsection (s) of section 3 of the Drugs Act 1976.

iii. M/S Ahmad Medical Store Committee Chowk Tehsil Fort Abbas, District Bahawalnager provided Invoice/warranty No 249211, dated 15-08-2020 issued by M/S Pharma Traders House No. 27/Jinnah Colony, Bahawalnager who in turn provided invoice/warranty no. L00005279, Dated. 30-06-2020 issued by M/S Vikor Enterprises (Pvt) Ltd, Plot No. Z 2-A , S.I.T.E, Manghopir Road, Karachi who in turn provided invoice/warranty No. 20018835, Dated. 30-06-2020 M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E, Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Pharma Traders House No. 27/Jinnah Colony, Bahawalnager and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E, Karachi and they were asked to provide the requisite information in this regard.

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

i. **Manufacturing for Sale /Sale of Misbranded & Substandard Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 07-03-2022.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 06-2020**
- **Expiry Date: 06-2023**
- **Sampling Date (Form 4): 25-08-2020**
- **Sent to DTL (Form 6): 29-08-2020**
- **Date of receipt in DTL: 31-08-2020**
- **DTL Report Date (Form 7): 21-10-2020**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 18-01-2021**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 03-01-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 5

PQCB/R-614/2020

Tehsil & District Bahawalpur

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan** through its Managing Director Iram Shakir. 2. Iram Shakir — Managing Director 3. Imtiaz Hussain — Production Manager 4. Khalid Mehmood Sheikh — Quality Operation Head 5. Nasir Aleem Qureshi — Warrantor of M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, District Bahawalpur reported that: -

i. He, on 23-06-2020, inspected the premises of M/S Medicine Store office of Chief Executive Officer [DHA] Bahawalpur and took three different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Suspension Zental [Albendazole 200mg/5ml, 10ml]	VS7F	M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan	01-77001879/DTL Dated. 21-10-2020	**Analysis with specifications applied: MS.** **Composition:** Each 5ml contains: Albendazole USP……..200mg **Description:** White to off white suspension with an orange odour contained in amber glass bottle, sealed and caped with aluminium cap, packed in outer hard carton. (Stated volume:10ml). **Note: Manufacturer specifies "USP Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in Labelling that "Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer's claim of USP Specification is false/misleading which is in violation to Drugs Act 1976, and is declared misbranded. (Does not comply)** **PH (MS):** **Limit** — **4.5-5.5** **Determined** — **6.774** **Does not comply with specifications.** **Identification (MS):** Albendazole is identified. **Assay (MS):** Albendazole: Stated — 200mg/5ml Determined — 208.36mg/5ml Percentage — 104.18%% Limit — 90.0-110.0% **Result:** The above sample is "**Substandard**" on the basis of PH test and is "**Misbranded**" as defined under clause (vi) of subsection (s) of section 3 of the Drug Act 1976..

iii. Store Keeper of M/S Medicine Store office of Chief Executive Officer [DHA] Bahawalpur provided Invoice/warranty No 20018189/20018184, dated 19-06-2020 issued by M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan 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-74000, Pakistan and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan and they were asked to provide the requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 07-03-2022

4. Personal hearing notice(s) issued to accused person(s) dated 29-03-2023

5. Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 6

PQCB R-726/2020

Tehsil and District Chakwal

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi** through its Managing Director, Erum Shakir Rahim 2. Erum Shakir Rahim — Managing Director 3. Saqib Azmat — Production Manager 4. Khurram Ahmed — Quality Control Manager 5. Nasir Aleem — Warrantor Of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 29-05-2020 inspected Main Medicine Store, Chief Executive Officer, District Health Authority, Chakwal, took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo No. 0000066721 Dated 29-05-2020.

ii. The following drug sample, after test/analysis was declared as **Substandard and Misbranded** 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
Suspension. Zentel 10mL Suspension [Albendazole…200mg/5mL] Mfg. Date: 04-2020 Exp. Date: 04-2023 Reg # 006730	YU5P	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi.	01-72001071/ DTL dated: 30 Jul 2020	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION:** White to off-white coloured viscous suspension having characteristic odour, filled in single dose amber coloured glass bottle with affixed label, sealed with golden coloured Aluminum screw cap imprinted with "GSK", further packed in labelled unit carton. **Manufacturer specifies "USP Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in labelling that "Label it to indicate that it is for veterinary use only" whereas manufacturer prescribes given sample for human use. (Does not comply)** **pH** Limit: 4.5-5.5 Determined: **6.752 at 25C (Does not comply)** **IDENTIFICATION** Albendazole identified **ASSAY:** Stated: 200mg/5mL Determined: 188.033mg/5mL Percentage 94.02% Limit: 90-110% **RESULT:** **The above sample is "Sub-standard" on the basis of pH performed and "Misbranded" as defined under clause (iv) of sub-section (s) of section 3 of The Drugs Act 1976**

iii. The Store Keeper, Main Medicine Store, Chief Executive Officer, District Health Authority, Chakwal provided warranty/invoice No. 20015272 dated 28-05-2020, issued by M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan.

iv. Warrantor Portion was sent to M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan.

v. A copy of Test/ Analysis reports was sent to **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi** and they were directed to explain their position and provide requisite information in this regard. The firm challenged the report and requested re-testing of the sample by the Appellate Laboratory, National institute of Health, Islamabad.

vi. The Re-testing request of the Firm was considered by Provincial quality Control Board in its 241st meeting held on 31-03-2022. The retesting request was **turned down** by the Board.

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

i. **Manufacture for Sale/Sale of Substandard and Misbranded Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 31-01-2023.

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

Summary:

Manufacturing Date: 04-2020

Expiry Date: 04-2023

Sampling Date: 29-05-2020

Sent to DTL (Form 6): 29-05-2020

Date of receipt in DTL: 01-06-2020

DTL Report Date: 30-07-2020

Time Extension: N/A

1ST DI Communication with firm on dated: 05-06-2020

Date of Retesting Request of Firm: -25-05-2021

Fate of Retesting Request: -Turned down in 241-M, 31-03-2022

Investigation Report Dated: 26-10-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 7

DISTRICT DERA GHAZI KHAN

PQCB/R-361/2020

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

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir Managing Director 3. Imtiaz Hussain Production Manager 4. Khalid Mehmood Sheikh Quality Operation Head 5. Nusrat Khalique Operational Quality Manager 6. Muhammad Asad Malik Warrantor of **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs DG Khan reported that: -

i. His Predecessor, on 20-07-2020, inspected the premises of Medicine Store Office of District Manager PHFMC DG Khan and took seven different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory **Multan**.

ii. One out of these seven drug samples after analysis was declared as **Sub-standard and Misbranded** by Government Analyst Drug Testing Laboratory **Multan**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Susp. ZENTEL (Albendazole 200mg/5ml)	VS7F	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No.01-87002052/DTL dated: 17-09-2020	**Analysis with specifications applied:** MS **Description:** White to off white color suspension in amber glass bottle sealed with aluminum cap packed in a labelled outer hard carton. Product States "USP specifications" as a Finished Drug Product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in "Labelling: Label it to indicate that it is for Veterinary use only" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded. **(Mis-Branded) Does not comply.** **Identification:** Albendazole identified. **Assay: Albendazole** Stated: 200mg/5ml Determined: 197.66 mg/5ml Percentage: 98.83% Limit: 90-110% **(Complies)** **pH:** Range: 4.5-5.5 **Determined: 6.76 at 25^0C** **Does not comply.** **Result:** The above sample is **Misbranded**, as defined under section 3(s)(iv) of the Drugs Act, 1976 and is **Sub-standard** on the basis of pH test performed. Same batch was declared substandard and misbranded previously via TRA-87001051 dated 4-8-2020.

iii. Store keeper at Medicine Store Office of District Manager PHFMC DG Khan provided Invoice/warranty No 20018188 dated 19-6-2020 issued by M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi and they were asked to provide requisite information in this regard

v. A copy of test/analysis report was sent to GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi and they were asked to provide the requisite information in this regard.

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

i. **Manufacturing for Sale /Sale of Misbranded & Substandard Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 03-01-2022.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 03-2020**
- **Expiry Date: 03-2023**
- **Sampling Date (Form 4): 20-07-2020**
- **Sent to DTL (Form 6): 21-07-2020**
- **Date of receipt in DTL: 22-07-2020**
- **DTL Report Date (Form 7): 17-09-2020**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 26-09-2020**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 25-11-2021**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 8

DISTRICT DERA GHAZI KHAN

PQCB/R-360/2020

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

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir — Managing Director 3. Imtiaz Hussain — Production Manager 4. Khalid Mehmood Sheikh — Quality Operation Head 5. Nusrat Khalique — Operational Quality Manager of **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs DG Khan reported that: -

i. He, on 27-07-2020, inspected the premises of Medicine Store Office of District Manager PHFMC DG Khan and took seven different types of drug samples on Form No.04 for the purpose of test/analysis.

ii. One out of these seven drug samples after analysis was declared as **Sub-standard and Misbranded** by Government Analyst Drug Testing Laboratory Multan, 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>Susp. ZENTEL (Albendazole 200mg/5ml)</td><td>L25Y</td><td>M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.</td><td>TRA No.01-87002157/DTL

dated: 17-09-2020</td><td>
Analysis with specifications applied: MS

<u>Description</u>: White to off white color suspension in amber glass bottle sealed with aluminum cap packed in a labeled outer hard carton.

Product States “USP specifications” as a finished Drug product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in “Labelling: Label it to indicate that it is for Veterinary use only” whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded.

(Misbranded) Does not comply.

<u>Identification:</u> Albendazole identified.

<u>Assay: Albendazole</u>
<table>
<tr><td>Stated</td><td>200mg/5ml</td></tr>
<tr><td>Determined</td><td>200.11 mg/5ml</td></tr>
<tr><td>Percentage</td><td>100.05%</td></tr>
<tr><td>Limit</td><td>90-110%</td></tr>
</table>
(Complies)

<u>pH:</u>
<table>
<tr><td>Range</td><td>4.5-5.5</td></tr>
<tr><td><u>Determined</u></td><td><u>6.82 at 25^0</u></td></tr>
</table>
Does not comply.

<u>Result</u>: The above sample is Misbranded, as defined under section 3(s)(iv) of the drugs act, 1976 and is Sub-standard on the basis of pH test performed.
</td></tr>
</table>

iii. Store keeper at Medicine Store Office of District Manager PHFMC DG Khan provided Invoice/warranty No 20022509 dated 27-07-2020 issued by M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent **to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** and they were asked to provide requisite information in this regard

v. A copy of test/analysis report was sent to GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi and they were asked to provide the requisite information in this regard.

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

i. **Manufacturing for sale /Stocking for Sale/sale of Substandard & Misbranded drug**

ii. **Issuance of false warranty**

3. Showcause notice(s) issued to the accused dated 19-02-2021

REPLY OF THE FIRM TO SHOW CAUSE NOTICE:

The firm vide letter No. Nil submitted written reply to Show-Cause notice, received in this office on 12-10-2020 stated that

Said product has been registered in 1985, since than it has been used for Human. There is no customer complaint has been received in this regard. The product, in its specification, fit for consumption and human use. However, due to an inadvertent error the information on artwork does not conform with specification of the product. As responsible pharmaceutical GSK has immediately taken to remove this anomaly in the label and the error has been rectified. Finally, we once again reiterate that as a renowned and reputable patient focused and ethical multinational company, GlaxoSmithKline Pakistan Limited strictly monitors all quality parameters for assuring quality of the final product and in this case, as adhered to all regulatory protocols for the said product that the GSK, by means of this reply, also request for having a personal meeting with the respected board in order to build the confidence of the sample for drop of further proceedings as being a responsible Pharmaceutical Company, GSK ensure our full support as usual for any further support in this regard.

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

5. 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 **237th meeting** held on **30-12-2021** under th chairmanship of Secretary Health Primary & Secondary Healthcare Department in the presence of Board members as mentioned above. Mr. Sadiq Hussain Secretar DQCB Dera Ghazi Khan and Mr. Faisal Mahmood Khan Drug Inspector Dera Ghazi Khan Urban Area were present along with original case record. No one among th nominated accused persons was present. However, Saeed Anjum Khokhar (Advocate) appeared before the Board on the behalf of **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.**

7. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample has been declared Misbranded an substandard by the Drug Testing Laboratory, Lahore under section 3(s)(iv) of the drugs act, 1976 and is **Sub-standard** on the basis of pH test performed i.e, "Product State "USP specifications" as a finished Drug product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazol Oral Suspension clearly mention in "Labelling: Label it to indicate that it is for Veterinary use only" whereas manufacturer prescribe given sample for human use Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded and Substandard as pH is 6.8 while the stated limit is 4.5-5.5".

8. Advocate of the firm stated that due to an inadvertent error the information on artwork does not conform with specification of the product. He stated th company has recalled these batches following all regulatory protocols for the said product. The Board observed that 41 cases of zental suspension of different batches ha been recorded. Moreover, previously registration of said product has been suspended for 6 months from 15-9-2021 and DRAP also deregistered this product. The boa asked the firm to submit recall record and financial trail to Board.

9. The Board after detailed scrutiny and comprehensive perusal of the record and statements of the representative of the firm unanimously decided to **pend th case and club all cases** for next meeting.

10. Personal hearing notice(s) issued to accused person(s).

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 07-2020**
- **Expiry Date: 07-2023**
- **Sampling Date (Form 4): 27-07-2020**
- **Sent to DTL (Form 6): 28-07-2020**
- **Date of receipt in DTL: 29-07-2020**
- **DTL Report Date (Form 7): 17-09-2020**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 26-09-2020**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 18-11-2020**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 9

PQCB/R-390/2021

Tehsil & District Gujrat

Misbranded

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir Managing Director 3. Khalid Mahmood Sheikh Quality Operation Head 4. Imtiaz Hussain Production Manager 5. Nasir Aleem Qureshi Warrantor of **M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.**

BRIEF FACTS OF THE CASE

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

i. He, on 26-04-2021, inspected the premises of Main Medicine Store of CEO-DHA Office, Gujrat and took sample of five different types of drugs on Form No.04 for the purpose of test/analysis and send the sample to Drug Testing Laboratory, Faisalabad.

ii. One out of five drug samples, after test/analysis, was declared **Misbranded** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension ZENTEL 10ml [Each 5 ml contains: Albendazole U.S.P. 200mg]	LV9U	M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No. 01-68008496/DTL dated:28-06-2021	**Analysis with specifications applied:** Manufacturer's Specifications **Description:** White color suspension with orange odor contained in amber color glass bottle sealed and caped with aluminum cap, packed in outer hard carton. **Note: Manufacturer specifies "U.S.P. Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2021, Monograph of Albendazole Oral Suspension clearly mention in "Labeling: Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/ misleading which is in violation to Drugs Act 1976, and is declared misbranded. (Does not Comply)** **Identification:** Albendazole identified. **Assay:** Stated: 200 mg/5ml Determined: 202.752 mg/ 5ml Percentage: 101.376% (Complies) Limit: 90-110% (Manufacturer's Specifications) **RESULT:** **Given sample is declared Misbranded with regards to Section 3 (s) (iv) of Drugs Act 1976.**

iii. Store keeper of Main Medicine Store of CEO-DHA Office, Gujrat, provided invoice/ warranty/ no. 20022271 dated 24-07-2020 issued by M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.

i. A copy of test report of the drug sample was sent **to** M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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. **Manufacture for Sale /Sale of Misbranded Drug**
ii. **Issuance of false warranty**

3. Show-cause was issued to accused person(s) vide dated 25-03-2022.

PREVIOUS PROCEEDINGS BY THE BOARD:

PQCB 242nd meeting held on **14-04-2022**

4. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **242nd meeting** held on **14-04-2022** under the Chairmanship of Secretary Primary & Secondary Healthcare Department, Punjab in the presence of Board members**.** Mr. Amtiaz Aslam Secretary DQCB District Gujrat and Mr. Rana Muhammad Akram Drug Inspector, Tehsil & District Sarai Alamgir, Gujrat were present along-with original case record. No-one from the nominated accused persons was present, however, Counsel Person of the firm Saeed Anjum Khokhar (Advocate) was present on behalf of **M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi** along-with representative from the firm, Muhammad Ali Mujahid (Compliance Co-Ordinator). The Board after due deliberation and discussion unanimously decided to **Pend** the case.

5. Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 10

PQCB/R-652/2021

Tehsil & District Hafizabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan through** its Managing Director, Erum Shakir Rahim 2. Erum Shakir Rahim — Managing Director 3. Saqib Azmat — Production Incharge 4. Khurram Ahmad — Quality Control Incharge 5. Nasir Aleem — Warrantor of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 25-10-2020, inspected the premises of Main Medicine Store, CEO Health Office 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. 76921 dated 05-11-2020)

ii. The subject drug sample after test/analysis, was declared **Substandard and Misbranded** 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
Suspension. ZENTEL 10ml [Each 5ml contains: Albendazole U.S.P 200mg] **Mfg Date** July 2020 **Expiry Date** July 2023 **Regn No.** 006730	LV9U	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.	01-68006103/ DTL Dated 06-01-2021	**Analysis with specifications applied:** MS **DESCRIPTION:** White color suspension with orange odor contained in amber color glass bottle sealed and caped with aluminum cap, packed in outer hard carton. **NOTE: Manufacturer specifies "U.S.P. Specifications" on the label of Immediate container as well as on outer unit carton. But in USP 2020, Monograph of Albendazole Oral suspension clearly mention in "Labeling: Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drugs Act 1976, and is declared misbranded. (Does Not Comply)** **IDENTIFICATION:** Albendazole Identified **ASSAY:** Stated: 200mg / 5ml Determined: 210.638 mg / 5ml Percentage: 105.342 % (Complies) Limit: 90–110% (Manufacturer's Specifications) **pH:** Stated: 4.5 – 5.5 (Manufacturer's Specifications) Determined: **6.72 at 20°C (Does Not Comply)** **RESULT: Given sample is declared Sub-Standard with regards to pH Test and Misbranded with regards to Section 3 (s) (iv) of Drugs Act 1976.**

iii. Main Medicine Store, CEO Health Office District Complex Hafizabad provided Invoice/Warranty bearing numbers 20022469, 20022471, 20022842 dated 20-07-2020 issued by M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf, Karachi Pakistan, as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.

v. A copy of test/analysis report was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, 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 Substandard & Misbranded drug**

b. **Issuance of false warranty**

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

4. Personal hearing notice(s) issued to accused person(s) dated 29-03-2023

5. Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 11

PQCB/R-720/2020

Tehsil & District Hafizabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan through** its Managing Director, Erum Shakir Rahim 2. Erum Shakir Rahim — Managing Director 3. Saqib Azmat — Production Incharge 4. Khurram Ahmad — Quality Control Incharge 5. Nasir Aleem — Warrantor of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 10-08-2020, inspected the premises of Main Medicine Store, PHFMC Office Chak Chatta 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. 73315 dated 12-08-2020

ii. The subject drug sample after test/analysis, was declared **Substandard and Misbranded** 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
Suspension. ZENTEL 10ml [Each 5ml contains: Albendazole U.S.P 200mg] **Mfg Date** July 2020 **Expiry Date** July 2023 **Regn No.** 006730	L26A	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.	01-68005364/ DTL Dated 05-10-2020	**Analysis with specifications applied:** MS **DESCRIPTION:** White color suspension with orange odor contained in amber color glass bottle sealed and caped with aluminium cap, packed in outer hard carton. **NOTE: Manufacturer specifies "U.S.P. Specifications" on the label of Immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in "Labeling: Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drugs Act 1976, and is declared misbranded. (Does Not Comply)** **IDENTIFICATION:** Albendazole Identified **ASSAY:** Stated: 200mg / 5ml Determined: 191.622 mg / 5ml Percentage: 95.811 % (Complies) Limit: 90–110% (Manufacturer's Specifications) **pH:** Stated: 4.5 – 5.5 (Manufacturer's Specifications) Determined: **6.86 (Does Not Comply)** **RESULT: Given sample is declared Sub-Standard with regards to pH Test and Misbranded with regards to Section 3 (s) (iv) of Drugs Act 1976.**

iii. Main Medicine Store, PHFMC Office Chak Chatta Hafizabad provided Invoice/Warranty bearing numbers 20022846, 20022470 dated 20-07-2020 issued by M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi, Pakistan, as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.

v. A copy of test/analysis report was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, 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 Substandard & Misbranded drug**

b. **Issuance of false warranty**

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

4. Personal hearing notice(s) issued to accused person(s) dated 29-03-2023

5. Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 12

DISTRICT JHANG

PQCB/R-495/2020

Tehsil & District Jhang

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan through** its Managing Director Erum Shakir Rahim 2. Erum Shakir Rahim — Managing Director 3. Saqib Azmat — Production Incharge 4. Khurram Ahmad — Quality Control Incharge 5. Nasir Aleem — Warrantor of **M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, District Jhang reported that: -

i. His Predecessor, on 01-06-2020, inspected the premises of medicine store office of the MSD O/O CEO DHA Jhang and took drug samples on Form No. 04 and sent the sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 0000067030 dated 01-06-2020 for the purpose of test and analysis.

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

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension Zentel 10ml [Each 5ml contains: Albendazole USP. 200mg] **Mfg date:** 03-2020 **Exp date:** 03-2023 **Regn. No.** 006730	VS7F	M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.	TRA No. 01-68004448/DTL Dated:25-07-2020	**Results of test/Analysis with specifications applied** MS **Description:** White color suspension with orange odor contained in amber color glass bottle sealed and caped with aluminium cap, packed in outer hard carton. **NOTE: Manufacturer specifies "USP" Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral Suspension clearly mention in "Labeling: Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specifications is false/misleading which is in violation to Drug Act 1976 and is declared misbranded. (Does not comply).** **Identification:** Albendazole Identified. **Assay** Stated: 200mg/5ml Determined: 188.757mg/5ml Percentage: 94.378% (Complies Limit: 90-110% **(Manufacturer's Specifications)** **pH:** Stated: 4.5-5.5 (Manufacturer's specifications) Determined: 6.73 at 25°C **(Does not comply)** **Result:** **Given sample is declared Substandard with regards to pH test and Misbranded with regards to Section 3 (s) (iv) of Drugs Act 1976.**

iii. Provincial inspector of drugs seized the said drug sample vide Form 5 dated 22-08-2020.

iv. Store incharge of medicine store office of the MSD O/O CEO DHA Jhang provided Invoice/Warranty No. 20015044 dated 16-05-2020 issued by M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan as a proof of purchase.

v. Warrantor portion and a copy of test report of drug sample were sent to M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan with directions to provide the requisite information and to explain their position in this regard.

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

i. **Manufacturing for Sale /Sale of Substandard & Misbranded Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 19-12-2022.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 03-2020**
- **Expiry Date: 03-2023**
- **Sampling Date (Form 4): 01-06-2020**
- **Sent to DTL (Form 6): 01-06-2020**
- **Date of receipt in DTL: 02-06-2020**
- **DTL Report Date (Form 7): 25-07-2020**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 17-09-2020**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 05-09-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 13

PQCB R-608/2020

Tehsil and District Khanewal

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir Managing Director 3. Imtiaz Hussain Production Incharge 4. Khalid Mehmood Sheikh Quality Operation Head 5. Nasir Aleem Qureshi Warrantor of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Khanewal reported that:-

i. His predecessor, on 27-07-2020, inspected the premises of Medicine Store, CEO (DHA) Khanewal and took samples of three different type of drugs on Form No. 04 for the purpose of test and analysis and sent to Drug Testing Laboratory, Multan.

ii. One out of these three drug samples, after test/ analysis was declared **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory, Multan as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension. ZENTEL (Albendazole 200mg/5ml)	L25Y	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No.01-87002179/DTL dated: 17-09-2020	**Analysis with specifications applied:** MS **Description:** White to off white color suspension in amber glass bottle sealed with aluminum cap packed in a labeled outer hard carton. **Product States "USP specifications" as a finished Drug product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in "Labelling: *Label it to indicate that it is for Veterinary use only*" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded.** **(Misbranded) Does not comply.** **Identification:** Albendazole identified. **Assay: Albendazole** Stated: 200mg/5ml Determined: 195.30 mg/5ml Percentage: 97.65% Limit: 90-110% **(Complies)** **pH:** Range: 4.5-5.5 **Determined: 6.87 at 25^0** **Does not comply.** **Result:** The above sample is **Misbranded**, as defined under section 3(s)(iv) of the drugs act, 1976 and is **Sub-standard** on the basis of pH test performed.

iii. Store keeper Medicine Store, CEO (DHA) Khanewal provided invoice/ Warranty No. 20022450 dated 27-07-2020 issued by GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase.

iv. Copy of test report was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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)/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 07-03-2022.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 14

DISTRICT KHUSHAB

PQCB/R-617/2020

Tehsil & District Khushab

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxosmithKline Pakistan Limited 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan through** its Director Maheen Rehman 2. Maheen Rehman — Director 3. Muhammad Nasir Khan — Production Incharge 4. Faheem Ud Din Bhutto — Quality Control Incharge 5. Nasir Aleem Qureshi — Warrantor of **M/s GlaxosmithKline Pakistan Limited 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, District Khushab reported that: -

i. His Predecessor, on 09-07-2020, inspected the premises of medicine store of DHA Khushab and took two different drug samples on Form No. 04 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi.

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

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension Zentel 10ml [Each 5ml contains: Albendazole USP. 200mg] **Mfg date:** 03-2020 **Exp date:** 03-2023 **Regn. No.** 006730	VS7F	M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.	TRA No. 01-71001154/DTL Dated:26-08-2020	**Results of test/Analysis with specifications applied** MS **Description:** White to off-white coloured, viscous suspension having characteristic odour, filled in single dose amber coloured glass bottle with affixed label, sealed with golden coloured Aluminium screw cap imprinted with ''GSK'', further packed in labelled unit carton. **Manufacturer specifies ''U.S.P Specifications" on the label of Immediate container as well as on outer carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in Labeling that ''Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use** **(DOES NOT COMPLY)**. **PH:** **Observed: 6.635 at 25^{O}C (DOES NOT COMPLY)** Limit: 4.5-5.5 **IDENTIFICATION:** Albendazole Identified **ASSAY:** Stated: 200mg/5ml; Determined: 213.234mg/5ml; Percentage: 103.63%; Limit: 90-110% **RESULT: The above sample is ''Substandard" on the basis of PH test performed and ''Misbranded" as defined under clause (iv) of sub-section (s) of section 3 of The Drug Act 1976.**

iii. Store keeper of medicine store of DHA Khushab provided Invoice/Warranty No. 20015198 dated 18-05-2020 issued by **M/s GlaxosmithKline Pakistan Limited 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan** as a proof of purchase.

iv. Warrantor portion of the drug sample was sent to **M/s GlaxosmithKline Pakistan Limited 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan**

v. Copy of test report of drug sample was sent to **M/s GlaxosmithKline Pakistan Limited 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan** with directions to provide the requisite information and to explain their position in this regard.

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

i. **Manufacturing for Sale /Sale of Misbranded & Substandard Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 10-03-2022.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 03-2020**
- **Expiry Date: 03-2023**
- **Sampling Date (Form 4): 09-07-2020**
- **Sent to DTL (Form 6): 09-07-2020**
- **Date of receipt in DTL: 20-07-2020**
- **DTL Report Date (Form 7): 26-08-2020**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 24-10-2020**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 01-01-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 15

PQCB R-581/2020

Tehsil and District Layyah

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir Managing Director 3. Imtiaz Hussain Production Incharge 4. Khalid Mehmood Sheikh Quality Operation Head 5. Nusrat Khaliq Operational Quality Manager **of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Tehsil Layyah, District Layyah reported that: -

i. His predecessor, on 03-06-2020, inspected the premises of Medicine Store of CEO (DHA) Office Layyah and took samples of four different type of drugs on Form No. 04 for the purpose of test and analysis.

ii. One out of these five drug samples, after test/ analysis was declared **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory, Multan as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension. ZENTEL (Albendazole 200mg/5ml)	VS7F	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No.01-87001051/DTL dated: 04-08-2020	**Analysis with specifications applied:** MS **Description:** White to off white color suspension in amber glass bottle sealed with aluminum cap packed in a labeled outer hard carton. **Product States "USP specifications" as a finished Drug product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in "Labelling: *Label it to indicate that it is for Veterinary use only*" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded.** **(Misbranded) Does not comply.** **Identification:** Albendazole identified. **Assay: Albendazole** Stated: 200mg/5ml Determined: 203.52 mg/5ml Percentage: 101.76% Limit: 90-110% **(Complies)** **pH:** Range: 4.5-5.5 **Determined: 6.79 at 25^0** **Does not comply.** **Result:** The above sample is **Misbranded**, as defined under section 3(s)(iv) of the drugs act, 1976 and is **Sub-standard** on the basis of pH test performed.

iii. Store keeper of Medicine Store of CEO (DHA)Layyah provided invoice/ Warranty No. 20015549 dated 20-05-2020 issued by M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase.

iv. Warrantor portion and copy of test report was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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)/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 13-12-2021

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 16

PQCB R-582/2020

Tehsil Chaubara, District Layyah

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir Managing Director 3. Imtiaz Hussain Production Incharge 4. Khalid Mehmood Sheikh Quality Operation Head 5. Nusrat Khaliq Operational Quality Manager of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi. 6. Bilal Ahmad Qureshi S/O Fazeel Ahmad Qureshi Proprietor of **M/s Vikor Enterprises Pvt Ltd 110,M Industrial Estate Kot Lakhpat, Lahore** 7. Farhan Awais Balouch S/o Sardar Imran Bakhsh Proprietor of **M/s Balouch Enterprises House No. 307, TDA near MC Girls School Layyah**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Tehsil Choubara, District Layyah reported that: -

i. He, on 24-09-2020, inspected the business premises of M/s Nadeem Medical Store, Tehsil Chaubara District Layyah and took samples of two different type of drugs on Form No. 04 for the purpose of test and analysis.

ii. One out of these two drug samples, after test/ analysis was declared **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory, Multan as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension. ZENTEL (Albendazole 200mg/5ml)	K38N	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No.01-89000463/DTL dated: 23-11-2020	**Analysis with specifications applied:** MS **Description:** White to off white color suspension in amber glass bottle sealed with aluminum cap packed in a labeled outer hard carton. **Product States "USP specifications" as a finished Drug product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in "Labelling: *Label it to indicate that it is for Veterinary use only*" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded.** **(Misbranded) Does not comply.** **Identification:** Albendazole identified. **Assay: Albendazole** Stated: 200mg/5ml Determined: 200.7 mg/5ml Percentage: 100.35% Limit: 90-110% **(Complies)** **pH:** Range: 4.5-5.5 **Determined: 6.75 at 25^0** **Does not comply.** **Result:** The above sample is **Misbranded**, as defined under section 3(s)(iv) of the drugs act, 1976 and is **Sub-standard** on the basis of pH test performed.

iii. M/s Nadeem Medical Store, Tehsil Chaubara District Layyah provided invoice/ Warranty No. SOB-0006155 dated 09-09-2020 issued by M/s Baloch Enterprises Layyah who in turn provided invoice/warranty No. L00005488 Dated 14-07-2020 issued by M/s Vikor Enterprises Pvt Ltd 110,M Industrial Estate Kot Lakhpat, Lahore who in turn provided invoice/warranty No. 20020435 Dated 09-07-2020 issued by M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Balouch Enterprises Layyah with directions to explain their position in this regard.

v. Copy of test report was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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)/DRAP Act 2012 and Rules framed there under by the way of: -

1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir Managing Director 3. Imtiaz Hussain Production Incharge 4. Khalid Mehmood Sheikh Quality Operation Head 5. Nusrat Khaliq Operational Quality Manager of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi	a. **Manufacture for Sale / Sale of Misbranded Drug.** b. **Issuance of false warranty**
6. Bilal Ahmad Qureshi S/O Fazeel Ahmad Qureshi Proprietor of **M/s Vikor Enterprises Pvt Ltd 110,M Industrial Estate Kot Lakhpat, Lahore**	a. **Stocking for sale / Sale of Misbranded & Substandard drug** b. **Issuance of false warranty**
7. Farhan Awais Balouch S/o Sardar Imran Bakhsh Proprietor of **M/s Balouch Enterprises House No. 307, TDA near MC Girls School Layyah**	a. **Stocking for sale / Sale of Misbranded & Substandard drug without valid authorization letter from licensed pharmaceutical manufacturer as his authorized agent**

3. Show cause notice(s) issued to the accused vide 13-12-2021

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 17

DISTRICT LODHRAN

PQCB/R-444/2020

Tehsil & District Lodhran

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E, Karachi Pakistan** through its Chief Executive Officer Erum Shakir Rahim 2. Erum Shakir Rahim — Chief Executive Officer 3. Khurram Rafiq Ahmed — Quality Control Incharge 4. Khalid Mahmood — Production Incharge 5. Samreen Yamin Khan — Compliance Coordinator 6. Abdul Fazal — Assistant Manager Warehouse **Of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E, Karachi Pakistan** 7. Bilal Ahmed Qureshi — Warrantor/ Proprietor 8. Syed Faheem Abbas — Qualified Person 9. Abdul Samad Udhi — Company Secretary **Of M/s Vikor Enterprises, 17-A, Birdwood Road, Lahore.** 10. Mazhar Jamal Khakwani — Warrantor/Proprietor 11. Jawad Haider Somra — Proprietor 12. Niaz Ahmed Sheikh — Qualified Person **Of M/s Pharma Traders House No. 1-C, Model Town A, Gulberg Road, Bahawalpur** 13. Farrukh Mansoob — Proprietor 14. Muhammad Arif — Qualified Person

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Lodhran reported that: -

i. He, on 22-08-2020, inspected the business premises of M/S Ayoob Medical Store, Ganga Wala Lodhran and took a drug sample on Form No.04 for the purpose of test and analysis.

ii. The drug sample after test/ analysis, was declared as **Substandard and Misbranded** by Government Analyst Drug Testing Laboratory **Multan**, 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>Susp. ZENTEL (Albendazole 200mg/5ml)</td><td>F43C</td><td>M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi Pakistan</td><td>TRA No.01-89000068/DTL

dated: 10-10-2020</td><td>
Result of test/Analysis with specifications applied: MS

<u>Description</u>: White to off white color suspension in amber glass bottle sealed with aluminum cap packed in a labelled outer hard carton.

Product States “USP specifications” as a Finished Drug Product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in “Labelling: Label it to indicate that it is for Veterinary use only” whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded.

(Mis-Branded) Does not comply.

<u>Identification:</u> Albendazole identified.

<u>Assay: Albendazole</u>
<table>
<tr><td>Stated</td><td>200mg/5ml</td></tr>
<tr><td>Determined</td><td>189.20 mg/5ml</td></tr>
<tr><td>Percentage</td><td>94.6%</td></tr>
<tr><td>Limit</td><td>90-110%</td></tr>
</table>
(Complies)

<u>pH:</u>
<table>
<tr><td>Range</td><td>4.5-5.5</td></tr>
<tr><td><u>Determined</u></td><td><u>6.76 at 25^{0}C</u></td></tr>
</table>
(Does not comply).

<u>Result</u>: The above sample is <u>Misbranded</u>, as defined under section 3(s)(iv) of the Drugs Act, 1976 and is <u>Sub-standard</u> on the basis of pH test performed.
</td></tr>
</table>

iii. The chemist M/S Ayoob Medical Store, Ganga Wala Lodhran provided Invoice/warranty No. R310866, dated 06-08-2020 issued by M/s Pharma Traders House No. 1-C, Model Town A, Gulberg Road, Bahawalpur as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M M/s Pharma Traders House No. 1-C, Model Town A, Gulberg Road, Bahawalpur who provided invoice/ warranty no. L00005280 dated 30-06-2020 issued by M/S Vikor Enterprises.

v. A copy of test/analysis report was sent to M/S Vikor Enterprises who inturn provided invoice/warranty no. 20018835 dated 24-06-2020 issued by M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E, Karachi Pakistan .

vi. M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E, Karachi Pakistan was directed to provide the requisite information and to explain their position in this regard.

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

i. **Manufacturing for Sale /Sale of Misbranded & Substandard Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 25-05-2021.

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

Case is placed before the Board for Decision

<u>Summary:</u>

- **Manufacturing Date: 06-2020**
- **Expiry Date: 06-2023**
- **Sampling Date (Form 4): 22-08-2020**
- **Sent to DTL (Form 6): 25-08-2020**
- **Date of receipt in DTL: 27-08-2020**
- **DTL Report Date (Form 7): 10-10-2020**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 26-12-2020**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 12-04-2021**

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

Case No. 18

PQCB/R-671/2020

Tehsil & District Mianwali

Sub-Standard (pH) & Misbrande

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir Managing Director 3. Khalid Mehmood Shah Quality Operation Head 4. Imtiaz Hussain Production Manager 5. Nasir Aleem Qureshi Warrantor of **M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.**

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 22-07-2020, inspected the premises of Main Medicine Store of CEO-DHA Office, Mianwali and took sample of two different types of drugs on Form No.04 for the purpose of test/analysis and send the sample to Drug Testing Laboratory, Rawalpindi.

ii. The drug sample, after test/analysis, was declared Substandard and Misbranded 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 ZENTEL 10ml [Albendazole 200mg/ 5ml] **Mfg. Date:** 03/2020 **Exp. Date:** 03-2023 **Reg. No.** 006730	VS7F	M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No. 01-71001190/DTL dated:20-08-2020	**Analysis with specifications applied:** Manufacturer's Specifications **Description:** Whit to off-white colored viscous suspension having characteristic odour, filled in single dose amber colored glass bottle with affixed label, sealed with golden colored aluminum screw cap imprinted with "GSK", further packed in labelled unit carton. **Note: Manufacturer specifies "U.S.P. Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral Suspension clearly mention in "Labelling: Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. (Does not Comply)** **Identification:** Albendazole identified. **Assay:** Stated: 200 mg/5ml Determined: 209.956 mg/ 5ml Percentage: 104.98 % (Complies) Limit: 90-110% (Manufacturer's Specifications) **pH:** Stated: 4.5-5.5 (Manufacturer's Specifications) Determined: **6.682 at 25°C (Does not comply)** **RESULT:** **Given sample is declared Substandard with regards to pH Test and Misbranded with regards to Section 3 (s) (iv) of Drugs Act 1976.**

iii. On 21-09-2020, he took the remaining stock of Substandard & Misbranded drug on Form 3 with directions to not to dispose-off the stock.

iv. Store keeper of Main Medicine Store of CEO-DHA Office, Mianwali, provided invoice/ warranty/ no. 20018612 dated 23-06-2020 issued by M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase of the said drug.

v. Warrantor portion of the drug sample was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.

vi. A copy of test report of the drug sample was sent **to** M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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. **Manufacture for Sale /Sale of Substandard & Misbranded Drug**
ii. **Issuance of false warranty**

3. Show-cause was issued to accused person(s) vide dated 03-06-2022.

REPLY OF THE FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

4. M/S Glaxo-Smith Kline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi submitted written reply stating that:

1. *That on 23-09-2020 the GSK informed the DRAP regarding an error on printing of product specification on packaging of its locally manufactured product Zentel suspension (RN 006730) because the patient safety remains GSK's utmost priority and in the interest of transparency. Therefore, the GSK made the DRAP aware about these details, anticipating a positive respond since the medical and quality assessment did not reveal any impact on the patient safety or product quality since product assay is well within the acceptable range of 90-110%.*
2. In response to the aforementioned letter the DRAP vide reply dated 25-09-2020 advised the GSK for
i. Stoppage of sale/distribution of mislabeled stocks of Zentel Suspension by distributors till further orders.
ii. Stoppage of release /supply of mislabeled stocks of Zentel Suspension lying at Company's own warehouse /distribution channels till further orders.
iii. Further manufacturing of Zentel Suspension will only be carried in rectification packaging.
That in compliance with DRAP's instructions GSK Pakistan immediately recalled mentioned batches of Zentel Suspension from distributors/channel partners and informed the DRAP in respect thereof. And also provided the details of the Zentel-Suspension quantities lying at our warehouse and distributors with the confirmation of not to release any further stock of the product to the market till DRA's decision /advice in this regard and also asked to kindly allow the firm to kindly allow us to consume existing stocks of Zentel-Suspension in order to maintain smooth supplies and avoid any shortages in the market while providing assurance that the future stocks/supplies will only be released with correct specification (GSK Specification) printed on them.
3. That the GSK received the recall letter from DRAP notifying the firm to recall the stocks of all the
suspected batches as part of the recall strategy and submit the compliance report as a requirement of the recall letter.
4. That the GSK submitted the status of the recall initiated for Zentel Suspension to the DRAP on dated 30-11-2020 as well as the compliance report as per the completion of the recall by GSK in regards to the requirements bestowed by DRAP and also provided details of the recalled stocks and product quantities lying at the warehouse and the distributor end and also providing information about communication to the distributor and acknowledgment regarding stoppage of supply to the pharmacies. and return of the stocks. Additionally, details were also provided for the stock existing at the Vikor enterprises warehouse with additional instructions also provided for recalling all available stock of Zentel-Suspension from all outlets and tracking of all the said batches of Zentel-Suspension with immediate communication to the firm.
5. That the GSK also requested the DRAP for the grant of permission to allow redressing of the mentioned stocks at the GSK Pakistan's licensed premises, in alignment with the completed recall of the product Zentel-Suspension from the distributors/channel partners.

6. That the GSK submitted the compliance report for additional batches for the product Zentel Suspension to the DRAP on dated 02-02-2021 as per the requirements bestowed by DRAP. The Zentel-Suspension recall stock verification was also duly verified by the area FID with the GSK team.

7. That the recalled stock for the drug product Zentel Suspension was also duly verified by the Area FID with the GSK team at the connect warehouse Zentel Suspension Recall Stock Verification.

8. That the GSK received a letter from the DRAP dated 28th October 2021, notifying GSK about the

suspension of the registration of the said product Zentel Suspension for 6 months or till decision of

registration board for verification of root cause analysis by duly designated panel members as well as providing approval to GSK for redressing the requested 14 batches by printing relevant specifications and complying drugs (labelling & packing) rules, 1986 and release of the batches by Quality Assurance Department as per their approved specifications and approved protocols for their work.

9. That the GSK received a letter from the DRAP dated 12 November 2021, notifying GSK about the

confirmation of the verification of the root cause analysis by duly designated panel members on 11-11-2021 and providing the detailed inspection report for further necessary action indicating that the firm had satisfactorily identified the gaps caused by the labelling error and also taken the necessary actions to avoid such errors in the future and recommending the resumption of the Zentel liquid production in larger public interest as there may be acute shortage of quality drug in the market.

10. That this Hon 'able Board heard the same case of another Batch i.e. Zentel Suspension Batch L25Y GSK on 13-03-2021 and vide order dated 13th March 2021 issued a warning to the answering Company M/S GlaxoSmithKline Pakistan Limited, F/268 S.I.T.E, to be careful in future, by acknowledging that the firm has submitted the rectified label in response to the labelling error deeming the product to be declared Misbranded. The board also observed the ph test complies with the limits if manufacturer specifications were considered instead of USP aspects.
11. That finally the answering respondent company GSK has received a letter from the DRAP dated 9th February 2022, notifying GSK about the satisfactory testing results of the analysis conducted by the Central Drugs Laboratory pertaining to the 14 redressed batches of Zentel Suspension duly declaring the batches to be complied with the standard specifications as mentioned in the updated test method for Zentel Suspension. Being a responsible Pharmaceutical Company, we ensure our full support as usual, for any further support in this regard.

4. Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 19

PQCB/R-672/2020

Tehsil & District Mianwali

Sub-Standard (pH) & Misbrande

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir Managing Director 3. Khalid Mehmood Shah Quality Operation Head 4. Imtiaz Hussain Production Manager 5. Nasir Aleem Qureshi Warrantor of **M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.**

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 21-07-2020, inspected the premises of Main Medicine Store of CEO-DHA Office, Mianwali and took sample of three different types of drugs on Form No.04 for the purpose of test/analysis and send the sample to Drug Testing Laboratory, Rawalpindi.

ii. The drug sample, after test/analysis, was declared Substandard and Misbranded 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 ZENTEL 10ml [Albendazole 200mg/ 5ml] **Mfg. Date:** 04-2020 **Exp. Date:** 04-2023 **Rg No.** 006730	YU5P	M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No. 01-71001188/DTL dated:20-08-2020	**Analysis with specifications applied:** Manufacturer's Specifications **Description:** Whit to off-white colored viscous suspension having characteristic odour, filled in single dose amber colored glass bottle with affixed label, sealed with golden colored aluminum screw cap imprinted with "GSK", further packed in labelled unit carton. **Note: Manufacturer specifies "U.S.P. Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral Suspension clearly mention in "Labelling: Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. (Does not Comply)** **Identification:** Albendazole identified. **Assay:** Stated: 200 mg/5ml Determined: 194.819 mg/ 5ml Percentage: 97.41 % (Complies) Limit: 90-110% (Manufacturer's Specifications) **pH:** Stated: 4.5-5.5 (Manufacturer's Specifications) Determined: **6.714 at 25°C (Does not comply)** **RESULT:** **Given sample is declared Substandard with regards to pH Test and Misbranded with regards to Section 3 (s) (iv) of Drugs Act 1976.**

iii. On 21-09-2020, he took the remaining stock of Substandard & Misbranded drug on Form 3 with directions to not to dispose-off the stock.

iv. Store keeper of Main Medicine Store of CEO-DHA Office, Mianwali, provided invoice/ warranty/ no. 20017133 dated 10-06-2020 issued by M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase of the said drug.

v. Warrantor portion of the drug sample was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.

vi. A copy of test report of the drug sample was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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. **Manufacture for Sale /Sale of Substandard & Misbranded Drug**
ii. **Issuance of false warranty**

3. Show-cause was issued to accused person(s) vide dated 03-06-2022.

REPLY OF THE FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

4. M/S Glaxo-Smith Kline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi submitted written reply stating that:

1. *That on 23-09-2020 the GSK informed the DRAP regarding an error on printing of product specification on packaging of its locally manufactured product Zentel suspension (RN 006730) because the patient safety remains GSK's utmost priority and in the interest of transparency. Therefore, the GSK made the DRAP aware about these details, anticipating a positive respond since the medical and quality assessment did not reveal any impact on the patient safety or product quality since product assay is well within the acceptable range of 90-110%.*
2. In response to the aforementioned letter the DRAP vide reply dated 25-09-2020 advised the GSK for
i. Stoppage of sale/distribution of mislabeled stocks of Zentel Suspension by distributors till further orders.
ii. Stoppage of release /supply of mislabeled stocks of Zentel Suspension lying at Company's own warehouse /distribution channels till further orders.
iii. Further manufacturing of Zentel Suspension will only be carried in rectification packaging.
That in compliance with DRAP's instructions GSK Pakistan immediately recalled mentioned batches of Zentel Suspension from distributors/channel partners and informed the DRAP in respect thereof. And also provided the details of the Zentel-Suspension quantities lying at our warehouse and distributors with the confirmation of not to release any further stock of the product to the market till DRA's decision /advice in this regard and also asked to kindly allow the firm to kindly allow us to consume existing stocks of Zentel-Suspension in order to maintain smooth supplies and avoid any shortages in the market while providing assurance that the future stocks/supplies will only be released with correct specification (GSK Specification) printed on them.
3. That the GSK received the recall letter from DRAP notifying the firm to recall the stocks of all the
suspected batches as part of the recall strategy and submit the compliance report as a requirement of the recall letter.
4. That the GSK submitted the status of the recall initiated for Zentel Suspension to the DRAP on dated 30-11-2020 as well as the compliance report as per the completion of the recall by GSK in regards to the requirements bestowed by DRAP and also provided details of the recalled stocks and product quantities lying at the warehouse and the distributor end and also providing information about communication to the distributor and acknowledgment regarding stoppage of supply to the pharmacies. and return of the stocks. Additionally, details were also provided for the stock existing at the Vikor enterprises warehouse with additional instructions also provided for recalling all available stock of Zentel-Suspension from all outlets and tracking of all the said batches of Zentel-Suspension with immediate communication to the firm.
5. That the GSK also requested the DRAP for the grant of permission to allow redressing of the mentioned stocks at the GSK Pakistan's licensed premises, in alignment with the completed recall of the product Zentel-Suspension from the distributors/channel partners.

6. That the GSK submitted the compliance report for additional batches for the product Zentel Suspension to the DRAP on dated 02-02-2021 as per the requirements bestowed by DRAP. The Zentel-Suspension recall stock verification was also duly verified by the area FID with the GSK team.

7. That the recalled stock for the drug product Zentel Suspension was also duly verified by the Area FID with the GSK team at the connect warehouse Zentel Suspension Recall Stock Verification.

8. That the GSK received a letter from the DRAP dated 28th October 2021, notifying GSK about the

suspension of the registration of the said product Zentel Suspension for 6 months or till decision of

registration board for verification of root cause analysis by duly designated panel members as well as providing approval to GSK for redressing the requested 14 batches by printing relevant specifications and complying drugs (labelling & packing) rules, 1986 and release of the batches by Quality Assurance Department as per their approved specifications and approved protocols for their work.

9. That the GSK received a letter from the DRAP dated 12 November 2021, notifying GSK about the

confirmation of the verification of the root cause analysis by duly designated panel members on 11-11-2021 and providing the detailed inspection report for further necessary action indicating that the firm had satisfactorily identified the gaps caused by the labelling error and also taken the necessary actions to avoid such errors in the future and recommending the resumption of the Zentel liquid production in larger public interest as there may be acute shortage of quality drug in the market.

10. That this Hon 'able Board heard the same case of another Batch i.e. Zentel Suspension Batch L25Y GSK on 13-03-2021 and vide order dated 13th March 2021 issued a warning to the answering Company M/S GlaxoSmithKline Pakistan Limited, F/268 S.I.T.E, to be careful in future, by acknowledging that the firm has submitted the rectified label in response to the labelling error deeming the product to be declared Misbranded. The board also observed the ph test complies with the limits if manufacturer specifications were considered instead of USP aspects.
11. That finally the answering respondent company GSK has received a letter from the DRAP dated 9th February 2022, notifying GSK about the satisfactory testing results of the analysis conducted by the Central Drugs Laboratory pertaining to the 14 redressed batches of Zentel Suspension duly declaring the batches to be complied with the standard specifications as mentioned in the updated test method for Zentel Suspension. Being a responsible Pharmaceutical Company, we ensure our full support as usual, for any further support in this regard.

4. Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 20

PQCB R-609/2020

Tehsil and District Muzaffargarh

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir 2. Iram Shakir — Managing Director 3. Imtiaz Hussain — Production Incharge 4. Khalid Mehmood Sheikh — Quality Operation Head 5. Nasir Aleem Qureshi — Warrantor of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Muzaffargarh reported that:-

i. He, on 21-08-2020, inspected the premises of Medicine Store of Chief Executive Officer DHA, Tehsil & District Muzaffargarh and took samples of eight different type of drugs on Form No. 04 for the purpose of test and analysis and sent it to Drug Testing Laboratory, Multan.

ii. One out of these eight drug samples, after test/ analysis was declared **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory, Multan as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension. ZENTEL (Albendazole 200mg/5ml)	L26A	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No.01-87002508/DTL dated: 05-10-2020	**Analysis with specifications applied:** MS **Description:** White to off white color suspension in amber glass bottle sealed with aluminum cap packed in a labeled outer hard carton. **Product States "USP specifications" as a finished Drug product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in "Labelling: *Label it to indicate that it is for Veterinary use only*" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded.** **(Misbranded) Does not comply.** **Identification:** Albendazole identified. **Assay: Albendazole** Stated: 200mg/5ml Determined: 187.82 mg/5ml Percentage: 93.91% Limit: 90-110% **(Complies)** **pH:** Range: 4.5-5.5 **Determined: 6.82 at 25^0** **Does not comply.** **Result:** The above sample is **Misbranded**, as defined under section 3(s)(iv) of the drugs act, 1976 and is **Sub-standard** on the basis of pH test performed.

iii. Medicine Store of Chief Executive Officer DHA, Tehsil & District Muzaffargarh provided invoice/ Warranty No. 20022876 dated 29-07-2020 issued by M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi with directions to explain their position in this regard.

v. Copy of test report was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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)/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 07-03-2022.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 21

PQCB R-517/2020

Tehsil Jatoi, District Muzaffargarh

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Chief Executive Officer Erum Shakir Rahim 2. Erum Shakir Rahim — Chief Executive Officer/G.M 3. Muhammad Nasir Khan — Production Incharge 4. Gohar Siddiqui — Quality Control Incharge 5. Muhammad Nasir Khan — Pharmacist 6. Khurram Rafiq Ahmed — Pharmacist 7. Khalid Mehmood Mirza — Pharmacist 8. Saqib Azmat — Pharmacist 9. Arshad Ali — Pharmacist 10. GlaxoSmithKline Pakistan Limited — Warrantor 11. Samreen Yamin Khan — Compliance-Coordinator of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Tehsil Jatoi, District Muzaffargarh reported 0that: -

i. He, on 07-10-2020, inspected the premises of Medicine Store of THQ Hospital Jatoi, District Muzaffargarh and took samples of five different type of drugs on Form No. 04 for the purpose of test and analysis.

ii. One out of these five drug samples, after test/ analysis was declared **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory, Multan as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension. ZENTEL (Albendazole 200mg/5ml)	L25Y	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No.01-89000483/DTL dated: 24-10-2020	**Analysis with specifications applied:** MS **Description:** White to off white color suspension in amber glass bottle sealed with aluminum cap packed in a labeled outer hard carton. **Product States "USP specifications" as a finished Drug product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in "Labelling: *Label it to indicate that it is for Veterinary use only*" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded.** **(Misbranded) Does not comply.** **Identification:** Albendazole identified. **Assay: Albendazole** Stated: 200mg/5ml Determined: 193 mg/5ml Percentage: 96.5% Limit: 90-110% **(Complies)** **pH:** Range: 4.5-5.5 **Determined: 6.84 at 25^0** **Does not comply.** **Result:** The above sample is Misbranded, as defined under section 3(s)(iv) of the drugs act, 1976 and is **Sub-standard** on the basis of pH test performed.

iii. Store keeper of Medicine Store of THQ Hospital Jatoi, District Muzaffargarh provided invoice/ Warranty No. 20022456 dated 27-07-2020 issued by M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase.

iv. Warrantor portion and copy of test report was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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)/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 16-07-2021.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 22

PQCB R-610/2020

Tehsil Kot Addu, District Muzaffargarh

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Eram Shakir 2. Eram Shakir Managing Director 3. Imtiaz Hussain Production Incharge 4. Khalid Mehmood Sheikh Quality Operation Head 5. Nasir Aleem Qureshi Warrantor of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Tehsil Kot Addu District Muzaffargarh reported that:-

i. He, on 22-09-2020, inspected the premises of Medicine Store THQ Level 50 bedded Hospital chowk Sarwar Shaheed Tehsil Kot Addu, District Muzaffargarh and took samples of five different type of drugs on Form No. 04 for the purpose of test and analysis.

ii. One out of these five drug samples, after test/ analysis was declared **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory, Multan as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension. ZENTEL (Albendazole 200mg/5ml)	VS7F	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.	TRA No.01-89000385/DTL dated: 24-10-2020	**Analysis with specifications applied:** MS **Description:** White to off white color suspension in amber glass bottle sealed with aluminum cap packed in a labeled outer hard carton. **Product States "USP specifications" as a finished Drug product specification on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in "Labelling: *Label it to indicate that it is for Veterinary use only*" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976, and is declared Misbranded.** **(Misbranded) Does not comply.** **Identification:** Albendazole identified. **Assay: Albendazole** Stated: 200mg/5ml Determined: 184.64 mg/5ml Percentage: 92.32% Limit: 90-110% **(Complies)** **pH:** Range: 4.5-5.5 **Determined: 6.79 at 25^0** **Does not comply.** **Result:** The above sample is **Misbranded**, as defined under section 3(s)(iv) of the drugs act, 1976 and is **Sub-standard** on the basis of pH test performed.

iii. Store keeper Medicine Store THQ Level 50 bedded Hospital chowk Sarwar Shaheed Tehsil Kot Addu, District Muzaffargarh provided invoice/ Warranty No. 20022876 dated 30-07-2020 issued by M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi with directions to explain their position in this regard.

v. Copy of test report was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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)/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 08-03-2022.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 23

PQCB R-694/2020

Tehsil and District Nankana Sahib

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi** through its Managing Director, Erum Shakir Rahim 2. Erum Shakir Rahim Managing Director 3. Saqib Azmat Production Manager 4. Khurram Ahmed Quality Control Manager 5. Nasir Aleem Warrantor Of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi.

BRIEF FACTS OF THE CASE

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

i. She, on 15-08-2020 inspected Main Medicine Store, Chief Executive Officer (Health), DHA, Nankana Sahib, took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No. 0000073747 Dated 19-08-2020.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Suspension. Zentel 10mL Suspension [Albendazole…200mg/5mL] Mfg. Date: 07-2020 Exp. Date: 07-2023 Reg # 006730	LV9U	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi.	01-143005533/ DTL dated: 16 Oct 2020	**Result of test/ analysis with specifications applied:** USP 2019 **PHYSICAL DESCRIPTION:** Off-white coloured uniform suspension in amber bottle with sealed screw cap. Claimed Volume: 10ml **pH** Limit: 4.5-5.5 Determined: **6.79 at 25.4C (Does not comply)** **IDENTIFICATION** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (Albendazole identified) **ASSAY:** Stated: 200mg/5mL Determined: 191.53mg/5mL Percentage 95.77% Limit: 90-110% Note: USP monograph of Albendazole Oral Suspension describes in additional requirements: "Labelling: Label it to indicate that it is for veterinary use only." **RESULT:** **The above sample is Sub-standard on the basis of pH performed as per USP.**

iii. The Store Keeper, Main Medicine Store, Chief Executive Officer (Health), DHA, Nankana Sahib provided warranty/invoice bearing No. 20022464/20022466/20022847 dated 27-07-2020, 27-07-2020, 29-07-2020 issued by M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan.

iv. Warrantor Portion was sent to M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan.

v. A copy of Test/ Analysis reports was sent to **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi** and they were directed to explain their position and provide requisite information in this regard.

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

i. **Manufacture for Sale/Sale of Misbranded Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated20-12-2022.

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

Summary:

Manufacturing Date: 06-2020

Expiry Date: 06-2023

Sampling Date: 22-08-2020

Sent to DTL (Form 6): 24-08-2020

Date of receipt in DTL: 26-08-2020

DTL Report Date: 23-10-20220

Time Extension: N/A

1ST DI Communication with firm on dated: 05-11-2020

Date of Retesting Request of Firm: -N/A

Fate of Retesting Request: -N/A

Investigation Report Dated: 03-09-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 24

PQCB/R-618/2020

Tehsil Khanpur, District Rahim Yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E., Karachi Pakistan through** its Managing Director Erum Shakir Rahim 2. Erum Shakir Rahim — Managing Director 3. Saqib Azmat — Production Incharge 4. Khurram Ahmed — Quality Control Incharge 5. Nasir Aleem — Warrantor of M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E., Karachi Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Khanpur, District Rahim Yar Khan reported that: -

i. His Predecessor, on 22-08-2020, inspected the business premises of M/s Al-Masoom Medical Store Adda Sehja Main Road Tehsil Khanpur, took a drug sample on Form No. 04 for the purpose of test/analysis and sent it to Drug Testing Laboratory Bahawalpur vide memorandum no. 73922 dated 24-08-2020.

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

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension Zentel [Albendazole 200mg/5ml] **Mfg. date**: 06-2020 **Exp. Date**: 06-2023 **Regn. No**: 006730	FX9X	M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.	TRA No. 01-77002252/DTL Dated: 21-10-2020	**Results of test/Analysis with specifications applied:** MS **Composition:** Each 5ml contains: Albendazole USP…… 200mg **Description:** A white to off white suspension with an orange odor contained in amber color glass bottle, sealed and caped with aluminium cap, packed in outer hard carton. (Stated volume: 10ml) **NOTE: Manufacturer specifies "USP Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral Suspension clearly mention in "Labeling: "Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer's claim of USP Specifications is false/misleading which is in violation to Drug Act 1976 and is declared misbranded. (Does not comply).** **pH:** Limit: ……..4.5-5.5 **Determined: ……7.024** **(Does not comply with specifications)** **Identification (MS):** Albendazole is Identified. **Assay (MS) Albendazole** Stated: 200mg/5ml Determined: 206.07mg/5ml Percentage: 103.04% Limit: 90-110% **Result:** The sample is declared **Substandard** on the basis of **pH** test and is **Misbranded** as defined under clause (vi) of subsection (s) of section 3 of Drug Act 1976**.**

iii. M/s Al-Masoom Medical Store Adda Sehja Main Road Tehsil Khanpur provided bill/warranty bearing invoice No. Aug/55141 dated 12-08-2020 issued by M/s Millat Agencies T.T.C Road Rahim Yar Khan.

iv. Warrantor portion of drug sample was sent to M/s Millat Agencies T.T.C Road Rahim Yar Khan.

v. M/s Millat Agencies T.T.C Road Rahim Yar Khan provided bill/warranty bearing invoice No. Aug/32386 dated 01-08-2020 issued by M/s Sunny Distributors Rahim Yar Khan who in turn provided bill/warranty bearing invoice No. S00500664 dated 04-07-2020 issued by M/s Vikor Enterprises Pvt Ltd., Plot No. Z 2-A S.I.T.E Manghopir Road Karachi, who in turn provided bill/warranty bearing invoice No. 20019065 dated 25-06-2020 and 20019880 dated 03-07-2020 issued by M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan as a proof of purchase.

vi. A copy of test report of the drug sample was sent to M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi 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. **Manufacture for Sale /Sale of Substandard & Misbranded Drug**
ii. **Issuance of false warranty**

3. Revised Show-cause issued to accused person(s) vide dated 19-12-2022

Firm did not submit reply of showcause notice

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

Cases are placed before the Board

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 25

PQCB/R-619/2020

Tehsil Khanpur, District Rahim Yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E., Karachi Pakistan through** its Managing Director Erum Shakir Rahim 2. Erum Shakir Rahim — Managing Director 3. Saqib Azmat — Production Incharge 4. Khurram Ahmed — Quality Control Incharge 5. Nasir Aleem — Warrantor of M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E., Karachi Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Khanpur, District Rahim Yar Khan reported that: -

i. His Predecessor, on 03-08-2020, inspected Main Medicine Store of Chief Executive Officer, (DHA) Govt. Altaf Hussain Eye Hospital Khanpur, took 6 different types of drug samples on Form No. 04 for the purpose of test/analysis and sent it to Drug Testing Laboratory Bahawalpur vide memorandum no 72871 dated 03-08-2020.

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 Results
Suspension Zentel [Albendazole: 200mg/5ml, 10ml] **Mfg. date**: 07-2020 **Exp. Date**: 07-2023 **Regn. No**: 006730	L25Y	M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.	TRA No. 01-77002214/DTL Dated: 03-11-2020	**Results of test/Analysis with specifications applied** MS **Composition:** Each 5ml contains: Albendazole USP…… 200mg **Description:** A white to off white suspension with an orange odor contained in amber color glass bottle, sealed and caped with aluminum cap, packed in outer hard carton. (Stated volume: 10ml) **NOTE: Manufacturer specifies "U.S.P. Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral Suspension clearly mention in "Labeling: "Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer's claim of USP Specifications is false/misleading which is in violation to Drug Act 1976 and is declared misbranded. (Does not comply).** **pH (MS):** Limit: ……..4.5-5.5 **Determined: ……6.961** **(Does not comply with specifications)** **Identification (MS):** Albendazole is Identified. **Assay (MS) Albendazole** Stated: 200mg/5ml Determined: 216.4mg/5ml Percentage: 108.20% (Complies Limit: 90-110% **Result:** The sample is declared **Substandard** on the basis of **pH test** and is **Misbranded** as defined under clause (vi) of subsection (s) of section 3 of Drug Act 1976**.**

iii. Chief Executive Officer, (DHA), Rahim Yar Khan provided bill/warranty bearing invoice No. 20022879 dated 30-07-2020 issued by M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.

iv. Warrantor portion of drug sample was sent to M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.

v. A Copy of test report of the drug sample was sent to M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi 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. **Manufacture for Sale /Sale of Substandard & Misbranded Drug**
ii. **Issuance of false warranty**

3. Revised Show-cause issued to accused person(s) vide dated 19-12-2022

Firm did not submit reply of showcause notice

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

Cases are placed before the Board

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 26

PQCB R-706/2020

Potohar Town, Rawalpindi

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi** through its Managing Director, Erum Shakir Rahim 2. Erum Shakir Rahim Managing Director 3. Saqib Azmat Production Manager 4. Khurram Ahmed Quality Control Manager 5. Nasir Aleem Warrantor Of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Potohar Town, Rawalpindi reported that:-

i. His predecessor, on 22-08-2020 inspected the M/s Medics Pharmacy, Bhakral Plaza, Plot No. 3, Mehfoz Road, Saddar Rawalpindi, took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No. 73913 Dated 24-08-2020.

ii. The following drug sample, after test/analysis was declared as **Misbranded** 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
Suspension. Zentel 10mL Suspension [Albendazole…200mg/5mL] Mfg. Date: 06-2020 Exp. Date: 06-2023 Reg # 006730	JP4H	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi.	01-74000012/ DTL dated: 23 Oct 2020	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION:** White to off-white coloured, viscous suspension having characteristic odour, filled in amber coloured glass bottle with affixed label, sealed with golden coloured Aluminum Screw cap imprinted with "GSK", further packed in labeled unit carton. **Manufacturer specifies "U.S.P." Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in labeling that "Label it to indicate that it is for veterinary use only" whereas manufacturer prescribes given sample for human use (DOES NOT COMPLY)** **pH** Determined: **6.78** Limit: 5.5-8.0 **IDENTIFICATION** Albendazole Identified **ASSAY:** Stated: 200mg/5mL Determined: 200.910mg/5mL Percentage 100.45% Limit: 95-110% **RESULT:** **The above sample is MISBRANDED as defined under clause (iv) of sub-section (s) of section 3 of the Drugs Act 1976.**

iii. The Proprietor, M/s Medics Pharmacy, Bhakral Plaza, Plot No. 3, Mehfoz Road, Saddar Rawalpindi provided warranty/invoice bearing No. 401658773 dated 28-07-2020 issued by M/s Vikor Enterprises (Pvt.) Ltd., House No. 102-A/II, Block-A, Satellite Town, Rawalpindi.

iv. Warrantor Portion was sent to M/s Vikor Enterprises (Pvt.) Ltd., House No. 102-A/II, Block-A, Satellite Town, Rawalpindi.

v. M/s Vikor Enterprises (Pvt.) Ltd Rawalpind provided warranty/invoice bearing No. 00005493 dated 14-07-2020 issued by M/s Vikor Enterprises Pvt. Ltd., 17-A, Birdwood Road, Lahore, who in turn provided warranty/invoice No. 2020070011 dated 09-07-2020 issued by M/s Vikor Enterprises (Pvt.) Ltd., Karachi, who in turn provided warranties/invoices bearing No. 20020434 dated 09-07-2020 issued by **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi**.

vi. A copy of Test/ Analysis reports was sent to **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi** and they were directed to explain their position and provide requisite information in this regard.

vii. A copy of Test/ Analysis reports was sent to M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi and they were directed to explain their position and provide requisite information in this regard.

i. **Manufacture for Sale/Sale of Misbranded Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated20-12-2022.

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

Summary:

Manufacturing Date: 06-2020

Expiry Date: 06-2023

Sampling Date: 22-08-2020

Sent to DTL (Form 6): 24-08-2020

Date of receipt in DTL: 26-08-2020

DTL Report Date: 23-10-20220

Time Extension: N/A

1ST DI Communication with firm on dated: 05-11-2020

Date of Retesting Request of Firm: -N/A

Fate of Retesting Request: -N/A

Investigation Report Dated: 03-09-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 27

PQCB R-726/2020

Tehsil and District Chakwal

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi** through its Managing Director, Erum Shakir Rahim 2. Erum Shakir Rahim — Managing Director 3. Saqib Azmat — Production Manager 4. Khurram Ahmed — Quality Control Manager 5. Nasir Aleem — Warrantor Of M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 29-05-2020 inspected Main Medicine Store, Chief Executive Officer, District Health Authority, Chakwal, took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo No. 0000066721 Dated 29-05-2020.

ii. The following drug sample, after test/analysis was declared as **Substandard and Misbranded** 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
Suspension. Zentel 10mL Suspension [Albendazole…200mg/5mL] Mfg. Date: 04-2020 Exp. Date: 04-2023 Reg # 006730	YU5P	M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E., Karachi.	01-72001071/ DTL dated: 30 Jul 2020	**Result of test/ analysis with specifications applied:** MS **PHYSICAL DESCRIPTION:** White to off-white coloured viscous suspension having characteristic odour, filled in single dose amber coloured glass bottle with affixed label, sealed with golden coloured Aluminum screw cap imprinted with "GSK", further packed in labelled unit carton. **Manufacturer specifies "USP Specifications" on the label of immediate container as well as on outer unit carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in labelling that "Label it to indicate that it is for veterinary use only" whereas manufacturer prescribes given sample for human use. (Does not comply)** **pH** Limit: 4.5-5.5 Determined: **6.752 at 25C (Does not comply)** **IDENTIFICATION** Albendazole identified **ASSAY:** Stated: 200mg/5mL Determined: 188.033mg/5mL Percentage 94.02% Limit: 90-110% **RESULT:** **The above sample is "Sub-standard" on the basis of pH performed and "Misbranded" as defined under clause (iv) of sub-section (s) of section 3 of The Drugs Act 1976**

iii. The Store Keeper, Main Medicine Store, Chief Executive Officer, District Health Authority, Chakwal provided warranty/invoice No. 20015272 dated 28-05-2020, issued by M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan.

iv. Warrantor Portion was sent to M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000, Pakistan.

v. A copy of Test/ Analysis reports was sent to **M/s GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E. Karachi** and they were directed to explain their position and provide requisite information in this regard. The firm challenged the report and requested re-testing of the sample by the Appellate Laboratory, National institute of Health, Islamabad.

vi. The Re-testing request of the Firm was considered by Provincial quality Control Board in its 241st meeting held on 31-03-2022. The retesting request was **turned down** by the Board.

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

i. **Manufacture for Sale/Sale of Substandard and Misbranded Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 31-01-2023.

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

Summary:

Manufacturing Date: 04-2020

Expiry Date: 04-2023

Sampling Date: 29-05-2020

Sent to DTL (Form 6): 29-05-2020

Date of receipt in DTL: 01-06-2020

DTL Report Date: 30-07-2020

Time Extension: N/A

1ST DI Communication with firm on dated: 05-06-2020

Date of Retesting Request of Firm: -25-05-2021

Fate of Retesting Request: -Turned down in 241-M, 31-03-2022

Investigation Report Dated: 26-10-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 28

DISTRICT SARGODHA

PQCB/R-398/2020

Tehsil & District Sargodha

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Glaxosmithkline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan through** its Chief Executive Erum Shakir 2. Erum Shakir Chief Executive/ Warrantor 3. Khalid Mehmood Production Manager 4. Khurram Rafiq Ahmed Quality Control Manager 5. Samreen Yamin Khan Compliance Coordinator of **M/s Glaxosmithkline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.**

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 10-07-2020, inspected the premises of Main Medicine Store Govt. TB Hospital Sargodha, took four different drug samples on Form No. 04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memorandum no. 0000071441 dated 10-07-2020

ii. Following drug sample, after test/analysis, was declared **Misbranded and Substandard** by Government Analyst Drug Testing Laboratory, Rawalpindi 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>Suspension Zentel 10ml (Albendazole 200 mg/5ml)
Mfg date:
04-2020
Exp date:
04-2023
Regn. No.
006730</td><td>YH9C</td><td>M/s Glaxosmithkline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.</td><td>TRA No. 01-71001141/DTL Dated:26-08-2020</td><td>Results of test/Analysis with specifications applied
MS
<u>PHYSICAL DESCRIPTION:</u>
White to off-white coloured, viscous suspension having characteristic odour, filled in single dose amber coloured glass bottle with affixed label, sealed with golden coloured Aluminium screw cap imprinted with ‘’GSK’’, further packed in labelled unit carton.
Manufacturer specifies ‘’U.S.P Specifications” on the label of Immediate container as well as on outer carton. But in USP 2019, Monograph of Albendazole Oral suspension clearly mention in Labeling that ‘’Label it to indicate that it is for veterinary use only” whereas manufacturer prescribe given sample for human use
(DOES NOT COMPLY).
<u>PH:</u>
Observed: 6.687 at 25^{O}C (DOES NOT COMPLY)
Limit: 4.5-5.5
<u>IDENTIFICATION:</u> Albendazole Identified
<u>ASSAY:</u>
<table>
<tr><td>Stated</td><td>Determined</td><td>Percentage</td><td>Limit</td></tr>
<tr><td>200mg/5ml</td><td>191.378mg/5ml</td><td>95.69%</td><td>90-110%</td></tr>
</table>
<u>RESULT: The above sample is ‘’Substandard” on the basis of PH test performed and ‘’Misbranded” as defined under clause (iv) of sub-section (s) of section 3 of The Drug Act 1976.</u></td></tr>
</table>

iii. Store keeper of Main Medicine Store Govt. TB Hospital Sargodha provided Invoice/Warranty No. 20016712 dated 05-06-2020 issued by M/s Glaxosmithkline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan as a proof of purchase.

iv. Warrantor portion of the drug sample was sent to M/s Glaxosmithkline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.

v. A copy of test/analysis report was sent to by M/s Glaxosmithkline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan and they were asked to provide the requisite information in this regard.

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

i. **Manufacturing for Sale /Sale of Misbranded & Substandard Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 05-05-2021.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 04-2020**
- **Expiry Date: 04-2023**
- **Sampling Date (Form 4): 10-07-2020**
- **Sent to DTL (Form 6): 10-07-2020**
- **Date of receipt in DTL: 17-07-2020**
- **DTL Report Date (Form 7): 26-08-2020**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 08-10-2020**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 18-03-2021**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 29

PQCB/R-611/2020

Tehsil & District Toba Tek Singh

Sub-Standard (pH) & Misbrande

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi** through its Managing Director Iram Shakir. 2. Iram Shakir Managing Director 3. Imtiaz Hussain Production Manager 4. Khalid Mehmood Sheikh Quality Operation Head 5. Nasir Aleem Qureshi Warrantor **of M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil & District Toba Tek Singh reported that: -

i. His Predecessor, on 16-05-2020, inspected the premises of M/S Main Medicine Store office of Chief Executive Officer [DHA] Toba Tek Singh and took seven different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Suspension Zental 10ml [Each 5ml contains: Albendazole U.S.P 200mg]	YH9C	M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi	01-68004322/DTL Dated. 25-07-2020	**Analysis with specifications applied: MS.** **Description:** White color suspension with orange odor contained in amber color glass bottle sealed caped with aluminum cap, packed in outer hard carton. Note: **Manufacturer specifies "USP Specifications" on the label of immediate contai as well as on outer unit carton. But in USP 2019, Monograph of Albendazole O suspension clearly mention in Labelling that "Label it to indicate that it is for veterin use only" whereas manufacturer prescribe given sample for human use. Therefo manufacturer claim of USP specification is false/misleading which is in violation Drugs Act 1976, and is declared misbranded. (Does not comply)** **Identification:** Albendazole is identified. **Assay:** **Stated: 200mg/5ml** **Determined: 191.756mg/5ml** **Percentage: 95.878% (Complies)** **Limit: 90-110% (MS)** **PH:** **Stated: 4.5-5.5 (Manufacturer Specification)** **Determined: 6.76 at 25°C** **Does not comply.** **Result:** Given sample is **declared Substandard with regards to PH Test and Misbranded w regards to Section 3(s)(iv) of Drugs Act 1976.**

iii. Store Keeper M/S Main Medicine Store office of Chief Executive Officer [DHA] Toba Tek Singh provided Invoice/warranty No L/48/2020, dated 08-05-2020 issued by M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S GlaxoSmithKline Pakistan Limited, F/268, S.I.T.E Karachi 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: -

i. **Manufacture for Sale /Sale of Substandard & Misbranded Drug**

ii. **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(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 30

PQCB/R-621/2020

Tehsil & District Vehari

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E., Karachi Pakistan through** its Managing Director Erum Shakir Rahim 2. Erum Shakir Rahim — Managing Director 3. Saqib Azmat — Production Incharge 4. Khurram Ahmed — Quality Control Incharge 5. Nasir Aleem — Warrantor of M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E., Karachi Pakistan

BRIEF FACTS OF THE CASE:

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

i. Her Predecessor, on 10-09-2020, inspected the premises of Medicine store PHFMC, Vehari, took subject drug sample on Form No. 04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan vide memorandum no 74400 dated 10-09-2020.

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

Name of drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Suspension Zentel [Albendazole: 200mg/5ml] **Mfg. date**: 07-2020 **Exp. Date**: 07-2023 **Regn. No**: 006730	L25Y	M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.	TRA No. 01-89000129/DTL Dated: 10-10-2020	**Results of test/Analysis with specifications applied** MS **Description:** White to off-white suspension in amber glass bottle sealed with aluminium cap, packed in a labelled outer hard carton. Product states "U.S.P. Specifications" as a finished Drug Product Specifications on the label of immediate container as well as on outer unit carton. But in USP, Monograph of Albendazole Oral Suspension clearly mention in "Labeling: "Label it to indicate that it is for veterinary use only" whereas manufacturer prescribe given sample for human use. Therefore, manufacturer claim of USP Specification is false/misleading which is in violation to Drug Act 1976 and is declared **Misbranded. (Does not comply).** **Identification:** Albendazole Identified. **Assay:** Albendazole Stated: 200mg/5ml Determined: 195mg/5ml Percentage: 97.5% Limit: 90-110% complies **pH: Range** …… …4.5-5.5 **Determined……**6.80 at 25°C **(Does not comply)** **Result:** The above sample is **Misbranded** as defined under section 3 (s) (iv) of the Drug Act, 1976 and is **Substandard** on the basis of **pH test** performed. Same batch was declared substandard & misbranded previously via TRA No. 01-87002179 dated 17-9-2020, TRA No. 01-87002157, dated 17-9-2020 & TRA No. 01-87002545 dated 05-10-2020.

iii. Storekeeper Medicine store, PHFMC, Vehari provided Invoice/Warranty No. 20022873 dated 30-07-2020 issued by M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan as a proof of purchase.

iv. Warrantor portion of drug sample was sent to M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi Pakistan.

v. A Copy of test report of the drug sample was sent to M/s GlaxosmithKline Pakistan Limited, F/268, S.I.T.E., Karachi 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. **Manufacture for Sale /Sale of Substandard & Misbranded Drug**
ii. **Issuance of false warranty**

3. Revised Show-cause issued to accused person(s) vide dated 19-12-2022

Firm did not submit reply of showcause notice

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD;

Case No. 31

DISTRICT LAHORE

PQCB/R-601/2021

Punjab Social Security Health Management Company, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s GlaxoSmithKline Pakistan Limited. Plot 5, Sector 21, Korangi Industrial Area, Karachi** through its Vice President & General Manger Erum Shakir Rahim 2. Erum Shakir Rahim — Vice President & General Manger 3. Syed Anwer Ali — Production Manager 4. Sammar Azeem — QualityControl Manager 5. Mushtaq Mallah — Warrantor Of **M/s GlaxoSmithKline Pakistan Limited. Plot 5, Sector 21, Korangi Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Punjab Social Security Health Management Company, Lahore reported that:-

i. He, on 01-12-2020, inspected the premises of Central Medical Store PSSHMC Hospital, Raiwind 8-km Manga Road and took sample of drug on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Lahore vide memorandum no. 0000078753 dated 01-12-2020.

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

iii. Store Keeper Central Medical Store PSSHMC Hospital, Raiwind 8-km Manga Road submitted Invoice/warranty No. 20/11/00030 dated 10-11-2020 issued nominated distributor M/s Muller & Phipps Pakistan Ltd. Zonal office Lahore, 10 KM, Multan Road, Near Social Security Hospital Lahore as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/s Muller & Phipps Pakistan Ltd. Zonal office Lahore, 10 KM, Multan Road, Near Social Security Hospital Lahore who in turn submitted invoice/ warranty No. 20025062 dated 27-08-2020 issued by M/s GlaxoSmithKline Pakistan Limited. Plot 5, Sector 21, Korangi Industrial Area, Karachi as a proof of its purchase of the said drug.

v. A copy of test/analysis report was sent to M/s GlaxoSmithKline Pakistan Limited. Plot 5, Sector 21, Korangi Industrial Area, Karachi and they were asked to provide the requisite information in this regard.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Quibron-T/SR Sustained Release Tablet (Theophylline Anhydrous USP 300 mg) **Mfg.date:** Jul-2020 **Exp. date:** Jul-2021 **Regn No.** 014866	S43X	M/s GlaxoSmithKline Pakistan Limited. Plot 5, Sector 21, Korangi Industrial Area, Karachi.	TRA No. 01-149002542/DTL Dated:-30-03-2021	**Analysis with specifications applied:** Manufacturer Specifications (MS) **Physical Characteristics:** WHITE COLOURED RECTANGULAR TABLETS WITH LINE OF BISECTIONON ONE SIDE AND LINE OF TRISECTION ON THE OTHER SIDE IN BLISTER PACKING OF 10 UNITS. **LABELING: THE PRODUCT BEARS DOUBLE SEPCIFICATIONS ON LABEL OF PRODUCT AS ''GSK SPECIFICATIONS ON BLIUSTER PACK AND U.S.P SPECIFICATIOS ON OUTER CARTON".** **(MISBRANDED)** **Dissolution Test:** Sample comply the limits as per MS. **Identification:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (THEOPHYLLINE IDENTIFIED). **Assay of Theophylline:**

Stated	Determined	Percentage	Limit
300 mg/Tablet	300.3 mg/ Tablet	100.1 %	94.0-106.0% of the Lbelled Potency

RESULT:

The above sample is **MISBRANDED**, due to misleading information as per **The Drugs Act 1976, 3 [s(iv)].**

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

i. **Manufacturing for Sale /Sale of Misbranded Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 05-01-2023.

Reply of firm to show cause notice vide letter no. nil dated 27-01-2023

We refer your letter No. PQCB/R-601/2021, dated: Lahore the 05-01-2023, subject: Show Cause Notice, received at site dated 23rd January 2023, regarding the Misbranded case of Quibron-T/SR Tablets, Batch No. S43X.
In this regard, we are to inform you that the company had under letter no. PSSHMC-Hosp-Rwd/DI/793/21, dated 29 April 2021, responded to the Drug Inspector-PSSHMC, Hospital Raiwind, Punjab, Lahore (Attachment 1)
Keeping in view, we explained our position and actions which were immediately taken in this regard as mentioned below, in response of letter no. PSSHMC-Hosp-Rwd/DI/793/21, dated 29 April 2021 letter.
1. That earlier during our periodic internal review and assessment process the concerned department of GSK at site had identified this matter of printing mismatch and had proactively communicated to DRA Pakistan in November 2020. Subsequently, on instructions of DRA Pakistan GSK Pakistan Limited had recalled the released stocks of said batch of Quibron T/ SR tablets from the market.
2. That compliance report on recall of the product has also been submitted to DRA Pakistan and GSK Pakistan Limited has already made necessary rectification in the artworks.
3. That it is very significant to mention here this is a minor printing mismatch which admittedly does not pose any product quality and patient safety risk where GSK Pakistan Limited has taken the remedial actions and also recalled the product. Accordingly, all fresh supplies of the product are being released in rectifies artworks.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 07-2020**
- **Expiry Date: 07-2021**
- **Sampling Date (Form 4): 01-12-2020**
- **Sent to DTL (Form 6): 01-12-2020**
- **Date of receipt in DTL: 03-12-2020**
- **DTL Report Date (Form 7): 30-03-2021**
- **Time Extension: Granted in 230th meeting dated 20-02-2021**
- **1ST DI Communication with firm on dated: 05-04-2021**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 11-10-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 32

PQCB R-143/2022

Tehsil and District Rajanpur

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 — Production Manager 4. Faheem ud Din Bhutto — Quality Control Manager 5. Irshad Sami — Marketing Manager 6. Hafiz Nadeem — Warrantor of M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, District Rajanpur reported that: -

i. His predecessor, on 03-11-2021, inspected the business premises of M/S Shehroz Medical Store, Zia Shaheed Road, Rajanpur, and took three different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Multan.

ii. Following drug sample, sent via memorandum no. 110467, dated 08-11-2021, after test/analysis was declared as **Misbranded** by Government Analyst Drug Testing Laboratory, Multan, 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>Corticosporin Eye Ointment [each gram contains: Bacitracin Zinc; 400units, Neomycin (sulfate); 3400units, polymyxin B Sulfate; 500units, Hydrocortisone: 10mg]

Mfg. date: July-2021

Exp: date: July-2026

Reg# 000357</td><td>KM3K</td><td>M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi</td><td>TRA No.01-94000474/DTL dated: 24-01-2022</td><td>
Analysis with specifications applied: MS

<u>Description</u>:

White to off white translucent ointment in an aluminum tube with white screw plastic cap packed in a labeled outer hard carton.

The label on the tube as well as on outer carton contains USP finished drug product specifications. USP states “ Neomycin and Polymyxin B sulfates, Bacitracin Zinc, and Hydrocortisone ointment contains the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labelled amount of Neomycin, Polymyxin B and Bacitracin, and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of Hydrocortisone “ while the label claim on the product is

“Bacitracin Zinc B.P…...400Units, Polymyxin B sulfate BP…...5000Units, Neomycin Sulfate B.P…...3400Units, Hydrocortisone B.P……10mg petroleum base to 1.0G” which is contradictory to USP specifications & is false/misleading.

(Misbranded) Does not comply.

<u>Identification:</u> Polymyxin B Sulphate, Bacitracin Zinc, Hydrocortisone & Neomycin Sulphate identified.

<u>Assay:</u> Micro Assay

<u>Polymyxin B Sulphate</u>
<table>
<tr><td>Stated</td><td>5000 Units/g</td></tr>
<tr><td>Determined</td><td>5315 Units/g</td></tr>
<tr><td>Percentage</td><td>1026.30%</td></tr>
<tr><td>Limit</td><td>4500- 6000 Units/g</td></tr>
</table>
(Complies)

<u>Bacitracin Zinc</u>
<table>
<tr><td>Stated</td><td>400 Units/g</td></tr>
<tr><td>Determined</td><td>384.28 Units/g</td></tr>
<tr><td>Percentage</td><td>96.07 %</td></tr>
<tr><td>Limit</td><td>360-480 Units/g</td></tr>
</table>
(Complies)

<u>Neomycin Sulphate</u>
<table>
<tr><td>Stated</td><td>3400 Units/g</td></tr>
<tr><td>Determined</td><td>3463.24 Units/g</td></tr>
<tr><td>Percentage</td><td>101.86 %</td></tr>
<tr><td>Limit</td><td>3060-4760 Units/g</td></tr>
</table>
(Complies)

<u>ASSAY</u>: HPLC

<u>Hydrocortisone</u>
<table>
<tr><td>Stated</td><td>10mg/g</td></tr>
<tr><td>Determined</td><td>9.007mg/g</td></tr>
<tr><td>Percentage</td><td>90.07%</td></tr>
<tr><td>Limit</td><td>90-110</td></tr>
</table>
(Complies)

<u>Sterility:</u> It conforms to sterility. (Complies)

<u>Result</u>: The above sample is Misbranded, as defined under section 3(s)(iv) of the drugs act, 1976
</td></tr>
</table>

iii. M/S Shehroz Medical Store, Zia Shaheed Road, Rajanpur provided Invoice/warranty No. 712900 Dated 04-10-2021 issued by M/s Faisal Pharma, Sakhi Sarwar Road, Near Gaddai Phatak, D.G. Khan as a proof of its purchase.

iv. Warrantor portion was sent to M/s Faisal Pharma, Sakhi Sarwar Road, Near Gaddai Phatak, D.G. Khan.

v. M/s Faisal Pharma, Sakhi Sarwar Road, Near Gaddai Phatak, D.G. Khan provided Invoice/warranty no. 5395946239, dated: 27-09-2021 issued by M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi, as a proof of its purchase.

vi. A copy of test/analysis report was sent to M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi, with the 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 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 21-12-2022.

Reply to Show Cause Notice:

This is with reference to your letter No. PQCB/R-143/2022 Dated 21.12.2022 received at site on dated 11.01.2023 of Corticosporin Eye Ointment 06 gm B.NO (http://b.no/). KM3K manufactured by M/S GlaxoSmithKline Pakistan, 35-dockyard road West Wharf Karachi and which was stated as Misbranded.
Referring to the letter testing results of Polymyxin B sulphate, Bacitracin zinc, Neomycin sulphate and Hydrocortisone observed within stated specification as per United States Pharmacopoeia. For clarity as per our specifications, we have tested our product as per the USP specification complying with the registered specifications for Polymyxin B sulphate, Bacitracin zinc and Neomycin sulphate i.e. 90-140 % respectively, for Hydrocortisone i.e. 90-110% however on the label under "contain" Polymyxin B sulphate B.P. Bacitracin zinc B.P., Neomycin sulphate B.P. and Hydrocortisone B.P., it is referring raw material specifications present in the product.
Therefore, there is no impact on overall potency and efficacy of Corticosporin Eye Ointment 06 gm B.NO (http://b.no/). KM3K. And GlaxoSmithKline Pakistan Limited, Karachi have updated the portfolio of Corticosporin Eye Ointment and all other registered products regarding the product specifications under the Drugs Act, 1976 / DRAP Act, 2012 and Rules framed thereunder and will not violate the Section 3 (s) (iv) of the Drugs Act, 1976 in future.

Being a responsible Pharmaceutical Company, we ensure our full support as usual, for any further support in this regard.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 33

PQCB R-144/2022

Tehsil and District Rajanpur

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 — Production Manager 4. Faheem ud Din Bhutto — Quality Control Manager 5. Irshad Sami — Marketing Manager 6. Hafiz Nadeem — Warrantor of M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, District Rajanpur reported that: -

i. His predecessor, on 21-10-2021, inspected the business premises of M/S Chorahi Medical Store, Near DHQ Hospital, Rajanpur, and took three different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Multan. The subject drug sample was sent vide memorandum no. 109515, dated 23-10-2021

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 TRA No. & Date	DTL Test Report Results
Corticosporin Eye Ointment [each gram contains: Bacitracin Zinc; 400units, Neomycin (sulfate); 3400units, polymyxin B Sulfate; 500units, Hydrocortisone: 10mg] **Mfg. date: July-2021** **Exp: date: July-2026** **Reg# 000357**	KM3K	M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi	TRA No.01-94000302/DTL dated: 24-01-2022	**Analysis with specifications applied:** MS **Description:** White to off white translucent ointment in an aluminum tube with white screw plastic cap packed in a labeled outer hard carton. **The label on the tube as well as on outer carton contains USP finished drug product specifications. USP states " Neomycin and Polymyxin B sulfates, Bacitracin Zinc, and Hydrocortisone ointment contains the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labelled amount of Neomycin, Polymyxin B and Bacitracin, and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of Hydrocortisone " while the label claim on the product is** **"Bacitracin Zinc B.P…...400Units, Polymyxin B sulfate BP…...5000Units, Neomycin Sulfate B.P……3400Units, Hydrocortisone B.P……10mg petroleum base to 1.0G" which is contradictory to USP specifications & is false/misleading.** **(Misbranded) Does not comply.** **Identification:** Polymyxin B Sulphate, Bacitracin Zinc, Hydrocortisone & Neomycin Sulphate identified. **Assay: Micro Assay** **Polymyxin B Sulphate** Stated: 5000 Units/g Determined: 5101 Units/g Percentage: 102.02% Limit: 4500- 6000 Units/g **(Complies)** **Bacitracin Zinc** Stated: 400 Units/g Determined: 377.32 Units/g Percentage: 94.33 % Limit: 360-480 Units/g **(Complies)** **Sterility:** It conforms to sterility. **(Complies)** **Result:** The above sample is **Misbranded**, as defined under section 3(s)(iv) of the drugs act, 1976

iii. M/S Chorahi Medical Store, Near DHQ Hospital, Rajanpur provided Invoice/warranty No. 712900 Dated 04-10-2021 issued by M/s Faisal Pharma, Sakhi Sarwar Road, Near Gaddai Phatak, D.G. Khan as a proof of its purchase.

iv. Warrantor portion was sent to M/s Faisal Pharma, Sakhi Sarwar Road, Near Gaddai Phatak, D.G. Khan.

v. M/s Faisal Pharma, Sakhi Sarwar Road, Near Gaddai Phatak, D.G. Khan provided Invoice/warranty no. 5395946239, dated: 27-09-2021 issued by M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi, as a proof of its purchase.

vi. A copy of test/analysis report was sent to M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi, with the 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 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 21-12-2022.

Reply to Show Cause Notice:

This is with reference to your letter No. PQCB/R-144/2022 Dated 21.12.2022 received at site on dated 11.01.2023 of Corticosporin Eye Ointment 06 gm B.NO (http://b.no/). KM3K manufactured by M/S GlaxoSmithKline Pakistan, 35-dockyard road West Wharf Karachi and which was stated as Misbranded.
Referring to the letter testing results of Polymyxin B sulphate, Bacitracin zinc, Neomycin sulphate and Hydrocortisone observed within stated specification as per United States Pharmacopoeia. For clarity as per our specifications, we have tested our product as per the USP specification complying with the registered specifications for Polymyxin B sulphate, Bacitracin zinc and Neomycin sulphate i.e. 90-140 % respectively, for Hydrocortisone i.e. 90-110% however on the label under "contain" Polymyxin B sulphate B.P. Bacitracin zinc B.P., Neomycin sulphate B.P. and Hydrocortisone B.P., it is referring raw material specifications present in the product.
Therefore, there is no impact on overall potency and efficacy of Corticosporin Eye Ointment 06 gm B.NO (http://b.no/). KM3K. And GlaxoSmithKline Pakistan Limited, Karachi have updated the portfolio of Corticosporin Eye Ointment and all other registered products regarding the product specifications under the Drugs Act, 1976 / DRAP Act, 2012 and Rules framed thereunder and will not violate the Section 3 (s) (iv) of the Drugs Act, 1976 in future.

Being a responsible Pharmaceutical Company, we ensure our full support as usual, for any further support in this regard.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 34

PQCB R-620/2021

Tehsil and District Rajanpur

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 — Production Manager 4. Faheem ud Din Bhutto — Quality Control Manager 5. Irshad Sami — Marketing Manager 6. Hafiz Nadeem — Warrantor of M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, District Rajanpur reported that: -

i. His predecessor, on 08-09-2022, inspected the business premises of M/S Bhatti Medical store, Aqil Pur Road, Tehsil Rajanpur and took three different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Multan.

ii. Following drug sample, sent via memorandum no. 109509, dated 23-10-2021, 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 TRA No. & Date	DTL Test Report Results
Eye Ointment Polyfax Eye Ointment (Polymyxin B Sulphate 10000IU/g, Bacitracin: 500IU/g, petrolatum base to 1gm) **Mfg date: Aug-2021** **Exp: date: Aug-2026** **Reg# 000372**	R86T	M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi	TRA No.01-94000297/DTL dated: 10-12-2021	**Analysis with specifications applied:** MS **Description:** White to off white translucent ointment in an aluminum tube with white screw plastic cap packed in a labeled outer hard carton. **The label on the tube as well as on outer carton contains USP finished drug product specifications. USP states "*Bacitracin Zinc and Polymyxin B Sulphate Ophthalmic ointment contains the equivalent of NLT 90.0% and NMT 130.0% of the labeled amount of Bacitracin & Polymyxin B*" while the label claim on the product is "*Polymyxin B sulphate BP 10,000units, Bacitracin Zinc BP 500 units, Petrolatum Base to 1.0G*" which is contradictory to USP specifications & is false/misleading.** **(Misbranded) Does not comply.** **Identification:** Polymyxin B Sulphate, Bacitracin Zinc identified. **Assay: Polymyxin B Sulphate** Stated: 10,000 Units/g Determined: 10303 Units/g Percentage: 103.03% Limit: 90-120% **(Complies)** **Bacitracin Zinc** Stated: 500 Units/g Determined: 470.35 Units/g Percentage: 94.07 % Limit: 90-120% **(Complies)** **Sterility:** It conforms to sterility. **(Complies)** **Result:** The above sample is **Misbranded**, as defined under section 3(s)(iv) of the drugs act, 1976

iii. M/S Bhatti Medical store, Aqil Pur Road, Tehsil Rajanpur provided Invoice/warranty No. 705351 Dated 10-10-2021 issued by M/s Faisal Pharma, Sakhi Sarwar Road, Near Gaddai Phatak, D.G. Khan as a proof of its purchase.

iv. Warrantor portion was sent to M/s Faisal Pharma, Sakhi Sarwar Road, Near Gaddai Phatak, D.G. Khan.

v. M/s Faisal Pharma, Sakhi Sarwar Road, Near Gaddai Phatak, D.G. Khan provided Invoice/warranty no. 5395946241, dated: 27-09-2021 issued by M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi, as a proof of its purchase.

vi. A copy of test/analysis report was sent to M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf Karachi, with the 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 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 21-12-2022.

Reply to Show Cause Notice:

This is with reference to your letter No. PQCB/R-620/2021 Dated 21.12.2022 received at site on dated 11.01.2023 of Polyfax Eye Ointment 06 gm B.NO (http://b.no/). R86T manufactured by M/S GlaxoSmithKline Pakistan, 35-dockyard road West Wharf Karachi and which was stated as Misbranded.
Referring to the letter testing results of Polymyxin B sulphate, Bacitracin zinc observed within stated specification as per United States Pharmacopoeia. For clarity as per our specifications, we have tested our product as per the USP specification complying with the registered specifications for both Polymyxin B sulphate, Bacitracin zinc i.e. 90-110% respectively, however on the label under "contain" Polymyxin B sulphate B.P. and Bacitracin zinc B.P., it is referring raw material specifications present in the product.

Therefore, there is no impact on overall potency and efficacy of Polyfax Eye Ointment 06 gm B.NO (http://b.no/). R86T. And GlaxoSmithKline Pakistan Limited, Karachi have updated the portfolio of Polyfax Eye Ointment and all other registered products regarding the product specifications under the Drugs Act, 1976 / DRAP Act, 2012 and Rules framed thereunder and will not violate the Section 3 (s) (iv) of the Drugs Act, 1976 in future.

Being a responsible Pharmaceutical Company, we ensure our full support as usual, for
any further support in this regard.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 35

PQCB/ R-163,164,165,166,167,168,169,170,171,172,173/2022

Lahore General Hospital, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan** through its Chief Executive Officer, Ashfaq Safdar Tarrar 2. Ashfaq Safdar Tarrar — Chief Executive Officer 3. Suhaib Bin Anees — Production Manager 4. Muhammad Nadeem Khan — Quality Control Manager/ Warrantor of M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Lahore General Hospital, District Lahore reported that: -

i. She, on 02-12-2021, inspected the premises of Main Medicine Store, Lahore General Hospital, District Lahore, took following drug samples on Form No.04 for t purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 111372, 111881, 111373, 111369, 111376, 111375, 111371, 111374, 11137 111880, 111377 all dated 02-12-2021.

ii. The following drug samples after test/analyses were declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, 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 Result</th></tr>
<tr><td>1</td><td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td><td>2111036</td><td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td><td>01-73010725/DTL
dated 28-01-2022</td><td>Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.34 at 23.1°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table><tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr><tr><td>Lactate</td><td>0.254% w/v</td><td>0.265% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr><tr><td>Sodium</td><td>0.301% w/v</td><td>0.299% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr><tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.399% w/v Complies)</td><td>0.37-0.42% w/v</td></tr><tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0364% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr></table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.</td></tr>
<tr><td>2</td><td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td><td>2111044</td><td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td><td>01-73010732/DTL
dated
28-01-2022</td><td>Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.34 at 23.8°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table><tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr><tr><td>Lactate</td><td>0.254% w/v</td><td>0.266% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr><tr><td>Sodium</td><td>0.301% w/v</td><td>0.301% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr><tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.412% w/v Complies)</td><td>0.37-0.42% w/v</td></tr><tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0371% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr></table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.</td></tr>
</table>

<table>
<tr>
<td>3</td>
<td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td>
<td>2111037</td>
<td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td>
<td>01-73010726/DTL
dated
28-01-2022</td>
<td>
Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.33 at 23.0°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table>
<tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr>
<tr><td>Lactate</td><td>0.254% w/v</td><td>0.266% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr>
<tr><td>Sodium</td><td>0.301% w/v</td><td>0.293% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr>
<tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.398% w/v Complies)</td><td>0.37-0.42% w/v</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0375% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr>
</table>
<u>STERI LITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.
</td>
</tr>
<tr>
<td>4</td>
<td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td>
<td>2111033</td>
<td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td>
<td>01-73010722/DTL
dated
28-01-2022</td>
<td>
Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.29 at 23.0°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table>
<tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr>
<tr><td>Lactate</td><td>0.254% w/v</td><td>0.266% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr>
<tr><td>Sodium</td><td>0.301% w/v</td><td>0.315% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr>
<tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.399% w/v Complies)</td><td>0.37-0.42% w/v</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0367% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr>
</table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.
</td>
</tr>
</table>

<table>
<tr>
<td>5</td>
<td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td>
<td>2111040</td>
<td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td>
<td>01-73010729/DTL
dated
28-01-2022</td>
<td>
Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.35 at 23.5°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table>
<tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr>
<tr><td>Lactate</td><td>0.254% w/v</td><td>0.265% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr>
<tr><td>Sodium</td><td>0.301% w/v</td><td>0.298% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr>
<tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.410% w/v Complies)</td><td>0.37-0.42% w/v</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0377% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr>
</table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.
</td>
</tr>
<tr>
<td>6</td>
<td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td>
<td>2111039</td>
<td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td>
<td>01-73010728/DTL
dated
28-01-2022</td>
<td>
Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.27 at 23.1°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table>
<tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr>
<tr><td>Lactate</td><td>0.254% w/v</td><td>0.267% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr>
<tr><td>Sodium</td><td>0.301% w/v</td><td>0.310% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr>
<tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.398% w/v Complies)</td><td>0.37-0.42% w/v</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0364% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr>
</table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.
</td>
</tr>
</table>

<table>
<tr>
<td>7</td>
<td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td>
<td>2111035</td>
<td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td>
<td>01-73010724/DTL
dated
28-01-2022</td>
<td>
Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.28 AT 24.9°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table>
<tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr>
<tr><td>Lactate</td><td>0.254% w/v</td><td>0.265% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr>
<tr><td>Sodium</td><td>0.301% w/v</td><td>0.294% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr>
<tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.419% w/v Complies)</td><td>0.37-0.42% w/v</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0346% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr>
</table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.
</td>
</tr>
<tr>
<td>8</td>
<td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td>
<td>2111038</td>
<td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td>
<td>01-73010727/DTL
dated
28-01-2022</td>
<td>
Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.60 at 25.1°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table>
<tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr>
<tr><td>Lactate</td><td>0.254% w/v</td><td>0.266% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr>
<tr><td>Sodium</td><td>0.301% w/v</td><td>0.303% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr>
<tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.419% w/v Complies)</td><td>0.37-0.42% w/v</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.03508% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr>
</table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.
</td>
</tr>
</table>

<table>
<tr>
<td>9</td>
<td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td>
<td>2111034</td>
<td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td>
<td>01-73010723/DTL
dated
28-01-2022</td>
<td>
Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.47 AT 24.6°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table>
<tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr>
<tr><td>Lactate</td><td>0.254% w/v</td><td>0.266% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr>
<tr><td>Sodium</td><td>0.301% w/v</td><td>0.301% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr>
<tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.407% w/v Complies)</td><td>0.37-0.42% w/v</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0377% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr>
</table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.
</td>
</tr>
<tr>
<td>10</td>
<td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td>
<td>2111043</td>
<td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td>
<td>01-73010731/DTL
dated
28-01-2022</td>
<td>
Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.48 AT 24.2°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table>
<tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr>
<tr><td>Lactate</td><td>0.254% w/v</td><td>0.265% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr>
<tr><td>Sodium</td><td>0.301% w/v</td><td>0.300% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr>
<tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.399% w/v Complies)</td><td>0.37-0.42% w/v</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0367% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr>
</table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.
</td>
</tr>
</table>

<table>
<tr>
<td>11</td>
<td>Infusion.
ZEESOL-H
[RINGER LACTATE]

Mfg Date:
Nov 2021

Expiry Date:
Oct 2024

Regn No.
019752</td>
<td>2111041</td>
<td>M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.</td>
<td>01-73010730/DTL
dated
28-01-2022</td>
<td>
Analysis with specifications applied: BP 2021

<u>PHYSICAL DESCRIPTION:</u> COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE.

<u>pH:</u>

Limits: 5.0 – 7.0

Determined: 6.48 AT 24.2°C (COMPLIES)

<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 (LACTATE IDENTIFIED)

<u>ASSAY:</u>
<table>
<tr><th>ASSAY</th><th>Stated</th><th>Determined</th><th>Limit</th></tr>
<tr><td>Lactate</td><td>0.254% w/v</td><td>0.266% w/v (Complies)</td><td>0.23-0.28% w/v</td></tr>
<tr><td>Sodium</td><td>0.301% w/v</td><td>0.306% w/v (Complies)</td><td>0.27-0.32% w/v</td></tr>
<tr><td>Total Chlorides</td><td>0.394% w/v</td><td>0.408% w/v Complies)</td><td>0.37-0.42% w/v</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0345% w/v (DOES NOT COMPLY)</td><td>0.025-0.029% w/v</td></tr>
</table>
<u>STERILITY:</u> The product is sterile. (COMPLIES)

<u>RESULT:</u> The above sample is <u>SUB-STANDARD</u> on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.
</td>
</tr>
</table>

iii. Chief Technician, Lahore General Hospital, District Lahore provided invoice/warranty bearing No. 0104 dated 17-11-2021 issued by M/S Shazeb Pharmaceutica Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan as a proof of its purchase.

iv. Warrantor portions of subject batches of the drug sample were sent to M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripu K.P.K-Pakistan.

v. Copies of test/analysis report was sent to M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan wit 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 firm's retesting request the Provincial Quality Control Board in its 243rd meeting held on 12-05-2022 **allowed** to send the sample to NIH, Islamabad fo retesting from where the sample was declared **Substandard** as detailed below:

<table>
<tr><th>Sr No</th><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>NIH Test Report No. & Date</th><th>NIH Test Report Result</th></tr>
<tr><td>1</td><td>Infusion ZEESOL-H RINGER LACTATE 1000ml</td><td>2111036</td><td>M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan.</td><td>0124-P/2022 dated 25-08-2022</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>Sodium</td><td></td><td>0.300% w/v</td><td>0.27-0.32% w/v</td><td>101.8 %</td></tr><tr><td>Potassium</td><td></td><td>0.0192% w/v</td><td>0.019-0.022% w/v</td><td>96.35 %</td></tr><tr><td>Total Chlorides</td><td></td><td>0.389% w/v</td><td>0.37-0.42% w/v</td><td>98.45%</td></tr><tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.0323% w/v</td><td>0.025-0.029% w/v</td><td>119.77%</td></tr><tr><td>Lactate</td><td></td><td>0.246% w/v</td><td>0.23-0.28% w/v</td><td>96.54%</td></tr></table>Does not comply with BP-2017

<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of test performed.</td></tr>
<tr><td>2</td><td>Infusion ZEESOL-H RINGER LACTATE 1000ml</td><td>2111044</td><td>M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan.</td><td>0125-P/2020 dated 25-08-2022</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>Sodium</td><td></td><td>0.292% w/v</td><td>0.27-0.32% w/v</td><td>99.09 %</td></tr><tr><td>Potassium</td><td></td><td>0.019% w/v</td><td>0.019-0.022% w/v</td><td>96.35 %</td></tr><tr><td>Total Chlorides</td><td></td><td>0.396% w/v</td><td>0.37-0.42% w/v</td><td>100.26%</td></tr><tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.031% w/v</td><td>0.025-0.029% w/v</td><td>117.5%</td></tr><tr><td>Lactate</td><td></td><td>0.246% w/v</td><td>0.23-0.28% w/v</td><td>96.48%</td></tr></table>Does not comply with BP-2017
<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of test performed.</td></tr>
<tr><td>3</td><td>Infusion ZEESOL-H RINGER LACTATE 1000ml</td><td>2111037</td><td>M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan.</td><td>0126-P/2022 dated 25-08-2022</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>Sodium</td><td></td><td>0.289% w/v</td><td>0.27-0.32% w/v</td><td>98.18 %</td></tr><tr><td>Potassium</td><td></td><td>0.0197% w/v</td><td>0.019-0.022% w/v</td><td>98.54 %</td></tr><tr><td>Total Chlorides</td><td></td><td>0.403% w/v</td><td>0.37-0.42% w/v</td><td>102.05%</td></tr><tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.032% w/v</td><td>0.025-0.029% w/v</td><td>118.6%</td></tr><tr><td>Lactate</td><td></td><td>0.254% w/v</td><td>0.23-0.28% w/v</td><td>99.73%</td></tr></table>Does not comply with BP-2017
<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of test performed.</td></tr>
<tr><td>4</td><td>Infusion ZEESOL-H RINGER LACTATE 1000ml</td><td>2111033</td><td>M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan.</td><td>0127-P/2022 dated 25-08-2022</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>Sodium</td><td></td><td>0.286% w/v</td><td>0.27-0.32% w/v</td><td>97.27 %</td></tr><tr><td>Potassium</td><td></td><td>0.0198% w/v</td><td>0.019-0.022% w/v</td><td>99.27 %</td></tr><tr><td>Total Chlorides</td><td></td><td>0.392% w/v</td><td>0.37-0.42% w/v</td><td>99.34%</td></tr><tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.032% w/v</td><td>0.025-0.029% w/v</td><td>119.7%</td></tr><tr><td>Lactate</td><td></td><td>0.244% w/v</td><td>0.23-0.28% w/v</td><td>95.86%</td></tr></table>Does not comply with BP-2017
<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of test performed.</td></tr>
</table>

5 | Infusion ZEESOL-H RINGER LACTATE 1000ml | 2111040 | M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan. | 0128-P/2022 dated 25-08-2022

Analysis with specifications applied:

British Pharmacopoeia 2017

ASSAY:

ASSAY	Stated	Found	Limit	Percentage
Sodium		0.300% w/v	0.27-0.32% w/v	101.8 %
Potassium		0.0198% w/v	0.019-0.022% w/v	99.27 %
Total Chlorides		0.40% w/v	0.37-0.42% w/v	101.43%
Calcium Chlorides Dihydrate	0.027% w/v	**0.032% w/v**	0.025-0.029% w/v	**121.9%**
Lactate		0.255% w/v	0.23-0.28% w/v	100.35%

Does not comply with BP-2017

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

6 | Infusion ZEESOL-H RINGER LACTATE 1000ml | 2111039 | M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan. | 0129-P/2022 dated 25-08-2022

Analysis with specifications applied:

British Pharmacopoeia 2017

ASSAY:

ASSAY	Stated	Found	Limit	Percentage
Sodium		0.395% w/v	0.27-0.32% w/v	100.0 %
Potassium		0.020% w/v	0.019-0.022% w/v	100.0 %
Total Chlorides		0.403% w/v	0.37-0.42% w/v	102.05%
Calcium Chlorides Dihydrate	0.027% w/v	**0.030% w/v**	0.025-0.029% w/v	**113.2%**
Lactate		0.247% w/v	0.23-0.28% w/v	97.21%

Does not comply with BP-2017

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

7 | Infusion ZEESOL-H RINGER LACTATE 1000ml | 2111035 | M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan. | 0130-P/2022 dated 25-08-2022

Analysis with specifications applied:

British Pharmacopoeia 2017

ASSAY:

ASSAY	Stated	Found	Limit	Percentage
Sodium		0.314% w/v	0.27-0.32% w/v	106.6 %
Potassium		0.0194% w/v	0.019-0.022% w/v	97.0 %
Total Chlorides		0.406% w/v	0.37-0.42% w/v	102.9%
Calcium Chlorides Dihydrate	0.027% w/v	**0.032% w/v**	0.025-0.029% w/v	**120.8%**
Lactate		0.2404% w/v	0.23-0.28% w/v	94.31%

Does not comply with BP-2017

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

8 | Infusion ZEESOL-H RINGER LACTATE 1000ml | 2111038 | M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan. | 0135-P/2022 dated 25-08-2022

Analysis with specifications applied:

British Pharmacopoeia 2017

ASSAY:

ASSAY	Stated	Found	Limit	Percentage
Sodium		0.298% w/v	0.27-0.32% w/v	101.3 %
Potassium		0.019% w/v	0.019-0.022% w/v	99.86 %
Total Chlorides		0.402% w/v	0.37-0.42% w/v	102.0%
Calcium Chlorides Dihydrate	0.027% w/v	**0.032% w/v**	0.025-0.029% w/v	**119.7%**
Lactate		0.248% w/v	0.23-0.28% w/v	97.6%

Does not comply with BP-2017

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

<table>
<tr>
<td>9</td>
<td>Infusion ZEESOL-H RINGER LACTATE 1000ml</td>
<td>2111034</td>
<td>M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan.</td>
<td>0131-P/2022 dated 25-08-2022</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>Sodium</td><td></td><td>0.290% w/v</td><td>0.27-0.32% w/v</td><td>98.6 %</td></tr>
<tr><td>Potassium</td><td></td><td>0.019% w/v</td><td>0.019-0.022% w/v</td><td>95.0 %</td></tr>
<tr><td>Total Chlorides</td><td></td><td>0.42% w/v</td><td>0.37-0.42% w/v</td><td>106.5%</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.032% w/v</td><td>0.025-0.029% w/v</td><td>121.9%</td></tr>
<tr><td>Lactate</td><td></td><td>0.249% w/v</td><td>0.23-0.28% w/v</td><td>98.02%</td></tr>
</table>
Does not comply with BP-2017
<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of test performed.</td>
</tr>
<tr>
<td>10</td>
<td>Infusion ZEESOL-H RINGER LACTATE 1000ml</td>
<td>2111043</td>
<td>M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan.</td>
<td>0132-P/2022 dated 25-08-2022</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>Sodium</td><td></td><td>0.279% w/v</td><td>0.27-0.32% w/v</td><td>94.6 %</td></tr>
<tr><td>Potassium</td><td></td><td>0.0195% w/v</td><td>0.019-0.022% w/v</td><td>97.8 %</td></tr>
<tr><td>Total Chlorides</td><td></td><td>0.42% w/v</td><td>0.37-0.42% w/v</td><td>106.5%</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.032% w/v</td><td>0.025-0.029% w/v</td><td>119.7%</td></tr>
<tr><td>Lactate</td><td></td><td>0.245% w/v</td><td>0.23-0.28% w/v</td><td>96.0%</td></tr>
</table>
Does not comply with BP-2017
<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of test performed.</td>
</tr>
<tr>
<td>11</td>
<td>Infusion ZEESOL-H RINGER LACTATE 1000ml</td>
<td>2111041</td>
<td>M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan.</td>
<td>0133-P/2022 dated 25-08-2022</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>Sodium</td><td></td><td>0.298% w/v</td><td>0.27-0.32% w/v</td><td>101.3 %</td></tr>
<tr><td>Potassium</td><td></td><td>0.0215% w/v</td><td>0.019-0.022% w/v</td><td>107.5 %</td></tr>
<tr><td>Total Chlorides</td><td></td><td>0.413% w/v</td><td>0.37-0.42% w/v</td><td>104.7%</td></tr>
<tr><td>Calcium Chlorides Dihydrate</td><td>0.027% w/v</td><td>0.032% w/v</td><td>0.025-0.029% w/v</td><td>119.7%</td></tr>
<tr><td>Lactate</td><td></td><td>0.25% w/v</td><td>0.23-0.28% w/v</td><td>98.2%</td></tr>
</table>
Does not comply with BP-2017
<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of test 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 drugs**

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 dated 27-01-2023</u>

The following submissions are made:

1. *That A COMMUNI OBSERVANTIA NON EST RECEDENDUM is a well cited maxim applicable to all proceeding under the Drugs Act 1976b where a thing is provided to be done in a particular manner, it has to be done in that manner and if not so done, the same would not be lawful. It is regretted that the special procedure/provisions prescribed under sections 11, 18, 19, 22, & 32 of the Drugs Act 1976 plus Rule 5 of the Punjab drugs Rules 2007.*
2. *That all the correspondence related to Zeesol-H (Ringer Lactate) Infusion between the Company M/s Shazeb Pharmaceutical Industries Limited Hazara Trunk Road Sarai Gadaee, District Haripur KPK and Provincial Drug Inspector Lahore + PQCB may* ***please be taken as an integral component of this reply to this SCN****.*
3. *That the SCN contains information of Batch Numbers. Reports of Government Analyst and federal government Analyst related to Zeesol-H l00ml in a disorderly manner which created lot of problem for sorting out different batch numbers.*
4. *That there is a need to understand that supply of medicines to the Private market and Public Sector Government Institutions are different. The Sale to private sector does not require any pretesting by lab and purchase requires procuring medicine under a valid warranty. In government supplies, the manufacturer gives warranty, but the medicines are not released for use by the patient until standard quality report received from the competent legal government Analyst. Furthermore, the manufacturer immediately receives payment while selling drugs to a purchaser in private market whereas the payment in government supplies is subjected to many checks including issuance of Standard Quality Report by the government Analyst. it is not possible to use any government Supply Medicine without being tested. The status of the stocks lying in Hospital/Institution prior to release of the standard quality report by the government Analyst is just like stock in quarantine.* ***the company has not received any payments against the Supply of Above medicines****. Therefore, sale is not complete as far as contractual terms and conditions are concerned.*
5. *That all 12 Batches of Zeesol H 1000ml were declared substandard by the Government Analyst DTL, Lahore. It was determined by the government Analyst that all the tests were in compliance except* ***clinically insignificant deviation of active ingredient Calcium Chloride*** *in all these 12 batches from the official limit. It is added that* ***result of Calcium Chloride was given on the basis of Dihydrate $CaCl_2.2H_2O$ instead of anhydrous $CaCl_2$ which is cause of higher result****. Similarly, federal Government Analyst determined that all the tests were in compliance except clinically insignificant deviation of active ingredient Calcium Chloride in all these 12 batches from the official limit. It would be appropriate to present a comparative study of analysis of Zeesol-H for determining Calium Chloride ($CaCl_2$ or $CaCl_2.2H_2O$) by Provincial Government Analyst, Federal Appellate lab NIH Islamabad and Atomic Absorption.* ***The NIH has issued all the reports by conduction Non-Aqueous titration whereas provincial Government Analyst has not given details about protocol of the tests conducted****.* ***The company has conducted the test by use of atomic absorption.***
6. *That the company conducted in depth in-house investigation related to the disputed Test /Analysis reports soon after receipt from the Drug inspector LGH Lahore. The outcomes had shown in a crystal-clear manner that Zeesol-H (Ringer Lactate) Infusion batches manufactured by M/s Shazeb Pharmaceutical Industries Limited Hazara Trunk Road Sarai Gadaee District Haripur KPK were* ***in compliance with all the prescribed specification****. All the SOP based systems of the company related to pharmaceutical product Zeesol-H were operating appropriately as per the SOPs.*
7. *That the company has great respect with highest possible level of compliance to all the prevailing law regulating Pharmaceutical Industry and has always worked within the legal frame work of the DRAP Act 2012, the Drugs Act 1976 and Rules framed there under in order to ensure delivery of high quality effective and safe drugs to the patients Regulatory legal advices related to uplifting quality and safety of medicines is always welcome with l00% compliance.* ***The inspection by DRAP recorded on the Inspection Book of the Company are the credible evidence****. Renewal of DML has been approved by DRAP Inspection Panel. Recently, on the invitation of the company.* ***a team of the PQCB had inspected the Pharmaceutical Unit of the company*** *established and operational in KPK. The report PQCB Panel had submitted its report for consideration of the same by PQCB in its meeting. After detailed discussion, the cases of minor violations were disposed of in favor of the company.*
8. *That Noncompliance to Section 19 (3) related to statutory requirement of sending warrantor 's portion within seven days is an illegality.* ***The Warrantor's portion has not been sent to the manufacturer within statutory period of seven days as prescribed under Section 19(3) (iv) of the Drugs Act 1976****. The non-observance to said procedure is highly doubtful and is an illegality. The PQCB has unanimously dropped a case no. PQCB R-577-9/2016 related to Infusion Dorcip Batch No. Dc-075 declared as Adulterated and Substandard by Government Analyst Drug Testing Laboratory Rawalpindi vide DL Report. TRA. No. 1077/DTL Dated 22-09-2016. The PQCB had observed that this case was fit for prosecution on the basis of report. But. this case was dropped as PQCB had observed that case would fail in court because warrantor portion was not sent to the manufacturer within statutory period as prescribed under Section 19(3) of the Drug Act 1976. PQCB members may kindly compare the present case of slight variation in pH of the reconstituted oral suspension of Levor 250 Dry Susp 60ml, B.NO. 032 with the IGNORED CASE of Infusion Dorcin ascertain level of potential and real clinical risks/ADR + both cases are similar with the ignored case may differentiated as of more severity. It is added that the author of the SCN has not mentioned date of dispatch/receipt of Warrantor 's portion in Para-iv due to reason bets known to him.*
9. *That the* ***Reference samples of the same Batch Numbers*** *of the Zee Sol H Infusion 1000ml have been tested at the Well Equipped Quality Control Laboratory of the Company by using Titration method (BP) and counterchecked/ verified by Atomic Absorption. The results have shown that all the specification are in compliance within the official limits.*
10. *That the* ***reports of both the laboratories are non-conclusive as well as unlawful*** ***because all protocols the test applied to reach the conclusion and Results of disputed drugs as substandard have not been given in the above lest reports****. The single bench of Lahore High Court has held that Reports of Analyst has to be conclusive and must disclose the tests applied to formulate opinion of government Analyst. There is always likelihood of errors in tests/ analysis report which would be of adverse consequence and definitely affects substantial rights of a person Therefore the description of the experiment including method evaluating standards/ results must be Crystal clear whenever report would be disputed.* ***Reliance on PLD 2003 Lah.*** *The Honorable Single Judge relied on these pdgments in the reported cases-Gyanendra Nath Mittal v. State AIR 1959 All 634; S. Dutta and another. The DB Judgments of Peshawar High Court and Quetta high Court had also held that report without protocol were fatally defective and unlawful.* ***Reliance on 1996 P Cr.LJ 1183*** *(Peshawar).115, PLJ 2012 Cr.C. (Quetta) 546 (DB). The reports are non-conclusive as well as unlawful because full protocols the test applied to reach the conclusion and Results of disputed drugs as substandard have not been given in the above test Report. The honorable Supreme Court has held in case reported as 2019 SCM 930 Report of the government Analyst must contain Protocol. The term protocol has not been defined in the rules. Its dictionary meaning is "A plan of scientific experiment or other procedure. It is also referred to as the precise method for carrying out or reproducing a given experiment. (Chambers 2lst Century Dictionary, 2007 Edition) These definitions are in line with the elaboration of the term "protocol" given in case of lmam Bakhsh wherein the Court stated the expression protocol to mean an explicit plan of an experiment, procedure or test. It is clarified that protocol is therefore, a recognized standard method or plan for carrying out the test applied to ascertain the nature of the substance under examination. No test can take place without a protocol.* ***The report of the government Analyst must show that the test applied was in accordance with a recognized standard protocol****. Any test conducted without a protocol loses its reliability and evidentiary value. Therefore, to serve the purposes of the Act and the rules, the Report of the Government Analyst must contain:*

    a) The Tests Applied

    b) The Protocols Applied to Carry Out These tests

    c) The Result of the Test(s)

11. *That there is violation of Mandatory Rule 3 of the Drug Act 1976 and the Drug Specification Rules 1978 which require that* ***latest version of the Pharmacopeia must be applied*** *when testing the Drugs under the Drug Act 1976*
12. *That the Para 2 of the SCN is vague as Well as misconstrued because the whole of the Section 23/27 has been mentioned as contravention. The application of the Section 27(2) dealing with false warranty is malice in law as well as malice in fact because good and sufficient reason are available that* ***warranty was given after determination and issuance of standard quality reports*** *of Zeesol H 1000ml by the well-equipped state of art quality Control lab of the Company. The PQCB is not empowered to take any action under the DRAP Act 2012 after implementation the Punjab Amendment Drug Act 2017/2018.*
13. *That the para 2 of SCN alleges that "In this Way you have Contravened the section 23/27 of the Drug Act 1976 (as amended) DRAP act 2012 and Rules framed thereunder by way of Manufacturing/Selling/stocking of Substandard drug and Issuance of false warranty*

Comments/Explanation

i. *The company has Neither contravened section 23/27 of the Drug Act 197G (as amended) Nor the DRAP act 2012 and Rules framed thereunder. The case is based upon the Non-Conclusive report of Government Analyst as sufficient evidence in controversion to this report is available as per requirement of section 22(4) of the Drug Act 1976. 23/27 of the Drug Act 1976 is maliciously applied by omitting the specific Sections. 23 (1) –(a-i-x, b-h, 10-i-ii and (27-1), (27-2). (27-3) and (27-4). The Punjab Amendment in the Drug Act 1976 and DRAP Act 2012 not applicable simultaneously on this case Because the Drug Act 1976 which is the part of Schedule VI of DRAP Act 2012 is different from the Drug Act 1976 with Punjab Amendment 2017/2018.*

ii. *The charge of Issuance of false warranty is based upon misreading of relevant law. The warranty was issued after release of standard quality report by Quality Control Department of the company. the offence of issuance of false warranty is added to enhance punishment with malafide intention. The application of the Section 27(2) dealing with false warranty is malice in law as well as malice in fact because good and sufficient reason were available that warranty was given atter release of medicines by quality Control Department of the Company. The section 27.(2),(b) is reproduced below:*

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

14. ***That PARA 3 of SCN is reproduced***

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/s/ in the Drug Court.*
ii. *The licensing Authority/ Drug registration Authority should not be recommended cancellation Suspension of your Drug Manufacturing Sale License and Drug Registration.*
iii. *Other suitable legal action (s) should not be taken against you*

Comments/Explanation

i. *The prosecution would be unlawful because it would be based upon the Non-Conclusive Report which cannot be used as evidence in any criminal trial. Furthermore Mandatory provisions of Drug Act 196 have been violated which would adversely affect the prosecution culminating into a futile exercise which would ultimately lead to acquittal of the accused. It is respectfully repeated reminded that reports of both the Analysts which form basis of this SCN are unlawful.*
ii. *The PQCB cannot give recommendation of the licensing Authority /Drug Registration Authority either for cancellation/ Suspension of your Drug Manufacturing or/ and Drug Registration because the PQCB has not conducted any inspection as per requirement of Section 11 (5)(a) of the Drug Act 1976 (Punjab Drug Amendment Act 2017/ 2018) is reproduced below:*
iii. *11 (5) The following shall be the powers and functions of the Provincial L quality Control Board, namely (a/to inspect any prem/ses where any drug is being, or is to be, manufactured or sold and to recommend to the appropriate authority the cancellation or suspension of the license to manufacture or sell drugs granted to any person wha is found to be contravening, or to have Contravened any of the provisions of this Act or the rules.*
iv. *The only legal action would be dropping of the case under the Drug Act 1876 because any other action would be equivalent to out of good faith - unlawful act outside the legal boundaries of the applicable prevailing Drug laws in Punjab / Pakistan. The only appropriated, just, fair and suitable action Para 3(iii) would be, to drop this open and shut case.*

15. *That comments on the Para 4 are that **the names are hereby verified** **with the submissions that Ashfaq Safdar Tarar CEO of the Company has no knowledge and consent related to the manufacturing or Quality Control processes**. This submission is given by keeping in view the prevailing Drug law read With latest Policy Board guided DRAP-Guideline circulated by Drug Regulatory Authority of Pakistan- Government of Pakistan Ministry of National Health Services Regulations & Coordination Islamabad, vide No. F.11-13/2022-LA Dated 2nd December 2022 reproduced below as ready reference.*

Subject: OFFENCES BY COMPANIES UNDER THE DRAP ACT, 2012 AND THE DRUGS ACT, 1976

The Pakistan Pharmaceutical Manufacturers 'Association (PPMA) has approached the Drug Regulatory Authority of Pakistan (DRAP) regarding implementation of the DRAP Act 2012 and the Drugs Act 1976 in a just and judicious manner in accordance with the following judgment of the Hon'ble Supreme Court of Pakistan reported as PLD 1978 SC 193

*"Whether Managing Director is liable. **Managing Director being assisted by various executives and workers**, it is difficult to presume that respondent is guilty of manufacture of substandard drugs. **Burden of proof lies on prosecution to prove offence** having been committed within knowledge and consent of the Director."*

2. Similarly, the Hon'ble Peshawar High Court in a recent judgment reported as PLD 2021 Peshawar 154 has held that:

13. .) true that under the provisions of section 34 of Drugs Act 1976; if a person guilty of an offence under ibid Act is a company, corporation, or firm: then every director, partner or officer of the said company, corporation, as firm with whose knowledge and consent the offence is committed shall be guilty of the offence. Albeit the ibid provision has placed emphasis upon the knowledge and consent of the director. partner, or officer of the said company, corporation, or firm, qua the offence, which under the law shall be proved by the prosecution,

3. Section 28 of the DRAP Act 2012 deals with offences by companies etc. It stipulates that where the Person guilty of an offence under this Act or the Drugs Act, 1976 (XXXI of 1976) is a company, corporation, firm or institution, every director, partner and employee of the company, corporation, firm or institution with whose knowledge or consent the offence was Committed shall be guilty of the offence. [Emphasis added]

*4. Noncompliance of the above referred provision with reference to **unnecessary involving the director(s)/employees/ who are not involved or who do not have knowledge or consent to the commission of the offence is adversely affecting the growth of the pharmaceutical industry**. Therefore, DRAP Authority has directed to issue policy guidance under section 7(f) of the DPAP Act 2012 that the name(s) of only those director(s), partner(s) and employee(s) of the company, corporation, firm or institution may be included in the prosecution whose knowledge or consent could be established through evidence under section 28 of the Drug Regulatory Authority of Pakistan Act 2012 and section 34 of the Drugs Act, 1976. (Aamar Latif) -Additional Director (Legal Affairs)*

*All the above persons are given full powers to ensure that all his operations and final finished products released tor market are in accordance with prevailing regulatory requirements in accordance with Drugs Laws of Pakistan. **No one including MD of the company ever has any advance Knowledge or Consent about their decision related to manufacture and sale** within the legal framework of the section 34 of the Drugs Act 1976 or any rule Framed thereunder.*

***It is requested that case may please be dropped as having no merit and is misfit for Prosecution** or any other action under Drug Act 1976, the DRAP Act 2012 and rules framed thereunder. Every citizen of Pakistan is entitled to be dealt in accordance with law and Due process as per requirement of 1973 Constitution of Islamic Republic of Pakistan.*

*It is further requested that **statutory meaningful personal hearing may please be given to the company** whenever case is fixed for hearing before the PQCB for any interim or final order*

4. Personal hearing notice(s) issued to accused person(s) dated 17-02-2023

5. Case is placed before the Board for decision.

SUMMARY:

All above mentioned batches

Manufacturing Date: 11-2021

Expiry Date: 10-2024

Sampling Date (Form 4): 02-12-2021

Sent to DTL (Form 6): 02-12-2021

Date of receipt in DTL: 02-12-2021

DTL Report Date (Form 7): 28-01-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 18-02-2022

Retesting Request of Firm: Yes (28-02-2022)

Fate of Retesting Request of Firm: Allowed in 243rd meeting dated 12-05-2022

Samples Sent to NIH: 16-05-2022

Samples Received by NIH: 23-05-2022

NIH Reports: 25-08-2022 (Substandard)

Investigation Report Dated: 04-11-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/ R-174/2022

Lahore General Hospital, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan** through its Chief Executive Officer, Ashfaq Safdar Tarrar 2. Ashfaq Safdar Tarrar — Chief Executive Officer 3. Suhaib Bin Anees — Production Manager 4. Muhammad Nadeem Khan — Quality Control Manager/ Warrantor of M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Lahore General Hospital, District Lahore reported that: -

i. She, on 20-12-2021, inspected the premises of Main Medicine Store, Lahore General Hospital, 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. 111378 dated 20-12-2021

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	TRA No. & Date	DTL Test Report Result
Infusion. ZEESOL-H [RINGER LACTATE] **Mfg Date:** Nov 2021 **Expiry Date:** Oct 2024 **Regn No.** 019752	2111042	M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan.	01-73010922/DTL dated 04-02-2022	**Analysis with specifications applied: BP 2021** **PHYSICAL DESCRIPTION:** COLOURLESS LIQUID IN SEALED PLASTIC INFUSION BOTTLE WITH HANGER AT BASE AND NO LEAKAGE OF BOTTLE. **pH:** Limits: 5.0 – 7.0 Determined: 6.44 AT 23.7°C (COMPLIES) **IDENTIFICATION:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (LACTATE IDENTIFIED)

ASSAY	Stated	Determined	Limit
Lactate	0.254% w/v	0.267% w/v (Complies)	0.23-0.28% w/v
Sodium	0.301% w/v	0.318% w/v (Complies)	0.27-0.32% w/v
Total Chlorides	0.394% w/v	0.412% w/v Complies)	0.37-0.42% w/v
Calcium Chlorides Dihydrate	0.027% w/v	**0.0340% w/v (DOES NOT COMPLY)**	0.025-0.029% w/v

STERILITY: The product is sterile. (COMPLIES)

RESULT: The above sample is **SUB-STANDARD** on the basis of ASSAY of Calcium chloride dihydrate performed as per BP.

iii. Chief Technician, Lahore General Hospital, District Lahore provided invoice/warranty bearing No. 0104 dated 17-11-2021 issued by M/S Shaze Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent to M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K Pakistan.

v. A copy of test/analysis report was sent to M/S Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadee Distt. Haripur, K.P.K-Pakistan wit 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 th 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 243rd meeting held on 12-05-2022 **allowed** to send the sample to NIH Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No. & Date	NIH Test Report Result
Infusion ZEESOL-H RINGER LACTATE 1000ml	2111042	M/s Shazeb Pharmaceutical Industries Limited, Hazara Trunk Road, Sarai Gadaee Distt. Haripur, K.P.K-Pakistan.	0134-P/2022 dated 25-08-2022	**Analysis with specifications applied:** British Pharmacopoeia 2017 **ASSAY:**

ASSAY	Stated	Found	Limit	Percentage
Sodium		0.306% w/v	0.27-0.32% w/v	104. %
Potassium		0.0202% w/v	0.019-0.022% w/v	101.2 %
Total Chlorides		0.406% w/v	0.37-0.42% w/v	102.9%
Calcium Chlorides Dihydrate	0.027% w/v	**0.033% w/v**	0.025-0.029% w/v	**123.0%**
Lactate		0.242% w/v	0.23-0.28% w/v	95.08%

Does not comply with BP-2017

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

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

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

b. **Issuance of false warranty**

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

Firm submitted combined reply to the show cause notice vide letter dated 27-01-2023 which has already been reproduced with the remaining cases mentioned above.

4. Personal hearing notice(s) issued to accused person(s) dated 17-02-2023

5. Case is placed before the Board for decision.

SUMMARY:

Manufacturing Date: 11-2021

Expiry Date: 10-2024

Sampling Date (Form 4): 22-12-2021

Sent to DTL (Form 6): 20-12-2021

Date of receipt in DTL: 21-12-2021

DTL Report Date (Form 7): 04-02-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 18-02-2022

Retesting Request of Firm: Yes (28-02-2022)

Fate of Retesting Request of Firm: Allowed in 243rd meeting dated 12-05-2022

Samples Sent to NIH: 16-05-2022

Samples Received by NIH: 23-05-2022

NIH Reports: 25-08-2022 (Substandard)

Investigation Report Dated: 04-11-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 36

PQCB R-243/2022

Tehsil and District Bhakkar

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan** through its Managing Director Ahmad Raza 2. Ahmed Raza Managing Director 3. Sohail Qaiyum Production In-charge 4. Yasir Mehmood Quality Control Incharge/Warrantor Of M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

BRIEF FACTS OF THE CASE

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

i. He, on 27-08-2022 inspected the Medicine Store CEO DHA Bhakkar, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 0000138291 dated 27-08-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tab Macrolex Vaginal Tablet [Clotrimazole 500mg] Mfg. Date: 06-2022 Exp. Date: 05-2024 Regn. No: 030364	360	M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan	01-75004734/DTL dated: 16-11-2022	**Result of test/ analysis with specifications applied BP 2022** **COMPOSITION:** Each vaginal tablet contains: clotrimazole USP……..….500mg **DESCRIPTION**: White color oblong biconvex tablet plain on both side Packed in Alu-PVC blister of 1x1, further packed in labelled unit carton. **Note**: As per DRAP order No. F.3-5/2020-I & VII (M-297) dated 7th February 2022 states that "**All registration holders shall follow official pharmacopoeial specifications for all such formulation for which official monograph of dug product is available in the most recent edition of such pharmacopoeia**". Product specification of given sample is "**Bloom Specification**" and it is manufactured after the expiration of timeline to apply such specifications despite the *availability of "**Clotrimazole Vaginal Tablet**" monograph in BP 2022*. So, the manufacturer's claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drug Act 1976. **(Does not comply)** **ASSAY:** Stated: 500mg/tab Determined: 497.386mg/tab Percentage: 99.48% Limit: 95-105% **RESULT:** The sample is declared **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. The Store Keeper, Medicine Store CEO DHA Bhakkar was asked not to dispose of stock of subject drug on Form 3.

iv. Storekeeper Medicine Store CEO DHA, Bhakkar, provided invoice/ warranty No. 17434 dated 19-07-2022 issued by M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

v. Warrantor Portion was sent to M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

vi. A copy of Test/ Analysis report was also sent to M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan and they were directed to provide requisite information in this regard.

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

i. **Manufacture for sale/ Sale of Misbranded Drug.**
ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 20-01-2023.

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

Summary:

Manufacturing Date: 06-2022

Expiry Date: 05-2024

Sampling Date: 27-08-2022

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

Date of receipt in DTL: 06-09-2022

DTL Report Date: 19-11-2022

Time Extension: granted in 253-M

1ST DI Communication with firm on dated: 26-11-2022

Date of Retesting Request of Firm: -N/A

Fate of Retesting Request: -N/A

Investigation Report Dated: 07-12-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 37

PQCB/R-248/2022

THQ Hospital, Kamoke

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan** through its Managing Director Ahmad Raza 2. Ahmed Raza Managing Director 3. Sohail Qaiyum Production In-charge 4. Yasir Mehmood Quality Control Incharge/Warrantor of M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, THQ Hospital, Kamoke reported that: -

i. He, on 17-08-2022 inspected the Medicine Store THQ Hospital, Kamoke, G.T Road, Kamoke, Gujranwala, took different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memo no. 137015 dated 17-08-2022.

ii. The following 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
Tablet. Macrolex [Each Vaginal tablet contains: Clotrimazole USP … 500mg] **Mfg. Date:** 06-2022 **Exp. Date:** 05-2024 **Regn. No:** 030364	360	M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan	01-68017819/DTL dated: 21-10-2022	**Result of test/ analysis with specifications applied USP** 2022 **DESCRIPTION**: Off-white colored, oblong shaped, biconvex, compressed tablets, plain from both sides, contained in Alu-PVC blister of 01 unit, packed in outer hard carton along with applicator. **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 formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia**". Product specifications of given sample is "**Product Complies**: **Bloom Specification**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of Clotrimazole Vaginal Inserts monograph in USP 2022. So, the manufacturer's claim regarding product specifications is in contradiction to DRAP circular and also in violation to Drug Act 1976. **(Does not Comply)** **UNIFORMITY OF DOSAGE UNIT (Weight Variation)** Complies the acceptance criteria of Uniformity of dosage unit (weight variation) as per USP 2022 (Average weight of Tablet= 964.65mg) Acceptance Criteria: Acceptance Value≤L1%= 15% Determined: Acceptance Value =3.695% (Complies) **IDENTIFICATION:** Clotrimazole is identified. **ASSAY:** Stated: 500mg/Tablet Determined: 512.875 mg /Tablet Percentage: 102.575% (Complies) Limit: 90-110% (USP 2022) **DISINTEGRATION TEST:** Stated: All 6 tablets should disintegrate within 20 minutes (USP 2022) Determined: All 6 units disintegrated within 20 minutes (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 of Medicine Store THQ Hospital, Kamoke, G.T Road, Kamoke, Gujranwala, provided invoice/ warranty No. 17180 dated 06-07-2022 issued by M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

iv. Warrantor Portion of the drug sample was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan with directions to explain the 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 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 persons dated 18-01-2023

Firm submitted reply of Show cause

It is submitted that we M/S Bloom Pharmaceuticals (Pvt) Ltd., manufactured and supplied Macrolex Vaginal Tablet in bulk quantity ***i.e. 219,573 tablets*** *to the various Government health institutions of the Punjab, Detail is mentioned as under:*

Sr. NO	Instituituins	Station	Quantity supplied
1	Chief Executive Officer (DHA) Attock	Attock	42100
2	Chief Executive Officer (DHA) Lahore	Lahore	67600
3	Chief Executive Officer (DHA) Kasur	kasur	50000
4	M.S THQ Hospital Wazirabad Gujranwala	Gujrawala	200
5	M.S THQ Hospital Kamoke Gujranwala	Gujrawala	1000
6	M.S Govt. Matemity Hospital Satellite Town	Gujranwala	1500
7	Chief Executive Officer (DHA) Bhakkar	Bhakkar	3400
8	Chief Executive Officer (DHA) Chakwal	Chakwal	3500
9	Chief Executive Officer (DHA) Jhelum	Khanewal	1700
10	Chief Executive Officer (DHA) Khanewal	Khanewal	3000
11	Chief Executive Officer (DHA) Narowal	Narowal	5600
12	Chief Executive Officer (DHA) Layyah	Layyah	3000
13	Chief Executive Officer (DHA) Toba Tek singh	Toba Tek Singh	1795
14	Chief Executive Officer (DHA)Hafizabad	Hafizabad	2500
15	THQ Hospital Chichawatni Sahiwal	Sahiwal	1000
16	THQ Hospital Kot Addu	Muzzafargarh	500
17	Hospital Chowk Sarwar Shaheed Muzaffargarh Muzaffargarh	Muzzafargarh	500
18	DHQ Hospital Muzaffargarh	Muzzafargarh	1000
19	M.S THQ Hospital Kabirwala Khanewal	Khanewal	500
20	Chief Executive Officer (DHA) Mianwali	Mianwali	2000
21	Bahawalnagar Chief Executive Officer (DHA)	Bahawalnagar	4800
22	M.S THQ Hospital Jahanian Khanewal	Khnaewal	1000
23	Chief Executive Officer (DHA) Vehari	Vehari	1750
24	Chief Executive Officer (DHA) Okara	Okara	2400
25	Chief Executive Officer (DHA) Mandi bahuddin	Mandi Bahauddin	3500
26	Chief Executive Officer (DHA)Rawalpindi	Rawalpindi	8780
27	Chief Executive Oficer Lodhran	Lodhran	4500
28	Chief Executive Oficer (DHA) Sahiwal	Sahiwal	448

The above said product is of Standard quality as it contains therapeutic active ingredient Clotrimazole within Pharmacopeia limit as assay along with other quality tests in the above said DTL report comply standard limits, inference is that the drug is effective and safe for use in patients. Furthermore, the drug is misbranded on the basis of labelling i.e., "Bloom Specs," instead of Pharmacopeial (USP / BP) Specs. But now, we have rectified the specifications of the subject product from "Bloom Specs." to "B.P. Specs". ***Remedied packaging material*** *consisting of Unit carton, Aluminium foil & leaflet of; Govt, packaging and Commercial packaging. It is requested that the above said product is of standard quality therefore please give us warning and also allow us to use the stock of above mentioned drug. Details of re-called stock: Nil,*

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

Case is placed before the Board

PROCEEDING & DECISIONS BY THE BOARD:

Case No. 38

PQCB/R-269/2022

Tehsil & District Hafizabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan** through its Managing Director, Ahmed Raza 2. Ahmad Raza — Managing Director 3. Sohail Qayyum — Production In-charge 4. Yasir Mehmood — Quality Control Incharge/Warrantor of M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 17-08-2022 inspected the Main Medicine Store District Complex CEO Health DHA Hafizabad, took different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memo no. 136969 dated 17-08-2022.

ii. The following 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
Tablet. Macrolex [Each Vaginal tablet contains: Clotrimazole USP … 500mg] **Mfg. Date:** 06-2022 **Exp. Date:** 05-2024 **Regn. No:** 030364	360	M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan	01-68017900/DTL dated: 21-10-2022	**Result of test/ analysis with specifications applied USP** 2022 **DESCRIPTION**: Off-white colored, oblong shaped, biconvex, compressed tablets, plain from both sides, contained in Alu-PVC blister of 01 unit, packed in outer hard carton along with applicator. **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 formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia**". Product specifications of given sample is "**Product Complies**: **Bloom Specification**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of Clotrimazole Vaginal Inserts monograph in USP 2022. So, the manufacturer's claim regarding product specifications is in contradiction to DRAP circular and also in violation to Drug Act 1976. **(Does not Comply)** **UNIFORMITY OF DOSAGE UNIT (Weight Variation)** Complies the acceptance criteria of Uniformity of dosage unit (weight variation) as per USP 2022 (Average weight of Tablet= 964.65mg) Acceptance Criteria: Acceptance Value≤L1%= 15% Determined: Acceptance Value =3.632% (Complies) **IDENTIFICATION:** Clotrimazole is identified. **ASSAY:** Stated: 500mg/Tablet Determined: 509.795mg/Tablet Percentage: 101.959% (Complies) Limit: 90-110% (USP 2022) **DISINTEGRATION TEST:** Stated: All 6 tablets should disintegrate within 20 minutes (USP 2022) Determined: All 6 units disintegrated within 20 minutes (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 of Main Medicine Store District Complex CEO Health DHA Hafizabad, provided invoice/ warranty No. 17241 dated 19-07-2022 issued by M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

iv. Warrantor Portion of the drug sample was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan with directions to explain the 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 20-01-2023

Firm replied to the show cause notice vide letter dated 25-01-2023

The above said product is of Standard quality as it contains therapeutic active ingredient Clotrimazole within Pharmacopeia limit as assay along with other quality tests in the above said DTL report comply standard limits, inference is that the drug is effective and safe for use in patients. Furthermore, the drug is misbranded on the basis of labelling i.e., "Bloom Specs." Instead of Pharmacopeial (USP / BP) Specs. But now, ***we have rectified the specifications of the subject product from "Bloom Specs. to "B.P. Specs"*** *It is requested that the above said product is of standard quality therefore please give us warning and also allow us to use the stock of above mentioned drug.*

4. Personal hearing notice(s) issued to accused person(s) dated 29-03-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 06-2022

Expiry Date: 05-2024

Sampling Date (Form 4): 17-08-2022

Sent to DTL (Form 6): 17-08-2022

Date of receipt in DTL: 23-08-2022

DTL Report Date (Form 7): 21-10-2022

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 10-12-2022

Retesting Request of Firm: NA

Investigation Report Dated: 19-12-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 39

DISTRICT LODHRAN

PQCB/R-236/2022

Tehsil & District Lodhran

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Bloom Pharmaceuticals (Pvt.) Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar-Pakistan** through its Managing Director Ahmed Raza 2. Ahmed Raza Managing Director 3. Sohail Qaiyum Production Incharge 4. Yasir Mehmood Quality Control Incharge/Warrantor Of **M/s Bloom Pharmaceuticals (Pvt.) Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar-Pakistan**.

BRIEF FACTS OF THE CASE

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

i. He, on 26-09-2022 inspected the premises of Main Medicine Store, office of Chief Executive Officer (DHA) Lodhran, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan vide memo no. 0000141679 dated 26-09-2022.

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
Macrolex (Clotrimazole 500 mg) Vagibal Tablet. **Mfg.** **Date:** 06-2022 **Exp. Date:** 05-2024 **Regn. No:** 030364	360	M/s Bloom Pharmaceuticals (Pvt.) Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar-Pakistan	01-94006305/DTL dated: 15-11-2022	**Result of test/ analysis with specifications applied USP** 2022 **Description**: White to off white colored, oblong tablet, plain on both sides of tablet, in ALU-PVC blister of 01 unit packed in a labeled outer hard carton. Each outer carton contains one blister i.e. (1*1=1) tablet along with an applicator per pack. **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 given sample is "**Manufacturer's Specifications"** and it is manufactured after the expiration of timeline to apply such specifications despite the availability of Clotrimazole Vaginal Inserts monograph in USP 2022. So, the manufacturer's claim regarding product specifications is in contradiction to DRAP circular and also in violation to Drugs Act 1976. **Mis-Branded (Does not Comply)** **Uniformity Of Dosage Unit (Weight Variation):** Max. AV=L1: 15% **(Complies)** **Identification:** Clotrimazole Identified. Analyticall technique: By HPLC **ASSAY:** Clotrimazole Stated: 500mg/tablet; Determined: 500.15mg/tablet; Percentage: 100.03 %; Limit: 90-110% **(Complies)** **Disintegration Test:** NMT 20 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.

i. Storekeeper Main Medicine Store, office of Chief Executive Officer (DHA) Lodhran provided invoice/ warranty No. 17505 dated 11-07-2022 issued by M/s Bloom Pharmaceuticals (Pvt.) Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar-Pakistan.

ii. Warrantor Portion was sent to M/s Bloom Pharmaceuticals (Pvt.) Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar-Pakistan.

iii. A copy of Test/ Analysis report was also sent to M/s Bloom Pharmaceuticals (Pvt.) Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar-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:

i. **Manufacturing for Sale /Sale of Misbranded Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 06-01-2023.

Reply of firm to show cause notice vide letter no. Bloom/1401-23-001 dated 14-01-2023

Refer to your good office Letter No. PQCB/R-236/2022 dated 06.01.2023, received on 14.01.2023 regarding Vaginal Tab Macrolex (Clotrimazole 500mg) Batch No. 360 manufactured by Bloom Pharmaceuticals (Pvt) Ltd., Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan, declared Misbranded by Drug Testing Laboratory, Multan Via TRA. No. 01-94006305/DTL dated 15-11-2022.

2. It is submitted that we M/S Bloom Pharmaceuticals (Pvt) Ltd., manufactured and supplied Macrolex Vaginal Tablet in bulk quantity i.e. 219,573 tablets to the various Government health institutions of the Punjab.

3. The above said product is of Standard quality as it contains therapeutic active ingredient Clotrimazole within Pharmacopeia limit as assay along with other quality tests in the above said DTL report comply standard limits, inference is that the drug is effective and safe for use in patients.

4. Furthermore, the drug is misbranded on the basis of labelling i.e., "Bloom Specs." instead of Pharmacopeial (USP/BP) Specs. But now, we have rectified the specifications of the subject product from "Bloom Specs." to "B.P. Specs". Remedied packaging material consisting of Unit carton, Aluminium foil & leaflet of; Govt. packaging is attached as Annex-A and Commercial packaging is attached as Annex-B.

5. **It is requested that the above said product is of standard quality therefore please give us warning and also allow us to use the stock of above mentioned drug**.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 06-2022**
- **Expiry Date: 05-2024**
- **Sampling Date (Form 4): 26-09-2022**
- **Sent to DTL (Form 6): 26-09-2022**
- **Date of receipt in DTL: 27-09-2022**
- **DTL Report Date (Form 7): 15-11-2022**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 26-11-2022**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 09-12-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 40

PQCB/R-289/2022

Tehsil & District Mianwali

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan** through its Managing Director Ahmad Raza 2. Ahmed Raza Managing Director 3. Sohail Qaiyum Production In-charge 4. Yasir Mehmood Quality Control Incharge/Warrantor of M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

BRIEF FACTS OF THE CASE:

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

i. He, on 12-09-2022 inspected the premesis of Warehouse of District Health Authority, Mianwali, took different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memo no. 139788 dated 12-09-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tablet. Macrolex [Clotrimazole: 500 mg] **Mfg. Date:** 06-2022 **Exp. Date:** 05-2024 **Regn. No:** 030364	360	M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan	01-75004897/DTL dated: 18-11-2022	**Result of test/ analysis with specifications applied:** BP 2022 **DESCRIPTION**: White colored, oblong shaped, biconvex, tablet, plain from both sides, packed in Alu-PVC blister of 1x 1, further packed in labelled unit applicator. **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 formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia**". Product specifications of given sample is "**Product Complies**: **Bloom Specification**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of Clotrimazole Vaginal Inserts monograph in USP 2022. So, the manufacturer's claim regarding product specifications is in contradiction to DRAP circular and also in violation to Drug Act 1976. **(Does not Comply)** **ASSAY:** Stated: 500mg/Tablet Determined: 501.965 mg /Tablet Percentage: 100.39 % (Complies) Limit: 90-110% **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)/ Human Import dated 7th February, 2022.

iii. Storekeeper of District Health Authority, Mianwali, provided invoice/ warranty No. 17426 dated 03-08-2022 issued by M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

iv. Warrantor Portion of the drug sample was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan with directions to explain the 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 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 persons dated 13-02-2023

Firm submitted reply of Show cause

It is submitted that we M/S Bloom Pharmaceuticals (Pvt) Ltd., manufactured and supplied Macrolex Vaginal Tablet in bulk quantity ***i.e. 219,573 tablets*** *to the various Government health institutions of the Punjab, Detail is mentioned as under:*

Sr. NO	Instituituins	Station	Quantity supplied
1	Chief Executive Officer (DHA) Attock	Attock	42100
2	Chief Executive Officer (DHA) Lahore	Lahore	67600
3	Chief Executive Officer (DHA) Kasur	kasur	50000
4	M.S THQ Hospital Wazirabad Gujranwala	Gujrawala	200
5	M.S THQ Hospital Kamoke Gujranwala	Gujrawala	1000
6	M.S Govt. Matemity Hospital Satellite Town	Gujranwala	1500
7	Chief Executive Officer (DHA) Bhakkar	Bhakkar	3400
8	Chief Executive Officer (DHA) Chakwal	Chakwal	3500
9	Chief Executive Officer (DHA) Jhelum	Khanewal	1700
10	Chief Executive Officer (DHA) Khanewal	Khanewal	3000
11	Chief Executive Officer (DHA) Narowal	Narowal	5600
12	Chief Executive Officer (DHA) Layyah	Layyah	3000
13	Chief Executive Officer (DHA) Toba Tek singh	Toba Tek Singh	1795
14	Chief Executive Officer (DHA)Hafizabad	Hafizabad	2500
15	THQ Hospital Chichawatni Sahiwal	Sahiwal	1000
16	THQ Hospital Kot Addu	Muzzafargarh	500
17	Hospital Chowk Sarwar Shaheed Muzaffargarh Muzaffargarh	Muzzafargarh	500
18	DHQ Hospital Muzaffargarh	Muzzafargarh	1000
19	M.S THQ Hospital Kabirwala Khanewal	Khanewal	500
20	Chief Executive Officer (DHA) Mianwali	Mianwali	2000
21	Bahawalnagar Chief Executive Officer (DHA)	Bahawalnagar	4800
22	M.S THQ Hospital Jahanian Khanewal	Khnaewal	1000
23	Chief Executive Officer (DHA) Vehari	Vehari	1750
24	Chief Executive Officer (DHA) Okara	Okara	2400
25	Chief Executive Officer (DHA) Mandi bahuddin	Mandi Bahauddin	3500
26	Chief Executive Officer (DHA)Rawalpindi	Rawalpindi	8780
27	Chief Executive Oficer Lodhran	Lodhran	4500
28	Chief Executive Oficer (DHA) Sahiwal	Sahiwal	448

The above said product is of Standard quality as it contains therapeutic active ingredient Clotrimazole within Pharmacopeia limit as assay along with other quality tests in the above said DTL report comply standard limits, inference is that the drug is effective and safe for use in patients. Furthermore, the drug is misbranded on the basis of labelling i.e., "Bloom Specs," instead of Pharmacopeial (USP / BP) Specs. But now, we have rectified the specifications of the subject product from "Bloom Specs." to "B.P. Specs". ***Remedied packaging material*** *consisting of Unit carton, Aluminium foil & leaflet of; Govt, packaging and Commercial packaging. It is requested that the above said product is of standard quality therefore please give us warning and also allow us to use the stock of above mentioned drug. Details of re-called stock: Nil,*

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

Case is placed before the Board

PROCEEDING & DECISIONS BY THE BOARD:

Case No. 41

PQCB/R-288/2022

Tehsil & District Narowal

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan** through its Managing Director Ahmad Raza 2. Ahmed Raza Managing Director 3. Sohail Qaiyum Production In-charge 4. Yasir Mehmood Quality Control Incharge/Warrantor of M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Narowal reported that: -

i. He, on 28-07-2022 inspected the premises of Medical Store Depot, CEO DHA, Narowal, took different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memo no. 134908 dated 28-07-2022.

ii. The following 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
Tablet. Macrolex [Each Vaginal tablet contains: Clotrimazole USP … 500mg] **Mfg. Date:** 06-2022 **Exp. Date:** 05-2024 **Regn. No:** 030364	360	M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan	01-68017376/DTL dated: 21-10-2022	**Result of test/ analysis with specifications applied USP** 2022 **DESCRIPTION**: Off-white colored, oblong shaped, biconvex, compressed tablets, plain from both sides, contained in Alu-PVC blister of 01 unit, packed in outer hard carton along with applicator. **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 formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia**". Product specifications of given sample is "**Product Complies**: **Bloom Specification**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of Clotrimazole Vaginal Inserts monograph in USP 2022. So, the manufacturer's claim regarding product specifications is in contradiction to DRAP circular and also in violation to Drug Act 1976. **(Does not Comply)** **UNIFORMITY OF DOSAGE UNIT (Weight Variation)** Complies the acceptance criteria of Uniformity of dosage unit (weight variation) as per USP 2022 (Average weight of Tablet= 957.43mg) Acceptance Criteria: Acceptance Value≤L1%= 15% Determined: Acceptance Value =3.695% (Complies) **IDENTIFICATION:** Clotrimazole is identified. **ASSAY:** Stated: 500mg/Tablet Determined: 489.95 mg /Tablet Percentage: 97.990% (Complies) Limit: 90-110% (USP 2022) **DISINTEGRATION TEST:** Stated: All 6 tablets should disintegrate within 20 minutes (USP 2022) Determined: All 6 units disintegrated within 20 minutes (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 of Medical Store Depot, CEO DHA, Narowal, provided invoice/ warranty No. 17239 dated 19-07-2022 issued by M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

iv. Warrantor Portion of the drug sample was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan with directions to explain the 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 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 persons dated 13-02-2023

Firm submitted reply of Show cause

It is submitted that we M/S Bloom Pharmaceuticals (Pvt) Ltd., manufactured and supplied Macrolex Vaginal Tablet in bulk quantity ***i.e. 219,573 tablets*** *to the various Government health institutions of the Punjab, Detail is mentioned as under:*

Sr. NO	Instituituins	Station	Quantity supplied
1	Chief Executive Officer (DHA) Attock	Attock	42100
2	Chief Executive Officer (DHA) Lahore	Lahore	67600
3	Chief Executive Officer (DHA) Kasur	kasur	50000
4	M.S THQ Hospital Wazirabad Gujranwala	Gujrawala	200
5	M.S THQ Hospital Kamoke Gujranwala	Gujrawala	1000
6	M.S Govt. Matemity Hospital Satellite Town	Gujranwala	1500
7	Chief Executive Officer (DHA) Bhakkar	Bhakkar	3400
8	Chief Executive Officer (DHA) Chakwal	Chakwal	3500
9	Chief Executive Officer (DHA) Jhelum	Khanewal	1700
10	Chief Executive Officer (DHA) Khanewal	Khanewal	3000
11	Chief Executive Officer (DHA) Narowal	Narowal	5600
12	Chief Executive Officer (DHA) Layyah	Layyah	3000
13	Chief Executive Officer (DHA) Toba Tek singh	Toba Tek Singh	1795
14	Chief Executive Officer (DHA)Hafizabad	Hafizabad	2500
15	THQ Hospital Chichawatni Sahiwal	Sahiwal	1000
16	THQ Hospital Kot Addu	Muzzafargarh	500
17	Hospital Chowk Sarwar Shaheed Muzaffargarh Muzaffargarh	Muzzafargarh	500
18	DHQ Hospital Muzaffargarh	Muzzafargarh	1000
19	M.S THQ Hospital Kabirwala Khanewal	Khanewal	500
20	Chief Executive Officer (DHA) Mianwali	Mianwali	2000
21	Bahawalnagar Chief Executive Officer (DHA)	Bahawalnagar	4800
22	M.S THQ Hospital Jahanian Khanewal	Khnaewal	1000
23	Chief Executive Officer (DHA) Vehari	Vehari	1750
24	Chief Executive Officer (DHA) Okara	Okara	2400
25	Chief Executive Officer (DHA) Mandi bahuddin	Mandi Bahauddin	3500
26	Chief Executive Officer (DHA)Rawalpindi	Rawalpindi	8780
27	Chief Executive Oficer Lodhran	Lodhran	4500
28	Chief Executive Oficer (DHA) Sahiwal	Sahiwal	448

The above said product is of Standard quality as it contains therapeutic active ingredient Clotrimazole within Pharmacopeia limit as assay along with other quality tests in the above said DTL report comply standard limits, inference is that the drug is effective and safe for use in patients. Furthermore, the drug is misbranded on the basis of labelling i.e., "Bloom Specs," instead of Pharmacopeial (USP / BP) Specs. But now, we have rectified the specifications of the subject product from "Bloom Specs." to "B.P. Specs". ***Remedied packaging material*** *consisting of Unit carton, Aluminium foil & leaflet of; Govt, packaging and Commercial packaging. It is requested that the above said product is of standard quality therefore please give us warning and also allow us to use the stock of above mentioned drug. Details of re-called stock: Nil,*

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

Case is placed before the Board

PROCEEDING & DECISIONS BY THE BOARD:

Case No. 42

PQCB/R-237/2022

Tehsil & District Okara

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan** through its Managing Director Ahmad Raza 2. Ahmed Raza Managing Director 3. Sohail Qaiyum Production In-charge 4. Yasir Mehmood Quality Control Incharge/Warrantor of M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

BRIEF FACTS OF THE CASE:

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

i. His predecessor, on 03-10-2022 inspected the medicine store CEO DHA office Okara, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 142738 dated 03-10-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tab Macrolex Vaginal Tablet [Clotrimazole 500mg] **Mfg. Date**: 06-2022 **Exp. Date**: 05-2024 **Regn. No:** 030364	360	M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan	01-10097000378/DTL dated: 16-11-2022	**Result of test/ analysis with specifications applied** USP 2022 **COMPOSITION:** Each vaginal tablet contains: clotrimazole USP…….500mg **DESCRIPTION**: White to off white color oblong biconvex tablet plain on both side. Packed in a blister pack (primary packing) of 01 tablet. The tablet blister along with applicator is packed in outer hard carton (secondary packing). **Note**: As per DRAP order No. F.3-5/2020-I & VII (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 dug product is available in the most recent edition of such pharmacopoeia**". Product specification of given sample is "**Product Complies**: **Bloom Specification**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "**Clotimazole Vaginal Inserts**" 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**). **Wt. VARIATION (USP):** **Limit**: AV10≤L1% (15.0) **Determined**: AV10=3.245 **DISINTEGRATION (USP):** **Limit**: all tablets must be disintegrated within NMT 20min. **Result**: All 06 tablets were disintegrated 20min **IDENTIFICATION (USP):** Clotrimazole is identified **ASSAY (USP): Clotrimazole** Stated: 500mg/tab Determined: 506.73mg/tab Percentage: 101.35% Limit: 90-110% **RESULT:** The sample is declared **Misbranded** as per Section 3 (s) (iv) of The 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 CEO DHA office Okara, provided invoice/ warranty No. 17430 dated 02-07-2022 issued by M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

iv. Warrantor Portion was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

v. A copy of Test/ Analysis report was also sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar 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 Misbranded Drug.**
ii. **Issuance of false warranty.**

3. Show-cause notice(s) issued to the accused dated 03-01-2023

Firm submitted reply of Show cause vide letter no. Bloom/1701-23 dated 17-01-2023

*It is submitted that we M/S Bloom Pharmaceuticals (Pvt) Ltd., manufactured and supplied Macrolex Vaginal Tablet in bulk quantity **i.e. 219,573 tablets** to the various Government health institutions of the Punjab, Detail is mentioned as under:*

Sr. No	Institution	Station	Quantity supplied
1	Chief Executive Officer (DHA)	Attock	42100
2	Chief Executive Officer (DHA)	Lahore	67600
3	Chief Executive Officer (DHA)	Kasur	50000
4	M.S THQ Hospital Wazirabad	Gujranwala	200
5	M.S THQ Hospital Kamoke	Gujranwala	1000
6	M.S Govt. Maternity Hospital Satellite Town	Gujranwala	1500
7	Chief Executive Officer (DHA)	Bhakkar	3400
8	Chief Executive Officer (DHA)	Chakwal	3500
9	Chief Executive Officer (DHA)	Jhelum	1700
10	Chief Executive Officer (DHA)	Khanewal	3000
11	Chief Executive Officer (DHA)	Narowal	5600
12	Chief Executive Officer (DHA)	Layyah	3000
13	Chief Executive Officer (DHA)	Toba Tek Singh	1795
14	Chief Executive Officer (DHA)	Hafizabad	2500
15	THQ Hospital Chichawatni	Sahiwal	1000
16	THQ Hospital Kot Addu	Muzaffargarh	500
17	THQ level 50 bedded Hospital Chowk Sarwar Shaheed	Muzaffargarh	500
18	DHQ Hospital	Muzaffargarh	1000
19	M.S THQ Hospital Kabir Wala	Khanewal	500
20	Chief Executive Officer (DHA)	Mianwali	2000
21	Chief Executive Officer (DHA)	Bahawalnagar	4800
22	M.S THQ Hospital Jahanian	Khanewal	1000
23	Chief Executive Officer (DHA)	Vehari	1750
24	Chief Executive Officer (DHA)	Okara	2400
25	Chief Executive Officer (DHA)	Mandi Bahauddin	3500
26	Chief Executive Officer (DHA)	Rawalpindi	8780
27	Chief Executive Officer	Lodhran	4500
28	Chief Executive Officer (DHA)	Sahiwal	448

3. The above said product is of Standard quality as it contains therapeutic active ingredient Clotrimazole within Pharmacopeia limit as assay along with other quality tests in the above said DTL report comply standard limits, inference is that the drug is effective and safe for use in patients.

*4. Furthermore, the drug is misbranded on the basis of labelling i.e., "Bloom Specs," instead of Pharmacopeial (USP/BP) Specs. But now, we **have rectified the specifications** of the subject product from "Bloom Specs." to "B.P. Specs". Remedied packaging material consisting of Unit carton, Aluminium foil & leaflet of; Govt, packaging and Commercial packaging.*

5. It is requested that the above said product is of standard quality therefore please give us warning and also allow us to use the stock of above-mentioned drug. Details of re-called stock: Nil,

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD

Case No. 43

PQCB R-261/2022

Tehsil and District Rawalpindi

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan** through its Managing Director Ahmad Raza 2. Ahmed Raza Managing Director 3. Sohail Qaiyum Production In-charge 4. Yasir Mehmood Quality Control Incharge/Warrantor Of M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

BRIEF FACTS OF THE CASE

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

i. He, on 13-09-2022 inspected the Medicine Store District Health Authority, Rawalpindi took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 0000139942 dated 13-09-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tab Macrolex Vaginal Tablet [Clotrimazole 500mg] **Mfg. Date**: 06-2022 **Exp. Date**: 05-2024 **Regn. No:** 030364	360	M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan	01-74005704/DTL dated: 01-12-2022	**Result of test/ analysis with specifications applied: BP 2022** **DESCRIPTION**: White color oblong biconvex tablet plain on both side Packed in Alu-PVC blister of 1x1, further packed in labelled unit carton with applicator. **Note**: As per DRAP order No. F.3-5/2020-I & VII (M-297) dated 7th February 2022 states that "**All registration holders shall follow official pharmacopoeial specifications for all such formulation for which official monograph of dug product is available in the most recent edition of such pharmacopoeia**". Product specification of given sample is "**Bloom Specification**" and it is manufactured after the expiration of timeline to apply such specifications despite the *availability of "**Clotrimazole Vaginal Tablet**" monograph in BP 2022*. So, the manufacturer's claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drug Act 1976. **(Does not comply)** **ASSAY:** Stated: 500mg/tab Determined: 496.950mg/tab Percentage: 99.39% Limit: 95-105% **RESULT:** The sample is declared **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. District Health Officer (Medical Services), District Health Authority, Rawalpindi, provided invoice/ warranty No. 17432 dated 17-06-2022 issued by M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

iv. Warrantor Portion was sent to M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

v. A copy of Test/ Analysis report was also sent to M/s Bloom Pharmaceuticals Pvt. Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan and they were directed to provide requisite information in this regard.

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

i. **Manufacture for sale/ Sale of Misbranded Drug.**

ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 30-01-2023.

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

Summary:

Manufacturing Date: 06-2022

Expiry Date: 05-2024

Sampling Date: 13-09-2022

Sent to DTL (Form 6): 13-09-2022

Date of receipt in DTL: 14-09-2022

DTL Report Date: 01-12-2022

Time Extension: granted in 254-M

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

Date of Retesting Request of Firm: -N/A

Fate of Retesting Request: -N/A

Investigation Report Dated: 14-12-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 44

PQCB/R-255/2022

Tehsil & District Sahiwal

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan** through its Managing Director Ahmad Raza 2. Ahmed Raza Managing Director 3. Sohail Qaiyum Production In-charge 4. Yasir Mehmood Quality Control Incharge/Warrantor of M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

BRIEF FACTS OF THE CASE:

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

i. He, on 10-08-2022 inspected the medicine store o/o CEO DHA Sahiwal, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 136231 dated 10-08-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tab Macrolex Vaginal Tablet [Clotrimazole 500mg] **Mfg**. Date: 06-2022 **Exp**. Date: 05-2024 **Regn**. No: 030364	360	M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan	01-10094000494/DTL dated: 27-10-2022	**Result of test/ analysis with specifications applied USP** 2022 **COMPOSITION:** Each vaginal tablet contains: Clotrimazole USP……..….500mg **DESCRIPTION**: White to off white color oblong biconvex tablet plain on both side. Packed in a blister pack (primary packing) of 01 tablet. The tablet blister along with applicator is 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 that "**All registration holders shall follow official pharmacopeial specifications for all such formulation for which official monograph of dug product is available in the most recent edition of such pharmacopoeia**". Product specification of given sample is "**Product Complies**: **Bloom Specification**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "**Clotimazole Vaginal Inserts**" 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**). **Wt. VARIATION (USP):** **Limit**: AV10≤L1% (15.0) **Determined**: AV10=3.27 **DISINTEGRATION (USP):** **Limit**: all tablets must be disintegrated within NMT 20min. **Result**: All 06 tablets were disintegrated 20min **IDENTIFICATION (USP):** Clotrimazole is identified **ASSAY (USP): Clotrimazole** Stated: 500mg/tab Determined: 506.82mg/tab Percentage: 101.36% Limit: 90-110% **RESULT:** The sample is declared **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 o/o CEO DHA, Sahiwal, provided invoice/ warranty No. 17261 dated 10-07-2022 issued by M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

iv. Warrantor Portion was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

v. A copy of Test/ Analysis report was also sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar 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 Misbranded Drug.**
ii. **Issuance of false warranty.**

3. Show-cause notice(s) issued to the accused dated 03-01-2023

Firm submitted reply of Show cause vide letter no. Bloom/0701-23 dated 07-01-2023

It is submitted that we M/S Bloom Pharmaceuticals (Pvt) Ltd., manufactured and supplied Macrolex Vaginal Tablet in bulk quantity ***i.e. 219,573 tablets*** *to the various Government health institutions of the Punjab, Detail is mentioned as under:*

Sr. No	Institution	Station	Quantity supplied
1	Chief Executive Officer (DHA)	Attock	42100
2	Chief Executive Officer (DHA)	Lahore	67600
3	Chief Executive Officer (DHA)	Kasur	50000
4	M.S THQ Hospital Wazirabad	Gujranwala	200
5	M.S THQ Hospital Kamoke	Gujranwala	1000
6	M.S Govt. Maternity Hospital Satellite Town	Gujranwala	1500
7	Chief Executive Officer (DHA)	Bhakkar	3400
8	Chief Executive Officer (DHA)	Chakwal	3500
9	Chief Executive Officer (DHA)	Jhelum	1700
10	Chief Executive Officer (DHA)	Khanewal	3000
11	Chief Executive Officer (DHA)	Narowal	5600
12	Chief Executive Officer (DHA)	Layyah	3000
13	Chief Executive Officer (DHA)	Toba Tek Singh	1795
14	Chief Executive Officer (DHA)	Hafizabad	2500
15	THQ Hospital Chichawatni	Sahiwal	1000
16	THQ Hospital Kot Addu	Muzaffargarh	500
17	THQ level 50 bedded Hospital Chowk Sarwar Shaheed	Muzaffargarh	500
18	DHQ Hospital	Muzaffargarh	1000
19	M.S THQ Hospital Kabir Wala	Khanewal	500
20	Chief Executive Officer (DHA)	Mianwali	2000
21	Chief Executive Officer (DHA)	Bahawalnagar	4800
22	M.S THQ Hospital Jahanian	Khanewal	1000
23	Chief Executive Officer (DHA)	Vehari	1750
24	Chief Executive Officer (DHA)	Okara	2400
25	Chief Executive Officer (DHA)	Mandi Bahauddin	3500
26	Chief Executive Officer (DHA)	Rawalpindi	8780
27	Chief Executive Officer	Lodhran	4500
28	Chief Executive Officer (DHA)	Sahiwal	448

3. The above said product is of Standard quality as it contains therapeutic active ingredient Clotrimazole within Pharmacopeia limit as assay along with other quality tests in the above said DTL report comply standard limits, inference is that the drug is effective and safe for use in patients.

4. Furthermore, the drug is misbranded on the basis of labelling i.e., "Bloom Specs," instead of Pharmacopeial (USP/BP) Specs. But now, we ***have rectified the specifications*** *of the subject product from "Bloom Specs." to "B.P. Specs". Remedied packaging material consisting of Unit carton, Aluminium foil & leaflet of; Govt, packaging and Commercial packaging.*

5. It is requested that the above said product is of standard quality therefore please give us warning and also allow us to use the stock of above-mentioned drug. Details of re-called stock: Nil,

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD

Case No. 45

PQCB/R-252/2022

Tehsil & District Vehari

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan** through its Managing Director Ahmad Raza 2. Ahmed Raza Managing Director 3. Sohail Qayum Production In-charge 4. Yasir Mehmood Quality Control Incharge/Warrantor of M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

BRIEF FACTS OF THE CASE:

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

i. She, on 21-09-2022 inspected the medicine store CEO DHA Vehari, took subject sample of the drug on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan vide memorandum No. 141247 dated 21-09-2022.

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
Tab Macrolex Vaginal Tablet [Clotrimazole 500mg] **Mfg. Date**: 06-2022 **Exp. Date**: 05-2024 **Regn. No:** 030364	360	M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan	01-94006140/DTL dated: 15-11-2022	**Result of test/ analysis with specifications applied** USP 2022 **DESCRIPTION**: White to off white color oblong tablet plain on both sides of tablet, in Alu-PVC blister of 01 unit packed in labelled outer hard carton. Each outer carton contains one blister i.e., (1x1=1) tablet along with an applicator per pack. **Note**: As per DRAP order No. F.3-5/2020-I & VII (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 dug product is available in the most recent edition of such pharmacopoeia". Product specification of given sample is "Manufacturer's **S**pecification" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "Clotrimazole Vaginal Inserts" 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. M**isbranded (Does not comply).** **Uniformity of Dosage Unit (Weight Variation):** **Max.** AV=L1 15% **Complies** **DISINTEGRATION:** NMT 20min. **complies** **IDENTIFICATION:** Clotrimazole is identified **ASSAY: Clotrimazole** **Analytical technique:** By HPLC **Stated**: 500mg/tab **Determined**: 499.10mg/tab **Percentage**: 99.82% **complies** **Limit**: 90-110% **RESULT:** The sample is declared **Misbranded** as per Section 3 (s) (iv) of The 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 CEO DHA office Vehari provided invoice/ warranty No. 17429 dated 02-07-2022 issued by M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan

iv. Warrantor Portion was sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar Pakistan.

v. A copy of Test/ Analysis report was also sent to M/s Bloom Pharmaceuticals Pvt Ltd., Plot No. 30 Phase I & II Industrial Estate Hattar 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 Misbranded Drug.**
ii. **Issuance of false warranty.**

3. Show-cause notice(s) issued to the accused dated 05-01-2023

Firm submitted reply of Show cause vide letter no. Bloom/2801-23-003 dated 28-01-2023

It is submitted that we M/S Bloom Pharmaceuticals (Pvt) Ltd., manufactured and supplied Macrolex Vaginal Tablet in bulk quantity ***i.e. 219,573 tablets*** *to the various Government health institutions of the Punjab, Detail is mentioned as under:*

Sr. No	Institution	Station	Quantity supplied
1	Chief Executive Officer (DHA)	Attock	42100
2	Chief Executive Officer (DHA)	Lahore	67600
3	Chief Executive Officer (DHA)	Kasur	50000
4	M.S THQ Hospital Wazirabad	Gujranwala	200
5	M.S THQ Hospital Kamoke	Gujranwala	1000
6	M.S Govt. Maternity Hospital Satellite Town	Gujranwala	1500
7	Chief Executive Officer (DHA)	Bhakkar	3400
8	Chief Executive Officer (DHA)	Chakwal	3500
9	Chief Executive Officer (DHA)	Jhelum	1700
10	Chief Executive Officer (DHA)	Khanewal	3000
11	Chief Executive Officer (DHA)	Narowal	5600
12	Chief Executive Officer (DHA)	Layyah	3000
13	Chief Executive Officer (DHA)	Toba Tek Singh	1795
14	Chief Executive Officer (DHA)	Hafizabad	2500
15	THQ Hospital Chichawatni	Sahiwal	1000
16	THQ Hospital Kot Addu	Muzaffargarh	500
17	THQ level 50 bedded Hospital Chowk Sarwar Shaheed	Muzaffargarh	500
18	DHQ Hospital	Muzaffargarh	1000
19	M.S THQ Hospital Kabir Wala	Khanewal	500
20	Chief Executive Officer (DHA)	Mianwali	2000
21	Chief Executive Officer (DHA)	Bahawalnagar	4800
22	M.S THQ Hospital Jahanian	Khanewal	1000
23	Chief Executive Officer (DHA)	Vehari	1750
24	Chief Executive Officer (DHA)	Okara	2400
25	Chief Executive Officer (DHA)	Mandi Bahauddin	3500
26	Chief Executive Officer (DHA)	Rawalpindi	8780
27	Chief Executive Officer	Lodhran	4500
28	Chief Executive Officer (DHA)	Sahiwal	448

3. The above said product is of Standard quality as it contains therapeutic active ingredient Clotrimazole within Pharmacopeia limit as assay along with other quality tests in the above said DTL report comply standard limits, inference is that the drug is effective and safe for use in patients.

4. Furthermore, the drug is misbranded on the basis of labelling i.e., "Bloom Specs," instead of Pharmacopeial (USP/BP) Specs. But now, we ***have rectified the specifications*** *of the subject product from "Bloom Specs." to "B.P. Specs". Remedied packaging material consisting of Unit carton, Aluminium foil & leaflet of; Govt, packaging and Commercial packaging.*

5. It is requested that the above said product is of standard quality therefore please give us warning and also allow us to use the stock of above-mentioned drug. Details of re-called stock: Nil,

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD

Case No. 46

DISTRICT LODHRAN

PQCB/R-123/2021

Tehsil Dunyapur, District Lodhran

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan through** its Director Muhammad Usman Qureshi 2. Muhammad Usman Qureshi Director 3. Nadeem Aftab Production Manager 4. Ghulam Ghaus Quality Control Manager/ Warrantor 5. Faisal Muzammil Owner (New Management) 6. Syed Talib Hashmi Owner (New Management) of **M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan**. 7. Allah Ditta Proprietor of **M/s Ali Medical Store, Kahror Pacca Road, Dunyapur, District Lodhran** 8. Faisal Rehman Proprietor/ Warrantor of **M/s New Ikram Medicine, Whole Sale Medicine Market, Town Hall, Multan.** 9. Shahid Raza Proprietor/ Warrantor of **M/s Marwa Trading 30-Khushal Colony, Near Molvi Ameer Shah Hospital, G.T Road, Peshawar.**

BRIEF FACTS OF THE CASE

Provincial Drug Inspector, Tehsil Dunyapur District Lodhran reported that: -

i. He, on 29-03-2021, inspected the busisness premises of M/s Ali Medical Store Kehror Pacca road, Dunyapur and took three different types of drug samples on Form No. 04 for the purpose of test and analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum no. 0000088068 dated 29-03-2021 .

ii. The subject drug sample after test/analysis, was declared **Substandard** by Government Analyst Drug Testing Laboratory, Multan 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>Capsule ESOFIX 40mg [Esomeprazole as Magnesium Trihydrate (pellets) eq. to Esomeprazole: 40mg]

Mfg date: May-2020

Exp. Date:

May-2022

RegNo.

054784</td><td>668</td><td>M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan.</td><td>TRA No. 01-89003174/DTL

dated: 24-05-2021</td><td>
Results of test/Analysis with specifications applied

USP 2019/MS

<u>STATED:</u>

Esomeprazole pellets in Blue/white shell.

<u>DESCRIPTION:</u>

White to off white color pellets in a hard gelatin capsule of Off-white body and red cap packed in a ALU-ALU blister of 14 units in a labelled outer carton. Each outer contains 1 blister of 14 units i.e 1*14=14 Capsules. (DOES NOT COMPLY)

<u>WEIGHT VARIATION:</u>

Average Weight: 179.92 mg

Limits: ±10% (NMT 2Capsules)
None deviate from ±20%
05 out of 20 Capsules deviate from ±10 %
Out of which one (01) deviates from ±20%

<table>
<tr><td>Sr. No</td><td>*1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>*6</td><td>*7</td><td>8</td><td>9</td><td>10</td></tr>
<tr><td>Filled capsule</td><td>282.2</td><td>229</td><td>243.5</td><td>241.5</td><td>238.9</td><td>260.6</td><td>209.8</td><td>227.2</td><td>259.7</td><td>235.2</td></tr>
<tr><td>Empty</td><td>61</td><td>64.3</td><td>61.1</td><td>58.5</td><td>60</td><td>62.2</td><td>62.4</td><td>62.6</td><td>65.8</td><td>63.1</td></tr>
<tr><td>Content/Wt.</td><td>221.2</td><td>164.7</td><td>182.4</td><td>183</td><td>178.4</td><td>198.4</td><td>146.9</td><td>164.6</td><td>143.4</td><td>172.1</td></tr>
<tr><td>%WV</td><td>-22.9</td><td>8.5</td><td>-1.4</td><td>-1.7</td><td>0.6</td><td>-10.3</td><td>18.4</td><td>8.5</td><td>-7.8</td><td>4.3</td></tr>
<tr><td>Sr. No</td><td>11</td><td>12</td><td>13</td><td>14</td><td>*15</td><td>16</td><td>17</td><td>*18</td><td>19</td><td>20</td></tr>
<tr><td>Filled capsule</td><td>255</td><td>244.7</td><td>240.1</td><td>254</td><td>207.1</td><td>241</td><td>226.5</td><td>266.8</td><td>246.1</td><td>224.8</td></tr>
<tr><td>Empty</td><td>58.3</td><td>62.7</td><td>60.1</td><td>61.6</td><td>62.4</td><td>59.2</td><td>63.8</td><td>63.5</td><td>65.3</td><td>61.9</td></tr>
<tr><td>Content/Wt.</td><td>196.7</td><td>182</td><td>180</td><td>192.4</td><td>144.7</td><td>181.8</td><td>162.7</td><td>203.3</td><td>180.8</td><td>167.4</td></tr>
<tr><td>%WV</td><td>-9.3</td><td>-1.2</td><td>0.0</td><td>-6.4</td><td>19.6</td><td>-1.0</td><td>9.6</td><td>-13</td><td>-0.5</td><td>6.7</td></tr>
</table>
* Capsules Deviates from the limit (DOES NOT COMPLY)

<u>DISSOLUTION TEST:</u>

Limit: NLT 75% (Q) of the labeled amount of Esomeprazole is dissolved.

<u>IDENTIFICATION:</u>

Esomeprazole as Magnesium Trihydrate identified.

<u>ASSAY</u>

Esomeprazole
Stated: 40mg/Capsule
Determined: 38.94/Capsule
Percentage: 97.355
Limit: 90-110%

<u>RESULT:</u>

The above sample is SUBSTANDARD on the basis of the test Uniformity of Weight (Mass).
</td></tr>
</table>

iii. M/s Ali Medical Store Kehror Pacca road, Dunyapur provided Invoice/Warranty No. 225000 dated 04-01-2021 issued by M/s New Ikram Medicine Company, Whole Sale Medicine Market, Town Hall, Multan as a proof of purchase.

iv. Warrantor portion of drug sample was sent to M/s New Ikram Medicine Company, Whole Sale Medicine Market, Town Hall, Multan who in turn provided invoice/warranty No. 2064 dated 30-06-2020 issued by M/s Marva Trading 30-Khushal Colony, Near Molvi Ameer Hospital G.t Road, Peshawar, Pakistan.

v. Copy of test report of the drug sample was sent to M/s Marva Trading 30-Khushal Colony, Near Molvi Ameer Hospital G.T Road, Peshawar, Pakistan who in turn provided invoice/warranty No. 7524-W dated 27-06-2020 issued by M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan.

vi. A copy of test report was sent to M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan with directions to provide the requisite information and to explain their position in this regard.

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

Names of Accused Persons	Offences
1. **M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan through** its Director Muhammad Usman Qureshi 2. Muhammad Usman Qureshi Director 3. Nadeem Aftab Production Manager 4. Ghulam Ghaus Quality Control Manager/ Warrantor of M/**s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan**.	a. **Manufacture for Sale /Sale of Substandard Drug** b. **Issuance of false warranty**
5. Allah Ditta Proprietor of **M/S Ali Medical Store, Kahror Pacca Road, Dunyapur, District Lodhran**.	a. **Stocking for sale/sale of the Substandard drug.**
6. Faisal Rehman Proprietor/ Warrantor of **M/S New Ikram Medicine, Whole Sale Medicine Market, Town Hall, Multan.**	a. **Stocking for sale/sale of the Substandard drug.** b. **Issuance of False warranty**
7. Shahid Raza Proprietor/ Warrantor of **M/S Marwa Trading 30-Khushal Colony, Near Molvi Ameer Shah Hospital, G.T Road, Peshawar.**	a. **Stocking for sale/sale of the Substandard drug.** b. **Issuance of False warranty**

3. Show cause notice(s) issued to accused person(s) dated 16-08-2021.

Reply of firm to show cause notice vide letter no Nil dated 30-08-2021

Referring to your letter No. PQCB/R-123/2021, dated 16-08-2021 which we received on Friday, 27th August, 2021, it is hereby stated that previously as per our internal SOPS, we used to check 10 capsules altogether and report average weight, there was no problem (Assay result is well within Limits, that is 97.35%).
However, as per Pharmacopoeia, we have started weighing capsules one by one, already initiated following corrective and preventive actions, namely;
1- Purchased and put in place a weighing balance with three decimal places to further control weight variation.
2- Changed Gelatin Empty shell's vendor.
Due to above mentioned reasons, I would request you to issue us a warning only this we could be stricter on this matter in future.

Reply of M/s Ali Medical Store to sow cause notice

It is submitted that I have purchased said medicine from Faisal Rehman (New Ikram Medicine Company Multan) whole sale medicine town hall Multan vide warranty # 225000 dated 04-01-2021 (copy of warranty enclosed). Original warranty I had submitted to Drug Inspector Dunyapur. The stock of said batch is not available now at my premises.

Reply of Distributor (M/s Marva Trading) to Show cause notice

1. It is to submitted that Marva Trading Company purchased ESOFIX 40MG CAP (ESOMEPRAZOLE) from NEOMEDIX PHARMACEUTICAL, Plot no.5,N/5, National Industrial Zone Rawat and provided the WARRANTY/INVOICE No. 7524-W Dated 27 June 2020 to the respective drug inspector which was evidence of legal purchase. Since we are only TRADING COMPANY hence are unable to identify the weight variation of pallets of the capsule. Moreover, the capsule shells were blistered in ALU ALU file and if there was any variation in the colour of the shells, it can also not be identified at our end.

2. Now Sir as we are Trading/Distribution Company and not Manufacturers so we do not have he means to test the drugs so in this regards we receive Written Warranties from the manufacturers claiming the product supplied is within the Standard Limits in all aspects and only then we proceed with the distribution.

3. Sir regarding this batch we had received warranty from the manufacturer at the time it was supplied (copy already provided) and only on the basis of this warranty we distributed the drugs in the market.
4. It is added that we purchased the product from Neomadix Pharmaceutical hence it would be appropriate to approach the said pharma for shell colour and pellet weight variation.
5. I am also attaching my drug license along with this letter and my whatsapp no.0335-9533902 for further corresponding required by your good self.
6. Requesting for your kind consideration in not taking any legal action against Marva Trading because we only distribute the drug supplied to us by Manufacturers with the warranties provided with each batch and QUALITY ASSURANCE is the responsibility of MANUFACTURER only.
7. It is humbly requested to take lenient and sympathetic view of above mentioned issue
8. Your cooperation in this regard will highly be appreciated.

Reply of M/s New Ikram Medicine Company to Show cause notice

It is submitted that I have purchased said medicine from Shahid Raza (Marva Trading Pharmaceuticals) 30-Khushal Colony near Molvi Ameer Shah Hospital G.T Road Peshawar Updated address Shop-11 1st Floor Qudrat Elahi Medicine Market Namak Mandi Peshawar. It is stated that we are the trading company and we are unable to identify the weight variation of pellets of the capsule.
Moreover the capsule shells were blistered in Aluminium file and if there was any variation in colour of the shell, it can also not be identified at our end.
It is added that we have purchased the product from Marva Trading vide invoice warranty # 2064 and letter #01 dated 30-06-2020 in which Marva Trading Own/ Confirm their warranty(copy enclosed).

Hence it would be appropriate to approach the said distributor for further action.
It is humbly requested to take sympathetic view of above mentioned issue.
Your cooperation in this regard will highly be appreciated. Please

4. Personal Hearing notice(s) issued to accused person(s) dated 19-05-2022.

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **244th meeting** held on **31-05-2022** in the presence of Board members as mentioned above. Dr. Misbah-ud-din Qamar, Secretary DQCB, District Lodhran and Mr. Faisal Farooq, Provincial Inspector of Drugs, Tehsil Dunyapur, District Lodhran was present along with the original case record.Among the nominated accused persons, Ghulam Ghous (Quality Control Manager) of M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan appeared before the Board.The representatives of the firm requested the Board to take a lenient view as the assay & dissolution test of their product meets the criteria.

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 Drugs Testing Laboratory, Multan on the basis that the manufacturer specify Esomeprazole pellets in Blue/white shell but given sample as observed by the DTL Multan is White to off white color pellets in a hard gelatin capsule of Off-white body and red cap packed in a ALU-ALU blister of 14 units in a labelled outer carton. Each outer contains 1 blister of 14 units i.e 1*14=14 Capsules which does not comply with manufacturer's description of color of capsules. Moreover, the Board also observed that 5 out of 20 capsules are deviating from its $\pm$ 10% limit.

7. The Board was apprised by the Secretary PQCB that the firm has submitted an affidavit in which they have nominated their new management to be responsible for pursuing the subject matters related to the firm. Hence, the Board after due delibration and discussion unanimously decided to **pend the case** and to club all cases of **M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan** and to present them collectively before the Board, making sure to serve personal hearing to both, the old and new management to address the issue once and for all.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 05-2020**
- **Expiry Date: 05-2022**
- **Sampling Date (Form 4): 29-03-2021**
- **Sent to DTL (Form 6): 29-03-2021**
- **Date of receipt in DTL: 30-03-2021**
- **DTL Report Date (Form 7): 24-05-2021**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 16-07-2021**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 05-08-2021**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 47

PQCB/R-666/2019

Tehsil & District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan** through its Director, Muhammad Usman Qureshi 2. Muhammad Usman Qureshi — Director 3. Nadeem Aftab — Production Manager 4. Ghulam Ghaus — Quality Control Manager 5. Rohi Asif — Warrantor of M/s Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan. Following **Co-Owners of M/s Neomedix**, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan are also served personal hearing notice (s): 1. Faisal Muzammil — Co-Owner 2. Syed Talib Hashmi — Co-Owner

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 27-05-2019, inspected the premises of Main Medicine Store, CEO DHA Mandi Bahauddin and took samples of ten different types of drugs on Fo No.04 for the purpose of test/analysis.

ii. One out of ten drug samples, after test/analysis, was declared **Substandard** by Government Analyst Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report No. & Date	DTL Test Report Results
Suspension. Calfit [Each 5ml contains: Calcium Phosphate (Tribasic),,,,…210mg Vitamin D3…350 IU]	512	M/S Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan.	01-56003625/ DTL dated:10-07-2019	**Analysis with specifications applied:** Manufacturer's Specifications **DESCRIPTION:** White milky color suspension having putrid/ repulsive odor, filled in amber color glass bottle sealed with metallic cap, packed in unit hard carton. **Note: Given sample have putrid or unpleasant smell and is not fit for use. (Does not comply)** **ASSAY:** **Calcium Phosphate (Tribasic)** Stated: 210mg/ 5ml Determined: 199.83 mg/ 5ml Percentage: 95.16 % (Complies) Limit: 90-110% (Manufacturer's specifications) **Cholecalciferol (Vitamin D3)** Stated: 350IU / 5ml Determined: 177.05 IU / 5ml Percentage: **50.58% (Does not comply)** Limit: 90-110% (Manufacturer's Specifications) **pH**: Stated: 3.5-7.0 (Manufacturer's Specifications) Determined: 4.02 (Complies) **Result:** Given sample is **Substandard** with regards to Physical Characteristics (putrid smell) and Assay.

iii. Store keeper of Main Medicine Store, CEO DHA Mandi Bahauddin, provided invoice/ warranty No.144 dated 16-05-2019 issued by M/S Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad.

v. A copy of test/analysis report of the drug sample was sent to M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad 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 31-05-2021

Firm replied to the show cause notice vide letter dated 11-06-2021

Referring to your letter No. PQCB/R-666/2019, regarding product, Calfit suspension, Batch # 514, ***it is hereby requested for the re-test of the samples****.*

4. Personal hearing notice(s) issued to accused person(s) along with co-owners dated 29-03-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 04-2019

Expiry Date: 04-2021

Sampling Date (Form 4): 27-05-2019

Sent to DTL (Form 6): 27-05-2019

Date of receipt in DTL: 01-06-2019

DTL Report Date (Form 7): 10-07-2019

Time Extension: Not Time Barred

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

Retesting Request of Firm: Yes (In Response to the Show Cause Notice on 11-06-2021)

Investigation Report Dated: 30-12-2020

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 48

PQCB/R-750/2019

Tehsil & District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan** through its Chief Executive Officer/ Partner, Muhammad Usman Qureshi 2. Muhammad Usman Qureshi — Chief Executive Officer/ Partner 3. Muhammad Saleem Qureshi — Partner 4. Nadeem Aftab — Production Manager 5. Roohi Asif Awan — Quality Control Manager/ Warrantor of M/s Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan. Following **Co-Owners of M/s Neomedix**, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan are also served personal hearing notice (s): 1. Faisal Muzammil — Co-Owner 2. Syed Talib Hashmi — Co-Owner

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 10-07-2019, inspected the premises of Medicine Store of CEO Office (DHA) Mandi Bahauddin and 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:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Suspension. TEMPNIL [each 5ml contains: 120 mg of paracetamol B.P]	526	M/S Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan.	01-56004185/DTL dated 30-08-2019	**Analysis with specifications applied: BP 2019** **DESCRIPTION:** Pink color suspension filled in amber color glass bottle sealed with silver metallic cap. **NOTE: According to British Pharmacopoeia 2019, "Suspensions may show a sediment, which is readily dispersed on shaking to give a suspension that remains sufficiently stable to enable the correct dose to be delivered."** **The given sample contains sediments of crystals which do not disperse upon shaking. So, does not comply BP specifications. (Does Not Comply)** **IDENTIFICATION:** Paracetamol Identified. **ASSAY:** Stated: 120 mg / 5ml Determined: 121.608 mg / 5ml Percentage: 101.34% (Complies) Limit: 95 - 105% (BP 2018) **RESULT:** Given sample is declared **Sub-Standard** on the basis of Physical characteristics.

iii. Storekeeper of Medicine Store of CEO Office (DHA) Mandi Bahauddin provided invoice/warranty bearing No. 230 dated 28-06-2019 issued by M/S Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan.

v. A copy of test/analysis report was sent to M/s Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 13th meeting held on 28-10-2020 **allowed** to send the sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result
TEMPNIL Suspension 60ml	526	M/s Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan.	0179-P/2020 dated 03-12-2020	**Analysis with specifications applied:** British Pharmacopoeia 2017 **DESCRIPTION: Blackish pink colored suspension contained in labeled amber colored glass bottle further packed in an outer carton having undispersed solid masses which don't disperse even on shaking. (Does not comply with B.P. 2017 which states that "Suspension may show a sediment which is readily dispersed on shaking")** **IDENTIFICATION:** Paracetamol identified. **VOLUME:** **Determined:** 60 ml Limit: 60 ml Complies with volume stated on the label. **ASSAY:** **Paracetamol:** Stated: 120 mg / 5ml Determined: 99.02 mg / 5ml Percentage: **82.51%** Limit: 95 - 105% **Does not comply with BP-2017** **CONCLUSION:** The sample is of **Sub-Standard** quality on the basis of the tests performed.

vii. A copy of NIH Test Report was sent to M/s Neomedix, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-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 06-04-2022

Firm replied to the show cause notice vide letter dated 19-04-2022

*It is stated that our product remained okay by all means throughout its shelf life at company's retained samples' area. The appearance of Ostwald Ripening (Crystal formation) with the passage of time was **only due to the applied storage conditions**, which in turn **also reduced the percentage assay** results.*

4. Personal hearing notice(s) issued to accused person(s) along with Co-Owners dated 29-03-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 04-2019

Expiry Date: 04-2021

Sampling Date (Form 4): 10-07-2019

Sent to DTL (Form 6): 10-07-2019

Date of receipt in DTL: 17-07-2019

DTL Report Date (Form 7): 30-08-2019

Time Extension: Not Time Barred

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

Retesting Request of Firm: Yes (23-04-2020)

Fate of Retesting Request of Firm: Allowed in 13th Committee meeting dated 28-10-2020

Sample Sent to NIH: 11-11-2020

Sample Received by NIH: 18-11-2020

NIH Report: 03-12-2020 (Substandard)

Investigation Report Dated: 09-02-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 49

PQCB R-472/2019

Tehsil Sambrial, District Sialkot

Substandard(Uniformity of Dosage units)

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Neomedix (Pvt) Limited Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad** through its Managing Director Dr. Muhammad Usman Qureshi 2. Dr. Muhammad Usman Qureshi Managing Director 3. Khalid Mehmood Production Incharge 4. Shahabud-Din Quality Control Incharge 5. Roohi Asif Quality Control Manager/ Warrantor Of **M/s Neomedix (Pvt) Limited Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad.** Following **Owners of M/s Neomedix**, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan are also served personal hearing notice (s): 6. Faisal Muzammil Owner (New Management) 7. Syed Talib Hashmi Owner (New Management) of **M/S Neomedix (Pvt.) Ltd., Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Sambrial, District Sialkot reported that:-

i. His predecessor, on 25-06-2019, inspected the premises of Medical Store situated at THQ Hospital Sambrial and took sample of four different types of drugs on Form No. 04 for the purpose of test and analysis.

ii. One out of four drug samples after test/ analysis was declared **Substandard** by Government Analyst Drug Testing Laboratory Faisalabad as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Capsule Transadix (Each capsule contains: Tranexamic Acid BP 500mg)	623	M/s Neomedix Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad	TRA No.01-56004102/DTL dated:06-08-2019	**Analysis with Specifications:** MS **Description:** White powder filled in clean shiny hard capsules having orange opaque cap and body shell visually free from foreign particles, contained in Alu-PVC blister of 10's packed in outer hard carton. **Identification:** tranexamic Acid identified (Manufacturer's Specifications) **Assay:** 94.027%(90-110%) **Disintegration Test:** Complies **Uniformity of Dosage Unit:** **Criteria: T**he requirement for dosage uniformity are met if the acceptance value of the 10 dosage unit is less than or equal to L1% (15.0). if the acceptance value is greater than L1%, test next 20 units and calculate the acceptance value, the requirement are met if the final acceptance value of the 30 dosage units is less than or equal to L1% and no individual content of any dosage unit is less than [1-(0.01)(L2)]M, not more than [1+(0.01)(L2)]M. (Manufacturer's Specifications) **Determined**: **L1% for 10 dosage units = 27.087% (Does not comply)** **L1% for 30 dosage units = 21.452% (Does not comply)** **Result:** The sample is **Substandard** with regards to Uniformity of Dosage Unit.

iii. He on 02-10-2019, also directed MS of THQ Hospital Sambrial not to dispose of the remaining sub-standard stock of Capsule Transadix 500mg (2000 capsules) vide Form No. 03.

iv. Medical Superintendent of THQ Hospital Sambrial provided invoice/ Warranty No. 149 dated 14-06-2019 issued by M/s Neomedix Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad as a proof of its purchase.

v. A copy of test report was sent to M/s Neomedix Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad 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 and Rules framed there under by the way of:

i. **Manufacturing & Selling of Sub-standard Drug**
ii. **Issuance of false warranty.**
iii. **Disobeying the lawful authority of the drug inspector by not providing the requisite information.**
iv. **Contravention of Section 18(1)g of the Drugs Act 1976 (as amended), DRAP Act 2012 & Rules framed thereunder.**

3. Showcause notice(s) issued to accused person(s) on 24-02-2020

REPLY OF THE FIRM:

4. M/S Neomedix vide letter dated 04-03-2020 submitted that:

It is requested that Transadix 500mg, Batch No. 623 be accepted and consumed as donation, since test results, that is assay (94.027%), disintegration etc. are satisfactory, we will not claim for the cost.

Moreover, we have established that results for Uniformity of contents are out of specification due to weight variation of hard shells used, and for that reason we have replaced our supplier as well.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB 225th meeting dated 31-08-2019

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **225th meeting held on 31-08-2019**. Ms. Farah Majeed Secretary DQCB District Sialkot was present along with original record of the case. Shahid (General Manager) of M/s Neomedix (Pvt) Limited Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad appeared before the Board and stated that the said sample has been declared sub-standard by DTL Faisalabad on the basis of Uniformity of dosage unit, while all other parameters are well within the prescribed limits. He added that the firm was purchasing capsule shells from a local supplier, for that reason they have now changed the supplier also. Furthermore, the same batch has also been declared to be of standard quality from DTL Faisalabad. He requested for lenient view from the Board. The Board after discussion unanimously decided to **pend the case** in the best interest of justice till next date of hearing.

PQCB 229th meeting held on 02-02-2021

6. Case was considered by the Provincial Quality Control Board (PQCB) under section 11 of the Drugs Act 1976 in its **229th meeting held on 02-02-2021.** Mr. Hafiz Muhammad Faisal Secretary DQCB District Sialkot and Mr. Amaad Ashraf Drug Inspector Tehsil Sambrial District Sialkot were present. No one among nominated accused persons was present on behalf of **M/s Neomedix (Pvt) Limited Plot No 5, N/5, National Industrial Zone, Rawat,** Islamabad. Secretary PQCB apprised the Board that personal hearing notice was duly served to the firm, however, no-one on behalf of the firm was present. The Board after discussion unanimously decided to **adjourn the case** till next meeting of the Board.

7. Personal Hearing Notice issued dated 27-01-2022

8. Personal Hearing Notice served earlier for 238th meeting on 08-02-2022 deemed to be served for re-scheduled 238th meeting dated 09-02-2022 at the same time & venue vide letter No. PQCB/Admin/Res-01/2022 dated 07-02-2022.

PQCB 238th meeting held on 09-02-2021

9. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **238th meeting** held on **09-02-2021** under the Chairmanship of Secretary Primary & Secondary Healthcare Department in the presence of Board members as mentioned above**.** Mr. Hafiz Muhammad Faisal Secretary DQCB District Sialkot and Mr Ammad Ashraf Drug Inspector Tehsil Sambrial, District Sialkot were present. No-one from the nominated accused persons were present, however, representative from the firm Faisal Muzammil and Talib Hussain appeared before the Board on behalf of M/s Neomedix (Pvt) Limited Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad. They submitted before the Board that they have recently purchased the firm from the previous management. They are in the phase of transition and requested for adjournment on behalf of accused persons nominated in the subject case. The Board after careful perusal of the case record, with due deliberation and detailed discussion unanimously decided to **adjourn the case** in best interest of justice. The Board further decide to provide another/ final opportunity of personal hearing to accused persons.

10. Personal Hearing Notice issued

PQCB 243rd meeting held on **12-05-2022**

11. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **243rd meeting** held on **12-05-2022** under the Chairmanship of Secretary Primary & Secondary Healthcare Department, Punjab in the presence of Board members as mentioned above**.** Mr. Hafiz M. Faisal Secretary DQCB District Sialkot and Mr. Amaad Ashraf Drug Inspector Tehsil Sambrial District Sialkot was present along-with original case record. No one among the nominated accused persons appeared before the Board on behalf of **M/s Neomedix Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad,** however, Representative of the firm, Ejaz Bhatti appeared before the Board on behalf of the firm and submitted that the firm is still in the phase of transition and the previous owner of the firm is out of country, therefore, the personal hearing notice was not served to the previous management of the firm. He requested for more time to contact to the previous management.

12. The Board after careful perusal of the case record observed the new management of the firm i.e., Faisal Muzammil and Syed Talib Hussain Hashmi has submitted an affidavit in the subject cases that they will represent M/s Neomedix as its co-owners in these cases/ matters and face any and all legal proceedings. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided **pend the case and directed to issue personal hearing notice to new management of the firm as the co-owners** in the subject case.

Personal Hearing Notice issued dated 29-03-2023

Summary:

Manufacturing Date: 05-2019

Expiry Date: 05-2021

Sampling Date (Form 4): 25-06-2019

Sent to DTL (Form 6): 25-06-2019

Date of receipt in DTL: 13-07-2019

DTL Report Date: 06-08-2019

Time Extension: N/A

1ST DI Communication with firm on dated: 19-11-2019

Date of Retesting Request of Firm: No Request

Fate of retesting Request: N/A

Investigation Report Dated: 03-12-2019

Case is placed before the Board for decision

PROCEEDINGS AND DECISION BY THE BOARD:

Case No. 50

PQCB R-599/2019

Tehsil Sambrial, District Sialkot

Substandard (Physical Description)

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Neomedix (Pvt.) Ltd., Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad** through its Managing Director Dr. Muhammad Usman Qureshi 2. Dr. Muhammad Usman Qureshi Managing Director 3. Nadeem Aftab Production Manager 4. Roohi Asif Quality Control Manager/Warrantor of **M/S Neomedix (Pvt.) Ltd., Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad.** Following **Owners of M/s Neomedix**, Plot No.5, N/5, National Industrial Zone, Rawat, Islamabad-Pakistan are also served personal hearing notice (s): 5. Faisal Muzammil Owner (New Management) 6. Syed Talib Hashmi Owner (New Management) of **M/S Neomedix (Pvt.) Ltd., Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Sambrial District Sialkot reported that:-

i. He, on 16-09-2019, inspected the premises of Main Medicine Store, THQ Hospital, Sambrial and took sample of three different types of drugs on Form No.04 for the purpose of test/analysis.

ii. One out of three drug samples, after test/analysis, was declared **Substandard** by Government Analyst Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Tablet. Tempnil [Each Tablet contains: Paracetamol (B.P)…500mg]	524	M/S Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad.	TRA No. 01-71000143/DTL dated:25-10-2019	**Analysis with specifications applied:** **BP 2019** **Description:** White colored, round shaped tablets bisect line on one side and plain from other side having brown and yellow colored spots on the surface of tablets contained in PVC-ALU blister of 10's. **Note: Brown and yellow colored spots on the surface of the tablets were observed which does not comply the manufacturers description of tablet.** **Uniformity of Weight**: Complies **Assay:** Complies **Dissolution Test**: Complies **Result:** Given sample is declared **Substandard**, on the basis of description (Physical Characteristics of tablets.

iii. Store keeper of Main Medicine Store, THQ Hospital, Sambrial, provided invoice/ warranty/ Bill No.227 dated 19-02-2019 issued by M/S Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad.

v. A copy of test report of the drug sample was sent to M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad with directions to explain their position and provide requisite information in this regard. In response, the firm has requested for re-test/ analysis of drug sample from Appellate Laboratory, NIH, Islamabad.

vi. Pursuant to their request, the PQCB portion of the drug sample was sent to National Institute of Health Sciences, Islamabad for re-test/ analysis. The sample was declared Substandard from NIH, Islamabad. Details are as under:

Name of drug	Batch No.	Name of manufacturer	NIH Report No. & Date	NIH Test Report Results
Tempnil Tablets 500mg	524	M/S Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad.	0125-P/2020 dated:07-09-2020	**Analysis with specifications applied:** **B.P. 2017** **Description:** **White, circular, uncoated tablets having a bisectional line on one side whereas plain from other side packed in blister packing further contained in an outer carton. Some tablets having stains and brown spots. (Does not comply with official pharmacopoeia which states that "Physical and chemical properties are retained throughout the shelf life of a pharmaceutical product").** **Weight Variation**: Complies with BP 2017 **Friability Test:** Complies with BP 2017 **Dissolution Test**: Complies with BP 2017 **Assay:** Percentage: 100.88% (Complies with BP-2017) **Result:** The sample is of **Substandard**, quality on the basis of the tests performed.

vii. A copy of NIH report of the drug sample was sent to M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad 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 and Rules framed there under by the way of:

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

3. Showcause notice(s) issued to accused person(s) on 12-01-2021

REPLY OF THE FIRM:

4. M/S Neomedix vide letter dated 21-01-2021 submitted that:

"*we would like to briefly highlight some points on the basis of the test results from the two respectable laboratories i.e. DTL and NIH as follows:*

DTL Tests as follows

Specifications	*BP 2019*
Description	*White colored round shaped tablets bisect line on one side and plain from other side having brown and yellow colored spots on the surface of tablets contained in PVC-ALU blister of 10's (Color spots do not comply)*
Uniformity of weight	*Complies*
Assay	*Complies*
Dissolution test	*Complies*

NIH Tests as follows:

Specifications	*BP 2019*
Description	*White circular uncoated tablets having bisectional line on one side whereas plain from other side packed in blister packing further contained in an outer carton, some tablets having stains and brown spots.*
Uniformity of weight	*Complies*
Assay	*Complies*
Dissolution test	*Complies*

- *Sir, as you can note that all the parameters related to the chemical properties of our product are of standard quality in every aspect, including assay, dissolution, friability and weight variation, from both labs.*
- *However, our product has been labelled as substandard merely because of some small brown spots/ discoloration found on only a minute quantity of tablets (less than 2%).*
- *Our internal investigation has found that the spots were the result of slight overheating of the machine during the blistering process, which in turn has caused due to frequent load shedding and fluctuations in electricity from the grid station.*
- *Moreover, we can confirm that this negligible discoloration does not, in any way, have any effect on the efficacy or general appearance of the drug, not is it of any harm to the consumer.*

Sir, in the light of these facts, we would like to humbly request your kind office to please allow the consumption of the product on the basis of all of its chemical properties being of standard quality, especially during these extremely hard and trying times of the COVID-19 pandemic.

As a gesture of appreciation for your kindness, we would also like to offer this supply to the government institution completely free of charge.

Lastly we assure you of our commitment to producing quality medicines and will be extremely careful not to overlook such things in the future."

5. Personal Hearing Notice issued dated 27-01-2022

6. Personal Hearing Notice served earlier for 238th meeting on 08-02-2022 deemed to be served for re-scheduled 238th meeting dated 09-02-2022 at the same time & venue vide letter No. PQCB/Admin/Res-01/2022 dated 07-02-2022.

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

PQCB 238th meeting held on **09-02-2021**

7. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **238th meeting** held on **09-02-2021** under the Chairmanship of Secretary Primary & Secondary Healthcare Department in the presence of Board members as mentioned above**.** Mr. Hafiz Muhammad Faisal Secretary DQCB District Sialkot and Mr. Ammad Ashraf Drug Inspector Tehsil Sambrial, District Sialkot were present. No-one from the nominated accused persons

were present, however, representative from the firm Faisal Muzammil and Talib Hussain appeared before the Board on behalf of M/s Neomedix (Pvt) Limited Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad. They submitted before the Board that they have recently purchased the firm from the previous management. They are in the phase of transition and requested for adjournment on behalf of accused persons nominated in the subject case. The Board after careful perusal of the case record, with due deliberation and detailed discussion unanimously decided to **adjourn the case** in best interest of justice. The Board further decide to provide another/ final opportunity of personal hearing to accused persons.

PQCB 243rd meeting dated **12-05-2022:**

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **243rd meeting** held on **12-05-2022** under the Chairmanship of Secretary Primary & Secondary Healthcare Department, Punjab in the presence of Board members as mentioned above**.** Mr. Hafiz M. Faisal Secretary DQCB District Sialkot and Mr. Amaad Ashraf Drug Inspector Tehsil Sambrial District Sialkot was present along-with original case record. No one among the nominated accused persons appeared before the Board on behalf of **M/s Neomedix Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad,** however, Representative of the firm, Ejaz Bhatti appeared before the Board on behalf of the firm and submitted that the firm is still in the phase of transition and the previous owner of the firm is out of country, therefore, the personal hearing notice was not served to the previous management of the firm. He requested for more time to contact to the previous management.

9. The Board after careful perusal of the case record observed the new management of the firm i.e., Faisal Muzammil and Syed Talib Hussain Hashmi has submitted an affidavit in the subject cases that they will represent M/s Neomedix as its co-owners in these cases/ matters and face any and all legal proceedings. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided **pend the case and directed to issue personal hearing notice to new management of the firm as the co-owners** in the subject case.

Personal Hearing Notice issued to the accused dated 29-03-2023

Summary:

Manufacturing Date: 06-2019

Expiry Date: 06-2021

Sampling Date (Form 4): 16-09-2019

Sent to DTL (Form 6): 16-09-2019

Date of receipt in DTL: 21-09-2019

DTL Report Date: 25-10-2019

Time Extension: N/A

1ST DI Communication with firm on dated: 15-11-2019

Date of Retesting Request of Firm: 21-11-2019

Fate of retesting Request: Allowed (222nd meeting dated 15-07-2020) (NIH Substandard)

Investigation Report Dated: 29-10-2020

Case is placed before the Board for decision

PROCEEDINGS AND DECISION BY THE BOARD:

Case No. 51

PQCB R-227/2022

Tehsil and District Attock

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad-Pakistan** through its Managing Director, Imran Asghar. 2. Imran Asghar Managing Director. 3. Abdul Majid Production Manager. 4. Junaid Zafar Quality Control Manager. 5. Ghulam Murtaza Warrantor Of M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad**.**

BRIEF FACTS OF THE CASE

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

i. He, on 13-07-2022 inspected the premises of Main Medicine Store CEO (DHA) Office Attock and took sample of Tablet Glanyl 2mg, Batch No. 81, manufactured by M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad on Form No. 4 memo no. 0000133176 dated 22-03-2021 for the purpose of test and analysis. The subject drug was sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo no. 87588 dated 13-07-2022.

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 Glanyl 2mg [Glimepiride 2mg] Mfg. Date: 06-2022 Exp. Date: 06-2024 Reg# 069114	81	M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad	01-74005012/ DTL dated: 05 Sep2022	**Result of test/ analysis with specifications applied:** MS/USP 2022 **PHYSICAL DESCRIPTION:** Green coloured, oblong shaped tablets, engraved "AXIS" on one side and break line on the other side, packed in ALU/PVC blister of 1x10's, further packed in labelled outer carton containing 10 blisters (100 Tablets). **Manufacturer Specification states that tablet should be present in ALU-ALU blister pack while in actual it is present in ALU-PVC blister pack. (MS)** **(DOES NOT COMPLY)** **DISSOLUTION TEST:** Result: All units comply the dissolution test at S1. Limit: NLT 80% (Q) **(USP 2022)** **IDENTIFICATION:** Glimepiride identified **(USP 2022)** **ASSAY:** Stated: 2mg/Tablet Determined: 2.011mg/Tablet Percentage: 100.5% Limit: 90%-110% **(USP 2022)** **RESULT:** The above sample is **Substandard with respect to Physical Characteristics observed.**

iii. Store Keeper, Main Medicine Store CEO (DHA) Office Attock provided warranty/invoice bearing No. 38080 dated 29-06-2022 issued by M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad.

iv. The Store Keeper was directed **not to dispose of stock** of the remaining said sub-standard drug on Form 3.

v. Warrantor Portion was sent to M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad.

vi. A copy of Test/ Analysis report was sent to M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad 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/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. Showcause was issued to accused person(s) vide dated 30-01-2023.

REPLY OF SHOW CAUSE NOTICE

Subject: - Reply to SHOW CAUSE NOTICE; Tab, Glanyl 2my (Batch # 81 & 82) PQCB/R-227/2022 dated 30/01/2023 and PQCB/R-300/2022 dated 30/01/2023
Respected Sir,
With reference to your letter No. PQCB/R-227/2022 dated 30/01/2023 and letter No. PQCB/R- 300/2022 dated 30/01/2023 received to us on 13h February 2023 regarding show cause for our product Tab. Glanvl 2mg (Batch # 81 & 82) declared as SUBSTANDARD.
2. It is hereby to write you that we are awarded purchase order to supply Glanyl 2mg in 100's Packm8 and to which our manufacturing specs for our product Glanyl 2mg, tablets is ALU- PVC.In this regard, we also have all relevant documentation and stability data maintained with us.
3. It is also to refer Innovator products as available in USA or European countries also have different packaging specs such as Bottle packing, PVC/PVdC etc.
4. Furthermore, it is also to highlight that our product claim is USP and all parameter are well within range as per USP monograph as evident from DTL Rawalpindi report No. TRA 01- 74005012/DTL dated 05th Sep 2022 (Tab. Glanyl 2mg Batch # 81) and TRA 01-74005011/DTL dated 05th Sep 2022 (Tab. Glanyl 2mg Batch # 82). Summary of results is tabulated below:

Parameter	IDENTIFICATION TEST	DISSOLUTION	ASSAY
Batch # 81	Glimepiride identified	All units comply the dissolution test at Sl All units comply the dissolution test at S1	100.5%
Batch # 82	Glimepiride identified	All units comply the dissolution test at Sl All units comply the dissolution test at S1	100.95%
Conclusion	COMPLIES	COMPLIES	COMPLIES

5. Moreover, the same batch of Glarnyl 2 mg (i.e. Batch # 81 & 82) was also supplied to other region of Punjab (a brief summary is tabulated below), and the same was tested and reported by DTL Multan, DTL Bahawalpur, DTL Lahore and DTL Faisalabad and declared as "STANDARD QUALITY". Summary is given for your kind perusal.

DHA's	DTL	Batch no.	Quantity Supplied (Tablets)	DTL sample receipt date	DTL result	DTL Result
Okara	Bahwalpur	81	341,400	29 Jul 2022	23 Aug 2022	Pass-of Standard Quality
Lahore	Lahore	82	166,000	26 Jul 2022	08 Sep 2022	Pass-of Standard Quality
Khanewal	Multan	82	355,000	18 Jul 2022	20 Aug 2022	Pass-of Standard Quality
Narowal	Faisalabad	82	62,300	18 Jul 2022	10 Aug 2022	Pass-of Standard Quality

6. Foregoing in view the aforementioned facts, and considering that packaging is not the part of USP monograph, and all quality testing parameters conducted by DTL Rawalpindi are within specifications. Hence product is of STANDARD quality and there is no harms to patient.
Therefore, we request honourable board for a lenient view and drop proceedings as we have not contravened any provision of Drug Act 1976 and Rules framed there under.

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

Summary:

Manufacturing Date: 06-2022

Expiry Date: 06-2024

Sampling Date: 13-07-2022

Sent to DTL (Form 6): 13-07-2022

Date of receipt in DTL: 14-07-2022

DTL Report Date: 05-09-2022

Time Extension: N/A

1ST DI Communication with firm on dated: 13-09-2022

Date of Retesting Request of Firm: -N/A

Fate of Retesting Request: -N/A

Investigation Report Dated: 28-09-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 52

PQCB R-300/2022

Tehsil and District Attock

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad-Pakistan** through its Managing Director, Imran Asghar. 2. Imran Asghar Managing Director. 3. Abdul Majid Production Manager. 4. Junaid Zafar Quality Control Manager. 5. Ghulam Murtaza Warrantor Of M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad**.**

BRIEF FACTS OF THE CASE

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

i. He, on 13-07-2022 inspected the premises of Main Medicine Store CEO (DHA) Office Attock and took sample of Tablet Glanyl 2mg, Batch No. 82, manufactured by M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad on Form No. 4 memo no. 0000133176 dated 22-03-2021 for the purpose of test and analysis. The subject drug was sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo no. 0000133175 dated 13-07-2022.

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 Glanyl 2mg [Glimepiride 2mg] Mfg. Date: 06-2022 Exp. Date: 06-2024 Reg# 069114	82	M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad	01-74005012/ DTL dated: 05 Sep2022	**Result of test/ analysis with specifications applied:** MS/USP 2022 **PHYSICAL DESCRIPTION:** Green coloured, oblong shaped tablets, engraved "AXIS" on one side and break line on the other side, packed in ALU/PVC blister of 1x10's, further packed in labelled outer carton containing 10 blisters (100 Tablets). **Manufacturer Specification states that tablet should be present in ALU-ALU blister pack while in actual it is present in ALU-PVC blister pack. (MS)** **(DOES NOT COMPLY)** **DISSOLUTION TEST:** Result: All units comply the dissolution test at S1. Limit: NLT 80% (Q) **(USP 2022)** **IDENTIFICATION:** Glimepiride identified **(USP 2022)** **ASSAY:** Stated: 2mg/Tablet Determined: 2.019mg/Tablet Percentage: 100.95% Limit: 90%-110% **(USP 2022)** **RESULT:** The above sample is **Substandard with respect to Physical Characteristics observed.**

iii. Store Keeper, Main Medicine Store CEO (DHA) Office Attock provided warranty/invoice bearing No. 38080 dated 29-06-2022 issued by M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad.

iv. The Store Keeper was directed **not to dispose of stock** of the remaining said sub-standard drug on Form 3.

v. Warrantor Portion was sent to M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad.

vi. A copy of Test/ Analysis report was sent to M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5Km, Khurrianwala-Sahianwala Road, Faisalabad 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/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. Showcause was issued to accused person(s) vide dated 30-01-2023.

REPLY OF SHOW CAUSE NOTICE

Subject: - Reply to SHOW CAUSE NOTICE; Tab, Glanyl 2my (Batch # 81 & 82) PQCB/R-227/2022 dated 30/01/2023 and PQCB/R-300/2022 dated 30/01/2023

Respected Sir,

With reference to your letter No. PQCB/R-227/2022 dated 30/01/2023 and letter No. PQCB/R- 300/2022 dated 30/01/2023 received to us on 13h February 2023 regarding show cause for our product Tab. Glanvl 2mg (Batch # 81 & 82) declared as SUBSTANDARD.

2. It is hereby to write you that we are awarded purchase order to supply Glanyl 2mg in 100's Packm8 and to which our manufacturing specs for our product Glanyl 2mg, tablets is ALU- PVC.In this regard, we also have all relevant documentation and stability data maintained with us.

3. It is also to refer Innovator products as available in USA or European countries also have different packaging specs such as Bottle packing, PVC/PVdC etc.

4. Furthermore, it is also to highlight that our product claim is USP and all parameter are well within range as per USP monograph as evident from DTL Rawalpindi report No. TRA 01- 74005012/DTL dated 05th Sep 2022 (Tab. Glanyl 2mg Batch # 81) and TRA 01-74005011/DTL dated 05th Sep 2022 (Tab. Glanyl 2mg Batch # 82). Summary of results is tabulated below:

Parameter	IDENTIFICATION TEST	DISSOLUTION	ASSAY
Batch # 81	Glimepiride identified	All units comply the dissolution test at Sl All units comply the dissolution test at S1	100.5%
Batch # 82	Glimepiride identified	All units comply the dissolution test at Sl All units comply the dissolution test at S1	100.95%
Conclusion	COMPLIES	COMPLIES	COMPLIES

5. Moreover, the same batch of Glarnyl 2 mg (i.e. Batch # 81 & 82) was also supplied to other region of Punjab (a brief summary is tabulated below), and the same was tested and reported by DTL Multan, DTL Bahawalpur, DTL Lahore and DTL Faisalabad and declared as "STANDARD QUALITY". Summary is given for your kind perusal.

DHA's	DTL	Batch no.	Quantity Supplied (Tablets)	DTL sample receipt date	DTL result	DTL Result
Okara	Bahwalpur	81	341,400	29 Jul 2022	23 Aug 2022	Pass-of Standard Quality
Lahore	Lahore	82	166,000	26 Jul 2022	08 Sep 2022	Pass-of Standard Quality
Khanewal	Multan	82	355,000	18 Jul 2022	20 Aug 2022	Pass-of Standard Quality
Narowal	Faisalabad	82	62,300	18 Jul 2022	10 Aug 2022	Pass-of Standard Quality

6. Foregoing in view the aforementioned facts, and considering that packaging is not the part of USP monograph, and all quality testing parameters conducted by DTL Rawalpindi are within specifications. Hence product is of STANDARD quality and there is no harms to patient.

Therefore, we request honourable board for a lenient view and drop proceedings as we have not contravened any provision of Drug Act 1976 and Rules framed there under.

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

Summary:

Manufacturing Date: 06-2022

Expiry Date: 06-2024

Sampling Date: 13-07-2022

Sent to DTL (Form 6): 13-07-2022

Date of receipt in DTL: 14-07-2022

DTL Report Date: 05-09-2022

Time Extension: N/A

1ST DI Communication with firm on dated: 13-09-2022

Date of Retesting Request of Firm: -N/A

Fate of Retesting Request: -N/A

Investigation Report Dated: 28-09-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 53

DISTRICT DERA GHAZI KHAN

PQCB/R-47/2022

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

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Pharmedic Laboratories (Pvt.) Ltd. 16 KM Multan Road, Lahore-Pakistan** through its Chief Executive Officer/Managing Director Waqar Ahmed Sheikh 2. Waqar Ahmed Sheikh — Chief Executive Officer/Managing Director 3. Muhammad Sohaib Iftikhar Baig — Production Incharge 4. Muhammad Nauman Ahmed — Quality Control Incharge 5. Ghazanfer Aman Ullah Khan — Warrantor Of **M/s Pharmedic Laboratories (Pvt.) Ltd. 16 KM Multan Road, Lahore-Pakistan** 6. Anees Ul Hasnain — Proprietor 7. Abdul Majeed — Salesman **Of M/s Millat Medical Hall situated at Fareedi Bazar near Traffic Chowk Dera Ghazi Khan.**

BRIEF FACTS OF THE CASE

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

i. He, on 05-01-2022, inspected the business premises M/s Millat Medical Hall situated at Fareedi Bazar near Traffic Chowk 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. 0000115156 dated 05-01-2022.

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

iii. M/s Millat Medical Hall situated at Fareedi Bazar near Traffic Chowk Dera Ghazi Khan submitted Invoice/warranty No. 696429 dated 26-09-2021 issued by M/s Faisal Pharma Sakhi Sarwar Road, Gaddai Phatak, Opp; CSD Market as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/s Faisal Pharma Sakhi Sarwar Road, Gaddai Phatak, Opp; CSD Market who in turn submitted invoice/ warranty No. 27267 dated 26-07-2021 issued by M/s Pharmedic Laboratories (Pvt.) Ltd. 16 KM Multan Road, Lahore-Pakistan as a proof of its purchase of the said drug.

v. A copy of test/analysis report was sent to M/s Pharmedic Laboratories (Pvt.) Ltd. 16 KM Multan Road, Lahore-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>Darvin (Tramadol as Hydrochloride…37.5mg & Paracetamol…325mg) Tablet.
Exp. date:
Jun-2023
Regn No.
074232</td><td>513</td><td>M/s Pharmedic Laboratories (Pvt.) Ltd. 16 KM Multan Road, Lahore-Pakistan</td><td>TRA No. 01-94001424/DTL
Dated:-21-04-2022</td><td>
<u>Analysis with specifications applied:</u>
Manufacturer Specifications (MS)
<u>Description:</u>
White, round, biconvex film coated tablet with inscription of ‘’PHARMEDIC’’ on one side while other side is plain, packed in ALU-PVC blister of 10 units.
The product claims USP Finished Drug Product Specifications and in USP the monograph claims ‘’Tramadol HCl and Paracetamol’’ while the label claim of the product is ‘’Tramadol as HCl and Paracetamol’’ which is false and misleading.
Mis-Branded (Does not Comply)
<u>Identification:</u> Tramadol Hydrochloride and Paracetamol are Identified.
<u>Assay:</u>
Paracetamol
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>325 mg/Tablet</td><td>325.02 mg/ Tablet</td><td>100.01 %</td><td>90-110 %</td></tr>
</table>
Tramadol
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>37.5mg/ Tablet</td><td>33.92mg/ Tablet</td><td>90.45 %</td><td>90-110 %</td></tr>
</table>
(Complies)
<u>Weight Variation:</u>
Average Weight 557.68mg
±5% (NMT2) and None Deviate from ±10%
(Complies)
<u>Dissolution Test:</u>
Acceptance Criteria: NLT 80% of labeled amount of Paracetamol & Tramadol as HCl is dissolved in 30 minutes. (Complies)
<u>RESULT:</u>
The above sample is <u>Mis-Branded</u> as defined under section 3(s) (iv) of the Drugs Act, 1976.
</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:

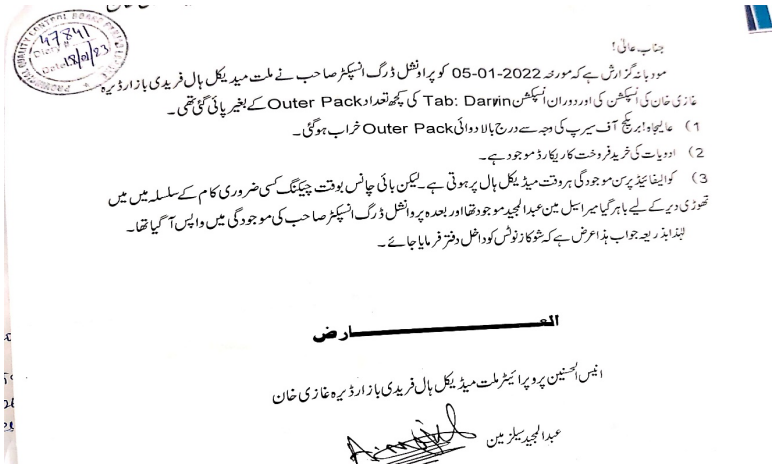
Names of Accused Persons	Offences
1. **M/s Pharmedic Laboratories (Pvt.) Ltd. 16 KM Multan Road, Lahore-Pakistan** through its Chief Executive Officer/Managing Director Waqar Ahmed Sheikh 2. Waqar Ahmed Sheikh Chief Executive Officer/Managing Director 3. Muhammad Sohaib Iftikhar Baig Production Incharge 4. Muhammad Nauman Ahmed Quality Control Incharge 5. Ghazanfer Aman Ullah Khan Warrantor Of **M/s Pharmedic Laboratories (Pvt.) Ltd. 16 KM Multan Road, Lahore-Pakistan**	a. **Manufacture for Sale /Sale of Substandard Drug** b. **Issuance of false warranty**
1. Anees Ul Hasnain Proprietor 2. Abdul Majeed Salesman **Of M/s Millat Medical Hall situated at Fareedi Bazar near Traffic Chowk Dera Ghazi Khan.**	a. **Stocking for Sale of Misbranded Drug without outer packing by destroying the outer packing.** b. **Without Sale Purchase record in violation of Section 23(1) (a) (x) of Drug Act 1976 (as amended) read with Rule 20(1) (f) of Punjab Drug Rules 2007.** c. **Sale of Drugs without Qualified Person.**

3. Show cause notice(s) issued to accused person(s) dated 05-01-2023.

Reply of firm to show cause notice vide letter no. PHL/LHR/PQCB/0123/002 dated 16-01-2023

With reference to your letter No. PQCB/R-47/2022 dated 05-01-2023 received on 16-01-2023, we, M/s Pharmedic Laboratories (Pvt.) Ltd., hereby are submitting the response for explanation of our Misbranded drug (Darvin Tablet Batch # 513) that we have already obtained formal approval letter for Standardization of Formulation from DRAP and changed our artwork (label and outer carton) as per your raised concern (evidence documents attached). It is further stated that our product meets all quality parameters which is evident from the testing report of Govt. Analyst TRA. 01-94001424/DTL dated 21-04-2022.

Reply of M/s Millat Medical Hall to show cause notice dated 16-01-2023



جناب عالی!

مودبانہ گزارش ہے کہ مورخہ 05-01-2022 کو پراونشل ڈرگ انسپکٹر صاحب نے ملت میڈیکل ہال فریدی بازار ڈیرہ غازی خان کی انسپکشن کی اور دوران انسپکشن Tab: Darvin کی کچھ تعداد Outer Pack کے بغیر پائی گئی تھی۔

1) عالیجاہ ایریچ آف سیرپ کی وجہ سے درج بالا دوائی Outer Pack خراب ہوگئی۔

2) ادویات کی خرید فروخت کا ریکارڈ موجود ہے۔

3) کوالیفائیڈ پرسن موجود گی ہر وقت میڈیکل ہال پر ہوتی ہے۔لیکن بائی چانس بوقت چیکنگ کسی ضروری کام کے سلسلہ میں میں تھوڑی دیر کے لیے باہر گیا میرا سیل مین عبدالمجید موجود تھا اور بعدہ پروانشل ڈرگ انسپکٹر صاحب کی موجودگی میں واپس آ گیا تھا۔

لہٰذا بذریعہ جواب ہذا عرض ہے کہ شوکاز نوٹس کو داخل دفتر فرمایا جائے۔

العـــــــــــــــــارض

انیس الحسنین پروپرائیٹر ملت میڈیکل ہال فریدی بازار ڈیرہ غازی خان

عبدالمجید سیلز مین

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 06-2021**
- **Expiry Date: 06-2023**
- **Sampling Date (Form 4): 05-01-2022**
- **Sent to DTL (Form 6): 05-01-2022**
- **Date of receipt in DTL: 06-01-2022**
- **DTL Report Date (Form 7): 21-04-2022**
- **Time Extension: Granted in 240th meeting dated 26-02-2022**
- **1ST DI Communication with firm on dated: 17-05-2022**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 03-10-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 54

PQCB/R-343/2022

Jaranwala Town, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.E., Sargodha Road, Faisalabad-Pakistan** through its Managing Director, Zahid Iqbal 2. Zahid Iqbal — Managing Director 3. Abdul Aleem — Production Incharge 4. Farhan Ali — Quality Control Incharge 5. Umar Habib Gaba — Warrantor of M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.I., Sargodha Road, Faisalabad-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Jaranwala Town, District Faisalabad reported that: -

i. He, on 30-07-2022, inspected the business premises of M/s Doctor and Medicine Pharmacy situated at shop khewat no. 682, Khatooni no. 782, maraba no. 302, chak no. 127/GB near Wapda Office, Tehsil Jaranwala 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. 135274 dated 30-07-2022.

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	TRA No. & Date	DTL Test Report Result
Syrup. Ahcuf 60ml [Each 5ml contains: Ammonium chloride B.P …. 100mg, Sodium Citrate B.P. …. 60mg, Menthol B.P …. 1mg] **Mfg Date:** Dec 2021 **Expiry Date:** Nov-2023 **Regn No.** 060749	AH-1090	M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.E., Sargodha Road, Faisalabad-Pakistan.	01-68017410/DTL dated: 02-09- 2022	**Analysis with specifications applied:** MS **DESCRIPTION:** Red color syrup contained in a white -colored plastic bottle with a sealed white plastic screw cap. **NOTE: Given sample is not labelled in the prescribed manner as "Name of drug" is not printed in Urdu on the label of given sample which is mandatory as per section 3 (h) (i) of The Drugs (Labelling and Packing) Rules 1986 (Does not Comply)** **ASSAY:** **Ammonium Chloride** Stated: 100 mg / 5ml Determined: 105.989 mg / 5ml Percentage 105.989% (Complies) Limit: 90 - 110% (Manufacturer's Specifications) **Sodium Citrate** Stated: 60 mg / 5ml Determined: 55.695 mg / 5ml Percentage 92.825% (Complies) Limit: 90 - 110% (Manufacturer's Specifications) **pH:** Limit: 4.0 - 6.0 (Manufacturer's Specifications) Determined: 5.20 (Complies) **RESULT:** Given sample is **Misbranded** with regards to Labelling (as per Section 3 (s) (i) of The Drugs Act 1976).

iii. Proprietor of M/s Doctor and Medicine Pharmacy situated at shop khewat no. 682, Khatooni no. 782, maraba no. 302, chak no. 127/GB near Wapda Office, Tehsil Jaranwala District Faisalabad provided invoice/ warranty bearing No. 68567 dated 24-04-2022 issued by M/s Sayam Enterprises (Distributors), Medicine Market, Faisalabad as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Sayam Enterprises (Distributors), Medicine Market, Faisalabad who provided invoice/ warranty bearing No. 9827 dated 17-01-2022 issued by M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.E., Sargodha Road, Faisalabad-Pakistan as a proof of its purchase.

v. A copy of test/analysis report was sent to M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.E., Sargodha Road, Faisalabad-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 10-02-2023

Firm replied to the Show Cause Notice vide letter no. AH/2023/0220 dated 20-02-2023 and verified names of the accused nominated by the drug inspector. Furthermore, firm also submitted rectified label of the subject drug sample.

4. Personal hearing notice(s) issued to accused person(s) dated 29-03-2023

5. Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 55

PQCB/R-555/2021

Lyallpur Town, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.E., Sargodha Road, Faisalabad-Pakistan** through its Managing Director, Zahid Iqbal 2. Zahid Iqbal Managing Director 3. Abdul Aleem Production Incharge 4. Farhan Ali Quality Control Incharge of M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.E., Sargodha Road, Faisalabad-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Lyallpur Town, District Faisalabad reported that: -

i. His predecessor, on 10-11-2021, inspected the premises of M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.E., Sargodha Road, Faisalabad-Pakistan, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide memorandum no. 111013 dated17-11-2021.

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	TRA No. & Date	DTL Test Report Result
Syrup. Ahcuf 60ml [Each 5ml contains: Ammonium chloride B.P …. 100mg, Sodium Citrate B.P. …. 60mg, Menthol B.P …. 1mg] **Mfg Date:** Oct 2021 **Expiry Date:** Sep-2023 **Regn No.** 060749	AH-1017	M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.I., Sargodha Road, Faisalabad-Pakistan.	01-68012631/DTL dated: 14-12- 2021	**Analysis with specifications applied:** MS **DESCRIPTION:** Red colored syrup contained in amber plastic bottle with white screw cap packed in outer hard carton. **NOTE: Name of drug is not printed in Urdu on the label of given sample which is mandatory as per section 3 (h) (i) of The Drugs (Labelling and Packing) Rules 1986 (Does not Comply)** **ASSAY:** **Ammonium Chloride** Stated: 100 mg / 5ml Determined: 106.377 mg / 5ml Percentage 106.377% (Complies) Limit: 90 - 110% (Manufacturer's Specifications) **Sodium Citrate** Stated: 60 mg / 5ml Determined: 55.196 mg / 5ml Percentage 91.993% (Complies) Limit: 90 - 110% (Manufacturer's Specifications) **pH:** Limit: 4.0 - 6.0 (Manufacturer's Specifications) Determined: 5.26 (Complies) **RESULT:** Given sample is **Misbranded** with regards to Labelling as per Section 3 (h) (i) of The Drugs (Labelling and Packing) Rules 1986.

iii. A copy of test/analysis report was sent to M/s A.H. Pharmaceuticals (Pvt) Ltd., 865-A, S.I.I., Sargodha Road, Faisalabad-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**

3. Show-cause notice(s) issued to accused person(s) dated 10-02-2023

Firm replied to the Show Cause Notice vide letter no. AH/2023/0220 dated 20-02-2023 and verified names of the accused nominated by the drug inspector. Furthermore, firm also submitted rectified label of the subject drug sample.

4. Personal hearing notice(s) issued to accused person(s) dated 29-03-2023

5. Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 56

PQCB/R-202/2022

Allied Hospital, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Elko Organization (Pvt) Ltd., Plot No. 27, 28, Sector 12-B, North Karachi Industrial Area, Karachi-Pakistan** through its Managing Director, Shakil Ahmed Chandna 2. Shakil Ahmed Chandna Managing Director 3. Shama Anees Production Incharge 4. Muneer Ahmed Quality Control Incharge 5. Mirza Ayaz Baig General Manager/ Warrantor of M/s Elko Organization (Pvt) Ltd., Plot No. 27, 28, Sector 12-B, North Karachi Industrial Area, Karachi-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Allied Hospital, District Faisalabad reported that: -

i. She, on 01-07-2022, inspected the premises of Central Pharmacy of Allied Hospital, District Faisalabad, took six different types of drug sample on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Faisalabad vide memorandum no. 132113 dated 01-07-2022.

ii. The following 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	TRA No. & Date	DTL Test Report Result
Gel. Micoral gel [Each gm gel contains: Miconazole: 20 mg] **Mfg Date:** Jun 2022 **Expiry Date:** June 2024 **Regn No.** 061086	131	**MFD By:** M/s Elko Organization (Pvt) Ltd., Plot No. 27, 28, Sector 12-B, North Karachi Industrial Area, Karachi-Pakistan. **Marketed By:** LADERLY BIO-TECH PHARMA	01-68016751/DTL dated: 21 Oct 2022	**Analysis with specifications applied:** BP 2022 **DESCRIPTION:** Clear colorless transparent gel contained in collapsible metal tube with screw cap packed in outer hard carton. **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 given sample is "**Manufacturer's Specifications**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of Miconazole gel monograph in 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)** **IDENTIFICATION:** Miconazole is identified. **ASSAY:** Stated: 20 mg/ gram Determined: 20.201 mg/ gram Percentage 101.005 % (Complies) Limit: 95-105% (BP 2022) **pH:** Limit: 4.0 - 7.5 (BP 2022) Determined: 6.08 (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. Chief Pharmacy Technician of Central Pharmacy of Allied Hospital, District Faisalabad provided warranty bearing No. 7450 dated 28-06-2022 issued by M/s Friends Enterprises, 40/8, Al-Rafi Plaza Behind State Bank of Pakistan, New Civil Lines Faisalabad as a proof of its purchase of the subject drug sample.

iv. Warrantor portion of drug sample was sent to M/s Friends Enterprises, 40/8, Al-Rafi Plaza Behind State Bank of Pakistan, New Civil Lines Faisalabad who provided warranty bearing No. 0073550 dated 25-06-2022 issued by M/s Elko Organization (Pvt) Ltd., Plot No. 27, 28, Sector 12-B, North Karachi Industrial Area, Karachi-Pakistan as a proof of its purchase of the subject drug sample.

v. A copy of test/analysis report was sent to M/s Elko Organization (Pvt) Ltd., Plot No. 27, 28, Sector 12-B, North Karachi Industrial Area, 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 23-01-2023

Firm replied to the show cause notice vide letter dated 31-01-2023

In this connection, we would like to mention that we have obtained permission from DRAP for the change of finished product specifications from Manufacturer's Specifications to Pharmacopeias reference that is "BP Specifications" as directed by DRAP. We have made necessary changes in packaging material.

4. Personal hearing notice(s) issued to accused person(s) dated 29-03-2023

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 06-2022

Expiry Date: 06-2024

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

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

Date of receipt in DTL: 01-07-2022

DTL Report Date (Form 7): 21-10-2022

Time Extension: Granted in 250-M dated 22-09-2022

1ST DI Communication with firm on dated: 12-11-2022

Retesting Request of Firm: NA

Investigation Report Dated: 30-11-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 57

PQCB/R-792/2019

Tehsil Kamoke, District Gujranwala

Misbrande

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Quaper (Pvt.) Ltd., 26-A S.I.E., Lahore Road, Sargodha** through its Director Muhammad Iftekhar 2. Muhammad Iftekhar — Director 3. Fozia Naheed — Production Incharge/ Warrantor 4. Muhammad Saleem — Quality Control Incharge of **M/S Quaper (Pvt.) Ltd., 26-A S.I.E., Lahore Road, Sargodha.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Kamoke, District Gujranwala reported that:-

i. He, on 22-06-2019, inspected the business premises of M/s Al-Noor Pharmacy near main bazar Kamoke, G.T. Road, Kamoke Gujranwala and took sample of three different types of drugs on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Faisalabad vide memo number 43542 dated 22-06-2019.

ii. One out of three drug samples, after test/analysis, were declared **Misbranded** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Film coated Tablet Bifen [Each film coated Tablet contain… Flurbiprofen (U.S.P)…100 mg] **Mfg. Date 11-2017** **Expiry Date: 10-2019**	GK-1727	M/S Quaper (Pvt.) Ltd., 26-A S.I.E., Lahore Road, Sargodha	TRA No. 01-56004052/DTL Dated: 30-08-2019	**Analysis with specifications applied:** USP 2019 **Description:** Blue colored, oval shaped tablet plain from one side and engraved with "Q" on other side, contained in PVC-ALU blister of 5's packed in outer unit carton. **Identification:** Flurbiprofen identified. **Assay:** Stated: 100 mg/ Tablet Determined: 105.89 mg/ Tablet Percentage: 105.89**%** Limit: 90-100% **Labelling Requirements:** **Stated:** **According to Drugs Act 1976 Section 3 (s) (vi), "Misbranded means a drug: "which is manufactured according to the specifications of a particular Pharmacopeia or any other document as may be prescribed and the label does not bear the name of that Pharmacopeia or document."** **Determined:** **In case of given sample, the specifications of dosage form according to which it is manufactured, are not printed on the label of inner blister as well as not printed on the label of outer unit carton. (Does not comply)** **RESULT:** Given sample is **"Misbranded"** on the basis of labelling as per defined in Section 3 (s) (vi) of Drugs Act 1976.

iii. M/s Al-Noor Pharmacy near main bazar Kamoke, G.T. Road, Kamoke Gujranwala, provided invoice/ warranty/ no. M10118 dated 10-01-2018 issued by M/S Quaper (Pvt.) Ltd., 26-A S.I.E., Lahore Road, Sargodha as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/S Quaper (Pvt.) Ltd., 26-A S.I.E., Lahore Road, Sargodha.

i. A copy of test report of the drug sample was sent **to** M/S Quaper (Pvt.) Ltd., 26-A S.I.E., Lahore Road, Sargodha 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. **Manufacture for Sale /Sale of Misbranded Drug**
ii. **Issuance of false warranty**

3. Show-cause was issued to accused person(s) vide dated 27-12-2022.

Note: Firm has submitted rectified label of the product

4. Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 58

PQCB/R-596/2021

Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat

Sub-Standard (Assay

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi through** its Chief Executive Officer Humza Obaid Naviwala 2. Humza Obaid Naviwala Chief Executive Officer 3. Zia ur Rehman Deputy GM/ Head of Production 4. Hamna Faizan Khan Deputy Manager/ Quality Control Operations 5. Dr. Waseem Shahzad Warrantor of **M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat reported that:-

i. He, on 08-03-2021, inspected the premises of Main Medicine Store of Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat and took sample of seven different types of drugs on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Faisalabad vide memo number 86519 dated 08-03-2021.

ii. One out of seven drug samples, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Injection Ferris [Each ampoule contains: 100mg of elemental iron as iron sucrose] **Mfg. Date 02-2021** **Expiry Date: 02-2023** **Reg No. 086898**	21B001	M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan.	TRA No. 01-68007685/DTL Dated: 05-05-2021	**Analysis with specifications applied:** BP 2021 **Description:** Reddish brown liquid filled in plastic ampoule sealed with twist off cap, packed in plastic tray of 5 units, packed in outer hard carton. **Identification:** Iron is identified. **Assay:** Stated: 100 mg/ 5ml Determined: 80.565 mg/ 5ml Percentage: 80.565**%** Limit: 95-105% (BP-2021) **pH:** Stated: 10.5-11.0 (BP-2021) Determined: 10.52 (Complies) Extractable Volume: Stated: Not less than nominal volume (BP 2021) Determined: 5.0 ml (Average of 03 ampoules) (Complies) Sterility: Stated: Must be sterile (BP 2021) Determined: Sterile (Complies) **RESULT:** Given sample is **"Substandard"** with regards to Assay.

iii. Store keeper of Main Medicine Store of Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat, provided invoice/ warranty/ no. INPQ/2021/2010 dated 25-02-2021 issued by M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan.

v. A copy of test report of the drug sample was sent to M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan with directions to provide the requisite information and to explain their position in this regard. In response, firm requested for re-test/ analysis of their drug sample from Appellate Laboratory, National Institute of Health Sciences, Islamabad.

vi. Pursuant to their request, the PQCB portion of the drug sample was sent to Appellate Laboratory, National Institute of Health Sciences, Islamabad for the purpose of retest/ analysis. The drug sample was declared Substandard from National Institute of Health Sciences, Islamabad as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Report No. & Date	NIH Test Report Results
Injection Ferris 5 ml (Iron Sucrose… 10mg)	21B001	M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan.	036-P/2022 dated 20th July, 2022	**Analysis with specifications applied:** BP-2017 **Assay:** **Stated:** 100 mg/5ml **Found: 56.24 mg/5ml** **Limit: 95-105%** **Percentage :56.24%** **Does not comply with BP 2017** **RESULT:** The sample is of **"Substandard"** quality on the basis of tests performed.

vii. A copy of NIH test report of the drug sample was sent **to** M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, 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 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.**

3. Show cause notice(s) issued to the accused persons dated 21-10-2022

4. Personal Hearing notice(s) issued to accused person(s) dated 09-01-2023

PREVIOUS PROCEEDINGS BY THE BOARD:

PQCB 256th meeting dated 19-01-2023:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **256th meeting** held on **19-01-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Amtiaz Aslam Secretary DQCB District Gujrat and Ms. Saba Ghalib Drug Inspector Aziz Bhatti Shaheed Teaching Hospital, Gujrat were present along-with original case record. No-one among the nominated accused persons was present, however, representative from the firm Rana Arsalan (RSM) was present on behalf of **M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan.** No-one appeared before the Board at the time of hearing. Keeping in view the facts of the case, the Board after due deliberation and detailed 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.

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

Summary:

Manufacturing Date: 02-2021

Expiry Date: 02-2023

Sampling Date (Form 4): 08-03-2021

Sent to DTL (Form 6): 08-03-2021

Date of receipt in DTL: 13-03-2021

DTL Report Date: 05-05-2021

Time Extension: N/A

1ST DI Communication with firm on dated: 14-06-2021

Date of Retesting Request of Firm: 22-06-2021

Fate of retesting Request: Allowed (NIH Substandard)

Investigation Report Dated: 18-08-2022

Case is placed before the Board

PROCEEDING & DECISIONS BY THE BOARD:

Case No. 59

PQCB R-694/2019

Aziz Bhatti Shaheed Teaching Hospital, Gujrat

Substandard (Assay)

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/S Gulf Pharmaceuticals Plot No. 49 Street No. S-5 National Industrial Zone Rawat Islamabad** through its Managing Director Wasi Shan 2. Wasi Shan Managing Director 3. Muhammad Ali Qamar Production In-charge 4. Waqar Alam Quality Control In-charge/ Warrantor of **M/S Gulf Pharmaceuticals Plot No. 49 Street No. S-5 National Industrial Zone Rawat Islamabad.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Aziz Bhatti Shaheed (DHQ)/ Teaching Hospital, Gujrat reported that:-

i. He, on 26-02-2019, inspected the premises of Medicine Store of Aziz Bhatti Shaheed (DHQ)/ Teaching Hospital, Gujrat and took sample of five different types of drugs on Form No.04 for the purpose of test/analysis.

ii. One out of five drug samples, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Cream Topidic 2% [Each tube contains: Fusidic Acid(BP)…2%]	050	M/S Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, National Industrial Zone, Rawat, Islamabad.	TRA No. 01-68001053/DTL dated:22-03-2019	**Analysis with specifications applied:** B.P 2019 **Description:** White homogeneous cream, free from visible and gritty particles, filled in collapsible aluminum cream, sealed and caped with white screw cap, packed in outer hard carton. **Identification:** Fusidic acid identified **Assay:** Stated: 20mg/ gram Determined: 16.7 mg/ gram Percentage: 83.5% **(Does not comply)** Limit: 90-110% (BP 2019) **Result:** Given sample is declared **Substandard** on the basis of Chemical Assay.

iii. Store keeper of Aziz Bhatti Shaheed (DHQ)/ Teaching Hospital, Gujrat, provided invoice/ warranty no. GP/A.B.T.H.G. Supply/002/01/2019 dated 04-02-2019 issued by M/S Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, National Industrial Zone, Rawat, Islamabad as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/S Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, National Industrial Zone, Rawat, Islamabad

v. A copy of test report of the drug sample was sent to M/S Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, National Industrial Zone, Rawat, Islamabad with directions to provide the requisite information and to explain their position in this regard. In response, the firm request for retest/ analysis of the drug sample.

vi. Pursuant to their request, the PQCB portion of the drug sample was sent to Appellate Laboratory, National Institute of Health Sciences, Islamabad for the purpose of retest/ analysis. The sample was declared Substandard from NIH Laboratory Islamabad as follows:

vii. A copy of NIH test report of the drug sample was sent to M/S Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, National Industrial Zone, Rawat, Islamabad with directions to provide the requisite information and to explain their position in this regard.

Name of drug	Batch No.	Name of manufacturer	NIH Report No. & Date	NIH Test Report Results
Cream Topidic 2%	050	M/S Gulf Pharmaceuticals, Plot No. 48, Street No. S-5, National Industrial Zone, Rawat, Islamabad.	0200-P/2019 dated 01-10-2019	**Analysis with specifications applied:** B.P 2017 **Description:** White semi solid cream contained in flexible labelled tube further contained in an outer carton. **Identification:** Fusidic acid identified. **Weight Variation:** Complies **Assay:** (Fusidic Acid) Stated: 20mg/ gram Determined: 16.33 mg/ gram Percentage: 81.68% **(Does not comply)** Limit: 90-110% (BP 2017) **Result:** The sample is of **Substandard quality** on the basis of tests performed.

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

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

3. Show-cause notice(s) issued to the accused dated 05-08-2021

4. Personal Hearing Notice issued to the accused person(s) dated 02-03-2022

PREVIOUS PROCEEDINGS BY THE BOARD:

PQCB 240th meeting dated 15-03-2022:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **240th meeting** held on **15-03-2022** under the Chairmanship of Secretary Primary & Secondary Healthcare Department, Punjab in the presence of Board members as mentioned above**.** M. Amtiaz Aslam Secretary DQCB District Gujrat and Mr. Raja Kamran Drug Inspector, Aziz Bhatti Shaheed Teaching Hospital, Gujrat were present. No-one from the nominated accused persons was present, however, Representative from the firm Zain Bukhari (Manager) appeared before the Board on behalf of M/S Gulf Pharmaceuticals Plot No. 49 Street No. S-5 National Industrial Zone Rawat and submitted written request for adjournment stating that they were unable to attend the meeting as their technical representative was admitted in hospital because of his surgery. The Board after due deliberation and discussion unanimously decided to **adjourn the case** on request of the firm in best interest of justice. The Board further decided to provide another/ final opportunity of personal hearing to the accused persons.

PQCB 245th meeting dated 16-06-2022

6. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **245th meeting** held on **16-06-2022** under the Chairmanship of vice chairperson in the presence of Board members as mentioned above**.** Mr. M. Amtiaz Aslam Secretary DQCB District Gujrat and Mr. Raja Kamran Drug Inspector, Aziz Bhatti Shaheed Teaching Hospital, Gujrat were present. No-one from the nominated accused persons was present, however, Representative from the firm Muhammad Khalique (Manager) appeared before the Board on behalf of M/S Gulf Pharmaceuticals Plot No. 49 Street No. S-5 National Industrial Zone Rawat.

7. The Board after careful perusal of the case record observed that the Drug Inspector has nominated the names of two managing directors in the subject case, therefore, the Board after due deliberation and detailed discussion has unanimously decided to remand back the case to drug inspector for **re-investigation** and further directed to submit the reinvestigation report after verifying the name of managing director from Drugs Regulatory Authority of Pakistan (DRAP)/ Securities Exchange Commission of Pakistan (SECP), within a week positively

8. Reinvestigation report received.

9. Revised Show-cause notice issued dated 19-10-2021

REPLY OF THE FIRM IN RESPONSE TO SHOW-CAUSE NOTICE

M/S Gulf Pharmaceuticals, Plot No. 48, Street No. S-5, National Industrial Zone, Rawat, Islamabad vide ref. no. Gf/QC/PQCB/023/22 dated 31-10-2022

1. *Tropidic cream Batch No. 050 Mfg Date 2019 Fxp. Date December 2020, declared sub-standard by DTL Faisalabad via report No. TRA No. 01-68001053/DTL 22-.03-2019.*
2. *Replacement of the said batch has already been supplied to Aziz Bhatti Hospital Gujrat on 26th February 2020 (Tropidic cream Batch No. G272 Mfg. date 02/2020, , Expiry 01/2020 was supplied in replacement.*
3. *The replacement of stock was accepted by the DHQ authorities*
4. *We have not received any payment of the stock including for that of the replacement sent to DGQ Gujrat.*
5. *The batch of Tropic cream was only supplied to the ABH DHO and not sent in the market hence, not consumed by any patient.therefore, there is no any harmful effect to any one.*
6. *QA retension sample stored in well controlled storage conditions in GULF when retested were found ok. (102.79%)*
7. *There might be some environmental effect on the samples sent to DTL & NIH during storage which may cause degradation and resulted in low active content.*

Personal Hearing Notice issued to the accused person(s) dated 29-03-2023

Summary:

Manufacturing Date: 01-2019

Expiry Date: 12-2020

Sampling Date (Form 4): 26-02-2019

Sent to DTL (Form 6): 26-02-2019

Date of receipt in DTL: 27-02-2019

DTL Report Date: 22-03-2019

Time Extension: N/A

1ST DI Communication with firm on dated: 11-04-2019

Date of Retesting Request of Firm: 17-04-2021

Fate of retesting Request: Allowed (10th committee meeting dated 22-07-2019)

(NIH Substandard)

Investigation Report Dated: 27-07-2021

Case is placed before the Board for decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 60

DISTRICT JHANG

PQCB/R-149/2022

Tehsil Ahmed Pur Sial, District Jhang

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Miracle Pharmaceuticals (Pvt) Ltd. Plot 8, Street S-5, National Industrial Zone, Rawat-Islamabad-Pakistan through its** Chief Executive Officer Altaf Hussain 2. Altaf Hussain Chief Executive Officer/ Warrantor 3. Khalid Mehmood Production Incharge 4. Muhammad Naveed Quality Control Incharge Of **M/s Miracle Pharmaceuticals (Pvt) Ltd. Plot 8, Street S-5, National Industrial Zone, Rawat-Islamabad-Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He, on 25-01-2022 inspected the business premises of M/s Bismillah Medical Store, Adda Sharifabad, Tehsil Ahmedpur Sial, District Jhang, took sample of drugs on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Faisalabad vide Memorandum No. 0000117053 dated 26-01-2022.

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

Name of drug	Batch no.	Name of manufacturer	DTL Test Report No. & Date	DTL Test Report Results
Tablet Maricox (Each tablet contains: Nimesulide… 100mg) **Mfg. date:** Apr-2021 **Exp. Date:** Mar-2024 **Reg.No.** 043874	A-143	M/s Miracle Pharmaceuticals (Pvt) Ltd. Plot 8, Street S-5, National Industrial Zone, Rawat-Islamabad-Pakistan	TRA No. 01-68013619/DTL dated: 16-03-2022	**Result of Test/Analysis with Specifications applied:** MS **Description:** Light yellow, round shaped tablets contained in ALU-ALU blister of 10 units, packed in outer hard carton along with leaflet. **Identification:** Nimesulide identified. **Assay:**

Stated	Determined	Percentage	Limit
100 mg/Tablet	105.713mg/Tablet	105.713% (Complies)	90.0-110.0% (Manufacturer's specifications)

Disintegration test:

Stated: Not more than 15 minutes (Manufacturer's Specifications)

Determined: All 6 units disintegrated within 15 minutes **(Complies)**

Labelling Requirements:

Stated: According to Drugs Act 1976 Section 3 (s) (iv), ''Misbranded'' means a drug: ''it's 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 case of given sample, ''B.P. Specifications.'' are printed on the label of outer unit carton and ''Miracle's Specifications'' on the label of immediate container (Blister) which are contradictory to each other and misleading. In addition, no any monograph of Nimesulide tablet is available in BP 2022 So manufacturer's claim regarding product specification is false/misleading abd in violation to Drugs Act 1976 **(Does Not Comply)**

RESULT: Given sample is **Misbranded** on the basis of labelling as per defined in Section 3 (s) (iv) of The Drugs Act 1976.

iii. M/s Bismillah Medical Store, Adda Sharifabad, Tehsil Ahmedpur Sial, District Jhang provided invoice/ Warranty No. 10008 dated 20-01-2022 issued by M/s Hashir Enterprises, Raza Street, Opposite Ghosia Mosque, Near Railway Crossing Gojra Road, Jhang Saddar as proof of their purchase.

iv. Warrantor Portion was sent to M/s /s Hashir Enterprises, Raza Street, Opposite Ghosia Mosque, Near Railway Crossing Gojra Road, Jhang Saddar and they were asked to provide requisite information in this regard.

v. M/s Hashir Enterprises, Raza Street, Opposite Ghosia Mosque, Near Railway Crossing Gojra Road, Jhang Saddar in turn provided the Bill/ Warranty bearing invoice No. LP-1989 dated 28-09-2021 issued by M/s Lyallpur Pharma, 30-Z-13 Irshad Road, Madina Town, Faisalabad who in turn provided invcoice/ Waarranty No. 1425 dated 30-06-2021 issued by M/s Miracle Pharmaceuticals (Pvt) Ltd. Plot 8, Street S-5, National Industrial Zone, Rawat-Islamabad-Pakistan as a proof of purchase of the said drug.

vi. A copy of Test/ Analysis report was sent to M/s Miracle Pharmaceuticals (Pvt) Ltd. Plot 8, Street S-5, National Industrial Zone, Rawat-Islamabad-Pakistan and they were asked to provide requisite information in this regard.

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

i. **Manufacturing for Sale /Sale of Misbranded Drug**

ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 01-12-2022.

Reply of firm to show cause notice vide letter no. nil dated 09-12-2022

With reference to letter No PQCB/R-149/2022 dated 01-12-2022 from Provincial Quality Control Board, Punjab received on dated 07/12/2022. it is here by stated that as our registered drug MARICOX Tablets Batch No A143 is declared misbranded as per DTL Faisalabad Report TEST/REPORT NO TRA.01-68013619/DTL, DATED: 16.03.2022 on the basis of different specifications on outer and inner labels.
Firm has immediately sent product recall notice to all relevant distributors for recall of said misbranded drug from market. Firm has also improved the labeling of said drug, improved labeling specimen are attached with letter.
Therefore it is highly requested that matter should be resolved in the favor of firm and firm will not repeat such things in future. Following documents and record is attached with letter.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 04-2021**
- **Expiry Date: 03-2024**
- **Sampling Date (Form 4): 25-01-2022**
- **Sent to DTL (Form 6): 26-01-2022**
- **Date of receipt in DTL: 01-02-2022**
- **DTL Report Date (Form 7): 16-03-2022**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 28-07-2022**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 27-10-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 61

DISTRICT JHANG

PQCB/R-301/2021

Tehsil Ahmed Pur Sial, District Jhang

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Alkemy Pharmaceuticals Laboratories (Pvt.) Ltd., P/9 S.I.T.E., Hyderabad, Pakistan** through its Managing Director, Faraz Ahmed Shaikh 2. Faraz Ahmed Shaikh Managing Director 3. Syed Muhammad Hyder Zaidi Production Manager 4. Asif Najeeb Laghari Quality Control Incharge / Warrantor of **M/s Alkemy Pharmaceuticals Laboratories (Pvt.) Ltd., P/9 S.I.T.E., Hyderabad, Pakistan**.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Tehsil Ahmed Pur Sial District Jhang reported that: -

i. He, on 28-08-2021, inspected the busisness premises of M/s Bismillah Medical store Main Bazar Pir Abdul Rehman, Tehsil Ahmed pur Sial, District Jhang and took two different drug samples on Form No. 04 for the purpose of test and analysis and sent to Drug Testing Laboratory, **Faisalabad**.

ii. The subject drug sample after test/analysis, was declared **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 TRA No. & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>Tablet Kemipan Plus [Each tablet contains: Diclofenac Potassium BP……..75mg]</td><td>057</td><td>M/s Alkemy Pharmaceuticals Laboratories (Pvt) Ltd., P/9, S.I.T.E., Hyderabad Pakistan.</td><td>01-68011668/DTL Dated: 30-10-2021</td><td>
<u>RESULT OF TEST/ANALYSIS WITH SPECIFICATIONS APPLIED</u>
MS
<u>DESCRIPTION:</u>
Orange color round shape tablets contained in ALU-ALU packing of 10 units.
<u>UNIFORMITY OF DOSAGE UNIT (WEIGHT VARIATION)</u>
Complies the acceptance criteria of uniformity of dosage unit (weight variation) as per MS.
(Average weight of Tablet): 208.092mg
Acceptance criteria: Acceptance value of first 10 dosage units is less than or equal to L1 % (i.e., 15%)
<u>Determined:</u> Acceptance value of 10 dosage units (L1) =11.185% (complies)
<u>IDENTIFICATION:</u>
Diclofenac potassium is identified.
<u>ASSAY:</u>
Stated: 75mg/Tablet
Determined: 77.273mg/Tablet
Percentage: 108.031% (Complies)
Limit: 90.0-110.0% (Manufacturer’s Specifications)
<u>DISSOLUTION TEST:</u>
Complies the dissolution test as per MS as detailed below:
Tolerance limit: Not less than 75% (Q) of the labelled amount is released within 45 minutes.
<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%</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>Unit 5</td><td>Unit 6</td></tr>
<tr><td>After 45 minutes</td><td>86.4%</td><td>90.1%</td><td>103.3%</td><td>97.6%</td><td>99.5%</td><td>90.1%</td></tr>
</table>
<u>LABELLING REQUIREMENTS</u>
<u>STATED:</u>
According to Drugs Act 1976 Section 3 (s) (iv), “Misbranded “means a drug: “It’s 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.”
<u>DETERMINED:</u>
In cases of given sample, “B.P, Specifications” are printed on the label but in BP 2021, no such monograph of Diclofenac potassium tablet is available, so manufacturer claim is false/misleading and in violation to Drugs act 1976, (Does not comply)
<u>RESULT:</u>
Given sample is Misbranded with regards to Labelling (as per Section 3(s) (iv) of the Drug Act 1976.
</td></tr>
</table>

iii. Proprieter of M/s Bismillah Medical store Main Bazar Pir Abdul Rehman, Tehsil Ahmed pur Sial, District Jhang provided Invoice/Warranty No. 0005152 dated 03-05-2021 issued by M/s ALM Pharma Bodla Town Qasoori Chowk Multan as a proof of purchase.

iv. Warrantor portion of drug sample was sent to M/s ALM Pharma Bodla Town Qasoori Chowk Multan who in turn provided invoice/warranty no. 1947 dated 20-04-2021 issued by M/s Alkemy Pharmaceuticals Laboratories (Pvt) Ltd., P/9, S.I.T.E., Hyderabad Pakistan.

v. Copy of test report of the drug sample was sent to M/s Alkemy Pharmaceuticals Laboratories (Pvt) Ltd., P/9, S.I.T.E., Hyderabad 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 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 Misbranded Drug

ii. Issuance of false warranty

3. Show cause notice(s) issued to the accused person(s) Dated 10-03-2022.

4. Personal hearing notice served earlier for 241st Meeting 30-03-2022 deem to be served for reschedule of 241st Meeting on 31-03-2022 at same time and venue vide letter No. PQCB/Admin/RES/01/2022 dated 24-03-2022.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

241ST MEETING DATED 31-03-2022

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **241st meeting** held on **31-03-2022** under the chairmanship of Secretary Health Primary & Secondary Healthcare Department, Punjab. Ms. Farwa Mansoor Secretary DQCB Jhang and Mr. Amir Liaqat Attia Nawaz Drug Inspector Tehsil Ahmed Pur Sial District Jhang was present alongwith original case record. No one among the nominated accused persons appeared before the Board on the behalf of **M/s Alkemy Pharmaceuticals Laboratories (Pvt) Ltd., P/9, S.I.T.E., Hyderabad Pakistan.**

6. The Board after due discussion decided to **adjourn the case** as company was absent. The Board further decided to provide another but final opportunity of personal hearing to the accused person(s).

7. Personal Hearing Notice was issued to the accused persons vide dated 12-08-2022.

249th MEETING DATED 23-08-2022:

8. Case was considered by the Provincial Quality Control Board, under Section 11 of the Drugs Act 1976 in its **249th meeting** held on **23-08-2022** under the Chairmanship of Vice-Chairperson, Provincial Quality Control Board, Punjab. Mst. Farwa Mansoor, Secretary District Quality Control Board, Jhang and Mr. Amir Liaqat, Provincial Inspector of Drugs, Tehsil Ahmedpur Sial, District Jhang was present along with original case record. No one among the nominated accused persons of M/s Alkemy Pharmaceuticals 203, Al-Amin Tower, Block 10 Gulshan-e-Iqbal Karachi Pakistan was present. The firm submitted the written request for adjournment. The Board after due deliberation and discussion unanimously decided to **adjourn** the case in the best interest of justice and further decided to provide the firm another/final chance of hearing.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 12-2020**
- **Expiry Date: 11-2022**
- **Sampling Date (Form 4): 28-08-2021**
- **Sent to DTL (Form 6): 28-08-2021**
- **Date of receipt in DTL: 03-09-2021**
- **DTL Report Date (Form 7): 30-10-2021**
- **Time Extension: NA**
- **1ST DI Communication with firm on dated: 18-11-2021**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 30-12-2021**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 62

DISTRICT KHUSHAB

PQCB/R-85/2022

Tehsil Noor Pur Thal, District Khushab

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Adamjee Pharmaceuticals (Pvt) Ltd., Plot No. 39, Sector 15, Korangi Industrial Area, Karachi-Pakistan** through its Managing Director, Farooq Hamirani 2. Farooq Hamirani — Managing Director 3. Shahid Ahmad Khan — Production Manager 4. Asim Kamal Ansari — Quality Control Manager 5. M. Ali — Warrantor of M/s Adamjee Pharmaceuticals (Pvt) Ltd., Plot No. 39, Sector 15, Korangi Industrial Area, Karachi-Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Noor Pur Thal, District Khushab reported that: -

i. He, on 07-03-2022, inspected the business premises of M/s Azam Medical Store Adhi Kot, Tehsil Noor Pur Thal, District Khushab, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide memorandum no. 120755 dated 08-03-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Film Coated Tablet FEELIX 500mg [Levofloxacin Hemihydrate Eq. to Levofloxacin: 500mg] **Mfg Date:** Sep-2020 **Expiry Date:** Sep-2023 **Regn No.** 039387	83	M/s Adamjee Pharmaceuticals (Pvt) Ltd., Plot No. 39, Sector 15, Korangi Industrial Area, Karachi-Pakistan.	01-75003106/DTL dated: 20-04-2022	**Analysis with specifications applied:** USP 2021 **DESCRIPTION:** Orange colored, oblong shaped, biconvex tablet, scored from one side and engraved with Company Logo on other side, packed in Alu/Alu blister of 1*10s, further packed in outer labelled carton. **Two different Manufacturing Specifications are mentioned on label; Adamjee specs on the blister and USP specs on carton. (DOES NOT COMPLY)** **IDENTIFICATION:** Levofloxacin identified. **ASSAY:** Stated: 500 mg/ Tablet Determined: 468.436 mg/Tablet Percentage 93.69% Limit: 90-110% **RESULT: The above sample is Misbranded as defined under clause (iv) of subsection (s) of section 3 of The Drugs Act 1976.**

iii. Proprietor of M/s Azam Medical Store at Main Bazar Adhi Kot, Tehsil Noor Pur Thal, District Khushab provided invoice/warranty bearing No. 40128 dated 06-02-2022 issued by M/s Kings Distributors, 10-A Link Club Road Sargodha who in-turn provided invoice/warranty bearing No. 246 dated 30-10-2021 issued by M/s Arfat Traders, Katchi Gali No. 2, Marriot Road, Karachi.

iv. Warrantor of M/s Arfat Traders, Katchi Gali No. 2, Marriot Road, Karachi finally provided invoice/warranty bearing No. AA072 dated 12-10-2020 issued by M/s Adamjee Pharmaceuticals (Pvt) Ltd., Plot No. 39, Sector 15, Korangi Industrial Area, Karachi-Pakistan.

v. Warrantor portion of drug sample was sent to M/s Kings Distributors, 10-A Link Club Road Sargodha.

vi. A copy of test/analysis report was sent to M/S Adamjee Pharmaceuticals (Pvt) Ltd., Plot No. 39, Sector 15, Korangi Industrial Area, 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:

i. **Manufacturing for Sale /Sale of Misbranded Drug**
ii. **Issuance of false warranty**

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

Reply of firm to show cause notice vide letter no. nil dated 31-10-2022

With reference to your letter dated 19-10-2022, ref No. PQCB/R-85/2022 regarding above said Misbranded drug, we are pleased to inform you that we have arranged both ''Al-Foil'' and ''Unit Carton'' on single specification which will be used in future batches.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 09-2020**
- **Expiry Date: 09-2023**
- **Sampling Date (Form 4): 07-03-2022**
- **Sent to DTL (Form 6): 08-03-2022**
- **Date of receipt in DTL: 12-03-2022**
- **DTL Report Date (Form 7): 20-04-2022**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 25-05-2022**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 13-08-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

PQCB R-253/2022

Jinnah Burn and Reconstructive Surgery Centre, AIMC, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan,** through its Managing Director Ch. Muhammad Israr Sharif 2. Ch. Muhammad Israr Sharif Managing Director 3. Maqsood ur Rehman Quality Control Incharge/Warrantor 4. Syed Faiz ul Haq Production Incharge of **M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan**

BRIEF FACTS OF THE CASE:

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

i. She, on 17-08-2022, 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.136937 dated: 17-08-2022, 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
Powder for Injection., Vancom 500mg [Vancomycin HCl USP EQ. to Vancomycin….500mg/Vial] **Mfg. date**: June-2022 **Exp. Date**; June-2024 **Regs. #** 088903	0040I036	M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan	01-177002475/DTL dated: 14-10-2022	**Result of test/ analysis with specifications applied: USP 2022** **Physical DESCRIPTION**: White Colored powder for injection in transparent glass vial having label pasted on it with rubber stopper, aluminum seal and purple colored flip off cover. **pH:** Range: 2.5-4.5 Determined 2.63 at 23.8°C **Microbial Assay of Vancomycin:** Stated 500mg/vial Determined 453.3mg/vial Percentage 90.66**%** Limit: 90-115% of the labeled amount **(Complies)** **Sterility Test:** The sample is sterile. **Endotoxin Test:** The sample complies the bacterial endotoxin test. **Labelling:** The product does not bear "Dosage and Instructions in Urdu" on label of its immediate container, i.e., Vial. Hence, misbranded as per The Drugs (Labelling and Packing) Rules, 1986, 3[h (ii, iii)]. **(Misbranded) (Does Not Comply)** **RESULT:** The sample is **Misbranded** as per The Drugs (Labelling and Packing) Rules, 1986, 3[h (ii, iii)].

iii. Store Keeper, Main Medicine Store of Jinnah Burn and Reconstructive Surgery Centre, AIMC, Lahore, provided invoice/warranty No. 6300000777 dated 11-08-2022 issued by M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.

iv. Warrantor Portion was sent M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.

v. Copy of test/analysis report was sent to M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, 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 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 31-10-2023.

Reply to Show Cause Notice:

1. That the correspondence (along with rectified labelling) between company and DI related to test / analysis report No. TRA/01 -177002475/ DTL, Dated: 14.10.2022 issued by Government Analyst Drug Testing Laboratory Lahore for the drug Powder for Injection., Vancom 500mg Batch No. 0040I036 may please be taken as an integral part of this reply this Show Cause Notice (S.C.N).

2. That Genix Pharma (Private) Limited was founded in the year 2004 with the vision to help and provide top quality and affordable medicine for all those in need. Since inception, Genix has grown from being a relatively humble contender to being one of the fastest growing companies in the Pakistani Pharmaceutical Arena. Having the best human capital, coupled with a state-of-the-art manufacturing facility spanning over 175,000 sq. feet and the prime focus on quality, the company aim to become the benchmark in the pharmaceutical industry. The product line ranges from specialty products to OTC medicines, as we believe in providing a wide range of products to cater to the needs of all types of requirements. The company is making an ever-increasing contribution to the export exchequer of Pakistan by exporting medicines to more than 10 countries including Afghanistan, Sri Lanka, Ivory Coast and African Countries. Genix is strongly committed to its responsibility towards community and patients. Genie's products bring a promise of QUALITY and ensure smooth and flawless operations at its facility with local manufacturing in compliance with global quality standards, which are strictly maintained and followed meticulously at every level in the process of manufacturing.

3. That Federal Government had laid down the criteria that advice should be issued in cases of misbranded drugs as such minor cases coming under remedial contraventions (No.F.6-15/ 2010- QC Dated 20.10.2010). Misbranding is minor contravention and protection provided for this type of cases under the Drugs Act 1976 because it is not related directly to effectiveness and safety of drug. Furthermore, cases of minor contravention are prescribed under Rule 5(5) of Punjab Drugs Rules 2007 framed under the Drugs Act 1976 whereby PQCB had declined permission for prosecution. That without prejudice" and keeping in view the Guideline of Federal Government, it is submitted that the minor labelling issues are not related to the quality, effectiveness, and safety of medicines. The labeling omission could easily be rectified without any impact on the quality and safety of the drug.

4. That without prejudice, by exercising its "option and right to remedify" provided under section 18-(1) (f) of the Drugs Act 1976, company has made improvement & rectification by taking remedial measure by printing Dosage abd instruction in urdu in the labelling of Injection Cilenem 500mg Batch No. 00801031. Updated artwork of Label, Unit Carton and undertaking as is attached as ready reference. The undertaking on Judicial paper that all batches from the date will be manufactured and marketed with updated rectified labelling with Urdu version of Dosage and Instruction.

5. Response on Para 1 SCN - No response on 1.i, 1.ii, 1.iii and 1.iv as proceedings were done without association of the company.

6. That the para 2. It is vehemently contested as company has not contravened any provision of the Drug Act 1976 / DRAP Act 2012 as evident from the following facts and law

i. The company has neither contravened section 23/27 of the Drug Act 1976 (as amended) nor the DRAP act 2012 and Rules framed thereunder. The case is based upon the Non-Conclusive Report of Government Analyst, as sufficient evidence in controversion to this report is available as per requirement of section 22(4) of the Drug Act 1976. 23/27 of the Drug Act 1976 is maliciously applied by omitting the specific sections. 23(1) (a-l-x, b-h, 10i-ii and (27-124 (27-2), (27-3) and (27-4). The Punjab Amendment in the Drug Act 1976 and DRAP Act 2012 not applicable simultaneously on this case because the Drug Act 1976 which is the part of Schedule VI of DRAP Act 2012 is different from the Drug Act 1976 with Punjab Amendment 2017/2018.

ii. The charge of Issuance of false warranty is based upon misreading of relevant law. The warranty was issued after release of standard quality report by Quality Control Department of the company. The offence of issuance of false warranty is added to enhance punishment with malafide intention. The application of the Section 27(2) dealing with false warranty is malice in law as well as malice in fact because good and sufficient reason were available as warranty was given after release of medicines by Quality Control Department of the Company. The section 27. (2). (b) is reproduced below

> **27 (2) whoever himself whoever himself or by any other person on his b(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**

7. That the **Para 3 of the SCN is responded**. The Section (11) of the Drugs Act, 1976 and Rules (5) of the Punjab Drug Rules 2007 (as amended) could not be invoked due following submission.

I. The company should not be prosecuted as has not committed any of the contravention[s] under the Drugs Act, 1976.

II. The licensing Authority / Drug Registration Authority should not be recommended for cancellation / suspension of your Drug Manufacturing / Sale License and Drug Registration as it would be against Section 11(5)(a) of the Drug Act 1976.

III The only appropriate and suitable legal action in this case is DROPPING without any adverse action.

8. "The company does not agree with all the names nominated by the Inspector who has acted mechanically while using long handle of Discretion in ascertaining name of Ch. **Muhammad Israr Sharif, Managing Director** as accused, in disrespect the section 11 & 34 of the Drugs Act 1976 and Rule 5 of the Punjab Drug Rules 2007. He is not directly related to the issues under consideration as all routine operations are done without his prior knowledge and consent. The specific persons are given full powers to ensure that all the operations and final finished products released for market are in accordance with prevailing regulatory requirements in accordance with Drugs Laws of Pakistan. No one including MD of the company ever has any advance Knowledge or Consent about their decision related to manufacture and sale within the legal framework of the section 34 of the Drugs Act 1976 or any rule framed thereunder. Additionally, the Honorable Supreme Court of Pakistan has settled the question of liability related to the company in a case reported as **PLD 1978** Supreme Court 193 (Superintendent of Police, Federal Investigation Agency, Lahore and another---Appellants Versus Akhtar Hussain Bhutta---Respondent). Therefore, it would be difficult to presume that the respondent was guilty of the manufacture of the said substandard drug for and on behalf of the Company, just because he happened to be its Managing Director. This submission is given by keeping in view the prevailing Drug law read with latest Policy Board guided DRAP-Guideline circulated by Drug. Regulatory Authority of Pakistan - Government of Pakistan Ministry of National Health Services, Regulations & Coordination Islamabad, vide No. F. 11-13/2022-LA Dated the 2nd December 2022 reproduced below as ready reference.

> Subject: OFFENCES BY COMPANIES UNDER THE DRAP ACT, 2012 AND THE DRUGS ACT, 1976.
>
> The Pakistan Pharmaceutical Manufacturers' Association (PPMA) has approached the Drug Regulatory Authority of Pakistan (DRAP) regarding implementation of the DRAP Act, 2012 and the Drugs Act, 1976 in a just and judicious manner in accordance with the following judgment of the Hon'ble Supreme Court of Pakistan reported as PLD 1978 SC 193:
>
> > Whether Managing Director is liable. Managing Director being assisted by various executives and workers, it is difficult to presume that respondent is guilty of manufacture of substandard drugs. Burden of proof lies on prosecution to prove offence having been committed within knowledge and consent of the Director."
>
> 2. Similarly, the Hon'ble Peshawar High Court in a recent judgment reported as PLD 2021 Peshawar 154, has held that:
>
> > "13. [...] true that under the provisions of section 34 of Drugs Act, 1976; if a person guilty of an offence under ibid Act is a company, corporation, or firm; then, every director, partner or officer of the said with whose or firm, company, corporation, knowledge and consent the offence is committed, shall be guilty of the offence. Albeit the ibid provision has placed emphasis upon the knowledge and consent of the director, partner, or officer of the said company, corporation, or firm, qua the offence which under the law shall be proved by the prosecution, [...]

3. Section 28 of the DRAP Act, 2012 deals with offences by companies etc. It stipulates that "where the person guilty of an offence under this Act or the Drugs Act, 1976 (XXXI of 1976) is a company, corporation, firm or institution, every director, partner and employee of the company, corporation, firm or institution with whose knowledge or consent the offence was committed shall be guilty of the offence." (emphasis added]

4 Noncompliance of the above referred provision with reference to unnecessary involving the director(s)/employee(s) who are not involved or who do not have knowledge or consent to the commission of the offence is adversely affecting the growth of the pharmaceutical industry, Therefore, DRAP Authority has directed to issue policy guidance under section 7(f) of the DRAP Act, 2012 that the name(s) of only those director(s), partner(s) and employee(s) of the company, corporation, firm or institution may be included in the prosecution whose knowledge or consent could be established through evidence under section 28 of the Drug Regulatory Authority of Pakistan Act, 2012 and section 34 of the Drugs Act, 1976.

(Aamar Latif)

Additional Director (Legal Affairs)

9. That, name of Mr. Maqsood Ur Rehman as Quality Control In-charge has been unlawfully included / ascertained for prosecution by Drug Inspector for the offences of Manufacturing / Sale of Substandard and issuance of False Warranty. Because manufacturing and Quality Control Department are Distinct and Independent. The definition of manufacture under section 3 of the Drugs Act 1976 is reproduced below as reference.

> 3(r) "manufacture" in relation to a drug, means all operations involved in the production of the drug, including processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labelling with a view to its storage, sale and distribution, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian and "to manufacture" shall be construed accordingly.

The rule 16 (e) of Drugs (Licensing, Registering and Advertising) Rules, 1976 dealing with Conditions for the grant or renewal of license to manufacture drugs by way of formulation reproduced below

> 16 (e) The Quality Control Department shall be independent of the manufacturing unit and its Incharge shall be whole time employee of the manufacturer and shall possess a degree in pharmacy, or a degree in science with chemistry or a degree in medicine or pharmacology (for pharmacological testing) or a degree in microbiology (for microbiological testing) and has sufficient experience in testing of drug.

In the light of above submissions, it is established beyond reasonable doubts that there is no contravention of the Drug Act 1976 or any Rules framed thereunder related to TRA/01 -177002475/ DTL, Dated: 14.10.2022 issued by Government Analyst Drug Testing Laboratory Lahore for the drug Injection Vancom 500mg Batch No. 0040I036. This case is not FIT FOR ISSUANCE OF SHOW CAUSE NOTICE as prescribed under the Section 11(5)(b) of the Drug Act 1976 read with Rule 5 of the Punjab Drug Rules 2007 .The case may please be forwarded to the Provincial Quality Control Board, Punjab, Lahore with the recommendation of dropping the Case on merit and in line with the PQCB Policy regarding MISBRANDED drug. Every citizen of Pakistan is entitled to be dealt in accordance with law and Due Process, without any discrimination, as per requirement of 1973 Constitution of Islamic Republic of Pakistan.

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

Case is placed before the Board for Decision.

Note: The subject drug sample has been manufactured (Mfg. date: June-2022) after the first warning issued to the same drug sample (Powder for Injection Vancom, Batch # 0131036, Mfg. date: June-2020) in 228th Meeting dated: 29-12-2020.

PROCEEDINGS & DECISION BY THE BOARD:

PQCB R-241/2022

Jinnah Burn and Reconstructive Surgery Centre, AIMC, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan,** through its Managing Director Ch. Muhammad Israr Sharif 2. Ch. Muhammad Israr Sharif — Managing Director 3. Maqsood ur Rehman — Quality Control Incharge/Warrantor 4. Syed Faiz ul Haq — Production Incharge of **M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan**

BRIEF FACTS OF THE CASE:

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

i. She, on 17-08-2022, 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.136927 dated: 17-08-2022, 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
Powder for Injection., Cilenem [Imipenem as monohydrate 500mg, Cilastatin as sodium 500mg] **Mfg. date**: June-2022 **Exp. Date**; June-2024 **Regs. #** 080602	0080I031	M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan	01-177002474/DTL dated: 05-10-2022	**Result of test/ analysis with specifications applied: USP 2022** **Physical DESCRIPTION**: White to off-white colored powder for injection in transparent glass vial having label pasted on it, with rubber stopper, aluminum seal and purplish pink flip off cover. **pH:** Range: 6.5-3.5 Determined 7.40 at 24.3ºC **Identification:** The retention time of the major peaks in the sample chromatogram corresponds to the retention time of the major peaks in standard chromatogram (Imipenem and Cilastatin Identified0 **Assay of Imipenem:** Stated 500mg/vial Determined 539.42mg/vial Percentage 107.88**%** Limit: 90-115% of the labeled amount **(Complies)** **Assay of Cilastatin:** Stated 500mg/vial Determined 552.05mg/vial Percentage 110.41% Limit: 90-115% of the labeled amount **(Complies)** **Sterility Test:** The sample is sterile. **Endotoxin Test:** The sample complies the endotoxin limit of NMT0.17EU/mg. **Labelling:** The product does not bear "Dosage and Instructions in Urdu" on label of its immediate container, i.e., Vial. Hence, misbranded as per The Drugs (Labelling and Packing) Rules, 1986, 3[h (ii, iii)]. **(Misbranded) (Does Not Comply)** **RESULT:** The sample is **Misbranded** as per The Drugs (Labelling and Packing) Rules, 1986, 3[h (ii, iii)].

iii. Store Keeper, Main Medicine Store of Jinnah Burn and Reconstructive Surgery Centre, AIMC, Lahore, provided invoice/warranty No. 6300000776 dated 11-08-2022 issued by M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.

iv. Warrantor Portion was sent M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.

v. Copy of test/analysis report was sent to M/S Genix Pharma Pvt Ltd., 44,45-B, Korangi Creek Road, Karachi-75190, 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 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 31-10-2023.

Reply to Show Cause Notice:

1. That the correspondence (along with rectified labelling) between company and DI related to test / analysis report No. TRA/01 -177002474/ DTL, Dated: 05.10.2022 issued by Government Analyst Drug Testing Laboratory Lahore for the drug Injection Cilenem 500mg Batch No. 00801031 may please be taken as an integral part of this reply this Show Cause Notice (S.C.N).

2. That Genix Pharma (Private) Limited was founded in the year 2004 with the vision to help and provide top quality and affordable medicine for all those in need. Since inception, Genix has grown from being a relatively humble contender to being one of the fastest growing companies in the Pakistani Pharmaceutical Arena. Having the best human capital, coupled with a state-of-the-art manufacturing facility spanning over 175,000 sq. feet and the prime focus on quality, the company aim to become the benchmark in the pharmaceutical industry. The product line ranges from specialty products to OTC medicines, as we believe in providing a wide range of products to cater to the needs of all types of requirements. The company is making an ever-increasing contribution to the export exchequer of Pakistan by exporting medicines to more than 10 countries including Afghanistan, Sri Lanka, Ivory Coast and African Countries. Genix is strongly committed to its responsibility towards community and patients. Genie's products bring a promise of QUALITY and ensure smooth and flawless operations at its facility with local manufacturing in compliance with global quality standards, which are strictly maintained and followed meticulously at every level in the process of manufacturing.

3. That Federal Government had laid down the criteria that advice should be issued in cases of misbranded drugs as such minor cases coming under remedial contraventions (No.F.6-15/ 2010- QC Dated 20.10.2010). Misbranding is minor contravention and protection provided for this type of cases under the Drugs Act 1976 because it is not related directly to effectiveness and safety of drug. Furthermore, cases of minor contravention are prescribed under Rule 5(5) of Punjab Drugs Rules 2007 framed under the Drugs Act 1976 whereby PQCB had declined permission for prosecution. That without prejudice" and keeping in view the Guideline of Federal Government, it is submitted that the minor labelling issues are not related to the quality, effectiveness, and safety of medicines. The labeling omission could easily be rectified without any impact on the quality and safety of the drug.

4. That without prejudice, by exercising its "option and right to remedify" provided under section 18-(1) (f) of the Drugs Act 1976, company has made improvement & rectification by taking remedial measure by printing Dosage abd instruction in urdu in the labelling of Injection Cilenem 500mg Batch No. 00801031. Updated artwork of Label, Unit Carton and undertaking as is attached as ready reference. The undertaking on Judicial paper that all batches from the date will be manufactured and marketed with updated rectified labelling with Urdu version of Dosage and Instruction.

5. Response on Para 1 SCN - No response on 1.i, 1.ii, 1.iii and 1.iv as proceedings were done without association of the company.

6. That the para 2. It is vehemently contested as company has not contravened any provision of the Drug Act 1976 / DRAP Act 2012 as evident from the following facts and law

i. The company has neither contravened section 23/27 of the Drug Act 1976 (as amended) nor the DRAP act 2012 and Rules framed thereunder. The case is based upon the Non-Conclusive Report of Government Analyst, as sufficient evidence in controversion to this report is available as per requirement of section 22(4) of the Drug Act 1976. 23/27 of the Drug Act 1976 is maliciously applied by omitting the specific sections. 23(1) (a-l-x, b-h, 10i-ii and (27-124 (27-2), (27-3) and (27-4). The Punjab Amendment in the Drug Act 1976 and DRAP Act 2012 not applicable simultaneously on this case because the Drug Act 1976 which is the part of Schedule VI of DRAP Act 2012 is different from the Drug Act 1976 with Punjab Amendment 2017/2018.

ii. The charge of Issuance of false warranty is based upon misreading of relevant law. The warranty was issued after release of standard quality report by Quality Control Department of the company. The offence of issuance of false warranty is added to enhance punishment with malafide intention. The application of the Section 27(2) dealing with false warranty is malice in law as well as malice in fact because good and sufficient reason were available as warranty was given after release of medicines by Quality Control Department of the Company. The section 27. (2). (b) is reproduced below

> **27 (2) whoever himself whoever himself or by any other person on his b(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**

7. That the Para 3 of the SCN is responded. The Section (11) of the Drugs Act, 1976 and Rules (5) of the Punjab Drug Rules 2007 (as amended) could not be invoked due following submission.

I. The company should not be prosecuted as has not committed any of the contravention[s] under the Drugs Act, 1976.

II. The licensing Authority / Drug Registration Authority should not be recommended for cancellation / suspension of your Drug Manufacturing / Sale License and Drug Registration as it would be against Section 11(5)(a) of the Drug Act 1976.

III The only appropriate and suitable legal action in this case is DROPPING without any adverse action.

8. "The company does not agree with all the names nominated by the Inspector who has acted mechanically while using long handle of Discretion in ascertaining name of Ch. Muhammad Israr Sharif, Managing Director as accused, in disrespect the section 11 & 34 of the Drugs Act 1976 and Rule 5 of the Punjab Drug Rules 2007. He is not directly related to the issues under consideration as all routine operations are done without his prior knowledge and consent. The specific persons are given full powers to ensure that all the operations and final finished products released for market are in accordance with prevailing regulatory requirements in accordance with Drugs Laws of Pakistan. No one including MD of the company ever has any advance Knowledge or Consent about their decision related to manufacture and sale within the legal framework of the section 34 of the Drugs Act 1976 or any rule framed thereunder. Additionally, the Honorable Supreme Court of Pakistan has settled the question of liability related to the company in a case reported as **PLD 1978** Supreme Court 193 (Superintendent of Police, Federal Investigation Agency, Lahore and another---Appellants Versus Akhtar Hussain Bhutta---Respondent). Therefore, it would be difficult to presume that the respondent was guilty of the manufacture of the said substandard drug for and on behalf of the Company, just because he happened to be its Managing Director. This submission is given by keeping in view the prevailing Drug law read with latest Policy Board guided DRAP-Guideline circulated by Drug. Regulatory Authority of Pakistan - Government of Pakistan Ministry of National Health Services, Regulations & Coordination Islamabad, vide No. F. 11-13/2022-LA Dated the 2nd December 2022 reproduced below as ready reference.

> Subject: OFFENCES BY COMPANIES UNDER THE DRAP ACT, 2012 AND THE DRUGS ACT, 1976.
>
> The Pakistan Pharmaceutical Manufacturers' Association (PPMA) has approached the Drug Regulatory Authority of Pakistan (DRAP) regarding implementation of the DRAP Act, 2012 and the Drugs Act, 1976 in a just and judicious manner in accordance with the following judgment of the Hon'ble Supreme Court of Pakistan reported as PLD 1978 SC 193:
>
> > Whether Managing Director is liable. Managing Director being assisted by various executives and workers, it is difficult to presume that respondent is guilty of manufacture of substandard drugs. Burden of proof lies on prosecution to prove offence having been committed within knowledge and consent of the Director."
>
> 2. Similarly, the Hon'ble Peshawar High Court in a recent judgment reported as PLD 2021 Peshawar 154, has held that:
>
> > "13. [...] true that under the provisions of section 34 of Drugs Act, 1976; if a person guilty of an offence under ibid Act is a company, corporation, or firm; then, every director, partner or officer of the said with whose or firm, company, corporation, knowledge and consent the offence is committed, shall be guilty of the offence. Albeit the ibid provision has placed emphasis upon the knowledge and consent of the director, partner, or officer of the said company, corporation, or firm, qua the offence which under the law shall be proved by the prosecution, [...]

3. Section 28 of the DRAP Act, 2012 deals with offences by companies etc. It stipulates that "where the person guilty of an offence under this Act or the Drugs Act, 1976 (XXXI of 1976) is a company, corporation, firm or institution, every director, partner and employee of the company, corporation, firm or institution with whose knowledge or consent the offence was committed shall be guilty of the offence." (emphasis added]

4 Noncompliance of the above referred provision with reference to unnecessary involving the director(s)/employee(s) who are not involved or who do not have knowledge or consent to the commission of the offence is adversely affecting the growth of the pharmaceutical industry, Therefore, DRAP Authority has directed to issue policy guidance under section 7(f) of the DRAP Act, 2012 that the name(s) of only those director(s), partner(s) and employee(s) of the company, corporation, firm or institution may be included in the prosecution whose knowledge or consent could be established through evidence under section 28 of the Drug Regulatory Authority of Pakistan Act, 2012 and section 34 of the Drugs Act, 1976.

(Aamar Latif)

Additional Director (Legal Affairs)

9. That, name of Mr. Maqsood Ur Rehman as Quality Control In-charge has been unlawfully included / ascertained for prosecution by Drug Inspector for the offences of Manufacturing / Sale of Substandard and issuance of False Warranty. Because manufacturing and Quality Control Department are Distinct and Independent. The definition of manufacture under section 3 of the Drugs Act 1976 is reproduced below as reference.

> 3(r) "manufacture" in relation to a drug, means all operations involved in the production of the drug, including processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labelling with a view to its storage, sale and distribution, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian and "to manufacture" shall be construed accordingly.

The rule 16 (e) of Drugs (Licensing, Registering and Advertising) Rules, 1976 dealing with Conditions for the grant or renewal of license to manufacture drugs by way of formulation reproduced below

> 16 (e) The Quality Control Department shall be independent of the manufacturing unit and its Incharge shall be whole time employee of the manufacturer and shall possess a degree in pharmacy, or a degree in science with chemistry or a degree in medicine or pharmacology (for pharmacological testing) or a degree in microbiology (for microbiological testing) and has sufficient experience in testing of drug.

In the light of above submissions, it is established beyond reasonable doubts that there is no contravention of the Drug Act 1976 or any Rules framed thereunder related to TRA/01 - 77002474/ DTL, dated: 05.10.2022 issued by Government Analyst Drug Testing Laboratory Lahore for the drug Injection Cilenem 500mg Batch No. 00801031. This case is not FIT FOR ISSUANCE OF SHOW CAUSE NOTICE as prescribed under the Section 11(5)(b) of the Drug Act 1976 read with Rule 5 of the Punjab Drug Rules 2007 .The case may please be forwarded to the Provincial Quality Control Board, Punjab, Lahore with the recommendation of dropping the Case on merit and in line with the PQCB Policy regarding MISBRANDED drug. Every citizen of Pakistan is entitled to be dealt in accordance with law and Due Process, without any discrimination, as per requirement of 1973 Constitution of Islamic Republic of Pakistan.

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

Case is placed before the Board for Decision.

Note: The subject drug sample has been manufactured (Mfg. date: June-2022) after the first warning issued to the same drug sample (Powder for Injection Cilinem, Batch # 053I031) in 232nd Meeting dated: 24-06-2021

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 65

PQCB/R-257,258/2022

Central Medical Store Depot Pessi, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan** through its Managing Director Pervaiz Hussain Sufi 2. Pervaiz Hussain Sufi — Managing Director 3. Faiz Ahmad Chishti — Production Manager 4. Imran Saddiqi — Quality Control Manager 5. Ameer Hassan — Warrantor of M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Central Medical Store Depot, Pessi reported that: -

i. He, on 27-09-2022 inspected the Central Medical Store Depot, Pessi, Lahore, took 4 different drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 142081 & 142082 dated 27-09-2022.

ii. Following drug samples, after test/analysis was declared as **Misbranded** 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	Suspension Ringacip [Ciprofloxacin (as HCl) 125mg/5ml, 60ml approx.] **Mfg**. **Date**: 09-2022 **Exp**. **Date**: 09-2024 **Regn**. **No**: 074466	22RG008	M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan	01-10097000329/DTL dated: 21-11-2022	**Result of test/ analysis with specifications applied: USP** 2022 **COMPOSITION:** Each 5ml of reconstituted suspension contains: Ciprofloxacin (as HCl)……..…125mg **DESCRIPTION**: White to off white color powder in amber color sealed labeled glass bottle which upon reconstitution gives yellow color suspension. Packed in outer hard carton. **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 "**Product Specification**: **Moringa's Spec**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "Ciprofloxacin for oral suspension" 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** **IDENTIFICATION (USP):** Ciprofloxacin is identified **ASSAY (USP): Cipofloxacin** Stated: 125mg/5ml Determined: 129.57mg/5ml Percentage: 103.65% Limit: 90-110% **RESULT:** The sample is declared **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.

2	Suspension Ringacip [Ciprofloxacin (as HCl) 250mg/5ml, 60ml approx after reconstitution] **Mfg**. **Date**: 09-2022 **Exp**. **Date**: 09-2024 **Regn**. **No**: 074467	22RA005	M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan.	01-10097000330/DTL dated: 21-11-2022	**Result of test/ analysis with specifications applied: USP 2022** **COMPOSITION:** Each 5ml of reconstituted suspension contains: Ciprofloxacin (as HCl)……..….250mg **DESCRIPTION**: White to off white color powder in amber color sealed labeled glass bottle which upon reconstitution gives yellow color suspension. Packed in outer hard carton. **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 "**Product Specification**: **Moringa's Spec**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "Ciprofloxacin for oral suspension" 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** **IDENTIFICATION (USP):** Ciprofloxacin is identified **ASSAY (USP): Ciprofloxacin** Stated: 250mg/5ml Determined: 259.16mg/5ml Percentage: 103.66% Limit: 90-110% **RESULT:** The sample is declared **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. CMSD, Pessi, provided invoice/ warranty No. 0144/09/22 dated 24-09-2022 issued by M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan.

iv. Warrantor Portions of subject drug samples were sent to M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan.

v. Copies of Test/ Analysis report were sent to M/s Moringa Pharmaceuticals Pvt Ltd., 35-A 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 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 Drugs**
ii. **Issuance of false warranty.**

3. Show-cause notice(s) issued to the accused dated 04-01-2023

Firm submitted reply of Show cause vide letter no. Doc#MoR-101-23 dated 25-01-2023

With reference to your letter No. PQCB/R-257 & 258/2022 stated that our product Suspension Ringacip 125mg/5ml, 60ml approx. Batch # 22RG008, Mfg. Date: 09-2022, Exp. Date: 09-2024. And Suspension Ringacip 250mg/5ml, 60ml approx. Batch # 22RA005, Mfg. Date:09-2022, Exp. Date:09-2024 declared Misbranded from Drug Testing Laboratory Bahawalpur.

It is Stated That We are Manufacturing this Product as per DRAP Registration Letter. We are manufacturing this product as per standards of BP 2022 which DTL Bahawalpur Report proved that as all the standards complies and tells us that our product is of standard quality as per BP 2022 but **unfortunately, we cannot mention the same on our product**.

Furthermore sir, we are thankful to PQCB and DTL to notify this matter. We are aware though this matter does not affect the patient Health it is necessary to get our registration Letter amended as per requirement DRAP Order No. F3-5/2020-1 & V-II (M-297). We have taken quick steps and updated ail products Monographs as per Latest Edition of Pharmacopoeias (Where applicable). You are therefore requested to conclude the issue since we have already taken the necessary measures to rectify points indicated in your letter no. PQCB/R-257 & 258/2022.

We assure you that we shall remain vigilant and not repeat the same again. We shall be very thankful to you for this act of kindness.

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD

PQCB/R-256/2022

Central Medical Store Depot Pessi, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan** through its Managing Director Pervaiz Hussain Sufi 2. Pervaiz Hussain Sufi Managing Director 3. Faiz Ahmad Chishti Production Manager 4. Imran Saddiqi Quality Control Manager 5. Ameer Hassan Warrantor of M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Central Medical Store Depot, Pessi reported that: -

i. He, on 27-09-2022 inspected the Central Medical Store Depot, Pessi, Lahore, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 142073 dated 27-09-2022.
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</th><th>DTL Test Report Result</th></tr>
<tr><td>Casule Amphozole [Fluconazole 150mg]]
Mfg. Date:
09-2022
Exp. Date:
09-2024
Regn. No: 074459</td><td>22AM003</td><td>M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan.</td><td>01-10097000337/DTL dated: 16-11-2022</td><td>
Result of test/ analysis with specifications applied BP 2022
<u>COMPOSITION:</u> Each capsule contains:
Fluconazole……..…150mg
<u>DESCRIPTION</u>: White to off white crystalline powder in dark pink pink body of hard gelatin capsule shell. Packed in a Alu-Alu bl packing) of 01 capsule. The capsule blister is packed in outer hard packing).
Note: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated states that “All registration holders shall follow official pharmaco for all such formulation for which official monograph of drug p in the most recent edition of such pharmacopoeia”. Product spe sample is “Product Specification: Moringa’s Spec.” and it is mar expiration of timeline to apply such specifications despite the availab capsule” monograph in BP 2022. So, the manufacturer’s claim reg specification is in contradiction to DRAP circular and also in vio 1976.Therefore, The product is Misbranded
<u>Wt. VARIATION (BP):</u> Limit: ±7.5%
Determined: 92.21-107.3%
<u>DISSOLUTION TEST (BP</u>)
Tolerance Limit: Not less than 75% (Q) Fluconazole in 45 mins
<table>
<tr><th>Units</th><th colspan="6">ACCEPTANCE CRITERIA</th></tr>
<tr><td>06</td><td colspan="6">Each unit is not less than 75% (Q) Fluconazole in 45 n</td></tr>
<tr><td></td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td></td></tr>
<tr><td>Fluconazole</td><td>113.29%</td><td>115.71%</td><td>114.80%</td><td>106.95%</td><td>104.23%</td><td></td></tr>
</table>
<u>IDENTIFICATION (BP):</u> Fluconazole is identified
<u>ASSAY (BP): Fluconazole</u>
Stated: 150mg/cap
Determined: 145.39mg/cap
Percentage: 96.93%
Limit: 95-105%
<u>RESULT:</u> The sample is declared Misbranded as per Section 3 (1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-2 dated 7th February, 2022.
</td></tr>
</table>

iii. CMSD, Pessi, provided invoice/ warranty No. 0144/09/22 dated 24-09-2022 issued by M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan.

iv. Warrantor Portion was sent to M/s Moringa Pharmaceuticals Pvt Ltd., 35-A Sundar Industrial Estate Raiwind Road, Lahore Pakistan.

v. A copy of Test/ Analysis report was also sent to M/s Moringa Pharmaceuticals Pvt Ltd., 35-A 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 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 04-01-2023

Firm submitted reply of Show cause vide letter no. Doc#MoR-102-23 dated 25-01-2023

With reference to your letter No. PQCB/R-256/2022 stated that our product cap Amphozole 150mg Batch # 22AM003 Mfg. Date: 09-2022, Exp. Date: 09-2024 declared Misbranded from Drug Testing Laboratory Bahawalpur.

It is Stated That We are Manufacturing this Product as per DRAP Registration Letter. We are manufacturing this product as per standards of BP 2022 which DTL Bahawalpur Report proved that as all the standards complies and tells us that our product is of standard quality as per BP 2022 but **unfortunately, we cannot mention the same on our product**.

Furthermore sir, we are thankful to PQCB and DTL to notify this matter. We are aware though this matter does not affect the patient Health it is necessary to get our registration Letter amended as per requirement DRAP Order No. F3-5/2020-1 & V-II (M-297). We have already taken quick steps and updated all products Monographs as per Latest Edition of Pharmacopoeias (Where applicable) and applied for change in specifications to DRAP where Required.

You are therefore requested to conclude the issue since we have already taken the necessary measures to rectify points indicated in your letter no. PQCB/R-256/2022.

We assure you that we shall remain vigilant and not repeat the same again.

4**.** Personal Hearing notice(s) issued to accused person(s) 29-03-2023

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD

Case No. 66

PQCB/R-259/2022

Central Medical Store Depot Pessi, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan** through its Director/Proprietor Salman Anwar Malik 2. Salman Anwar Malik — Director/Proprietor 3. Safder Ali Bhatti — Production Manager 4. Muhammad Fiaz — Quality Control Manager 5. Shahid Mashhood — Warrantor of M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Central Medical Store Depot, Pessi reported that: -

i. He, on 05-10-2022 inspected the Central Medical Store Depot, Pessi, Lahore, took 14 different drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 143424 dated 05-10-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Film coated Tablet Tenovir 300mg [Tenofovir disoproxil Fumarate 300mg] **Mfg. Date**: 09-2022 **Exp. Date**: 08-2024 **Regn. No**: 065743	QJ20	M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan	01-10097000531/DTL dated: 30-11-2022	**Result of test/ analysis with specifications applied: I**P 2020 **COMPOSITION:** Each film coated tablet contains: Tenofovir Disoproxil Fumarate (MS)…….300mg **DESCRIPTION**: Sea green color biconvex tablet, which is plain on both sides. packed in Alu-Alu blister pack (primary packing) of 10 tablets. three blisters are packed in outer hard carton. (Secondary Packaging) **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 "**Product specification**: **CCL pharmaceuticals specification.**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "**Tenofovir Disoproxil Fumarate tablets** (Tenofoviri disoproxili Fumerati compressi)" monograph in ***International Pharmacopoeia, Tenth Edition 2020***. 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** **Wt. VARIATION (IP): Limit**: Avg. weight ± 5% **Determined**: 97.27-102.96% **DISSOLUTION TEST (IP)**: Tolerance limit: NLT 80% release of Tenofovir disproxil Fumarate in 45 mins.

ACCEPTANCE CRITERIA						Avg
Each unit is not less than 80% (Q) Tenofovir disproxil Fumarate in 45 mins						
1	2	3	4	5	6	
97.26%	99.42%	107.65%	107.51%	102.51%	99.82%	100.70%

IDENTIFICATION (IP): Tenofovir disproxil Fumerate is identified

ASSAY (IP): Tenofovir disproxi Fumarate

Stated: 300mg/tab

Determined: 323.13mg/tab

Percentage: 107.71%

Limit: 90-110%

RESULT: The sample is declared **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. CMSD, Pessi, provided invoice/ warranty No. 22091703 dated 30-09-2022 issued by M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan.

iv. Warrantor Portion of subject drug sample was sent to M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan dated 10-10-2022.

v. A Copy of Test/ Analysis report was sent to M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore 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 Misbranded Drug.**
ii. **Issuance of false warranty.**

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

Firm submitted reply of Show cause vide letter ref no. CCL/23/R-244 dated 17-02-2023

Please refer to your letter no. PQCB/R-259/2022 dated 8h February 2023 on the captioned subject wherein DTL Bahawalpur report declares Tenovir tab 300mg batch no. QJ20 as MISBRANDED on account of Pharmacopeial specs as not mentioned on the product pack, however, the said product COMPLIES with the quality parameters in terms of Dissolution tests, identification and Assay, as specified in USP 2022.

1. Reference to the letter, point 3. It is humbly submitted that:

The DTL has tested the product against USP 2022 and the product complies, the packaging component alignment w.r.t. Pharmacopeia, Drug labelling Rules 1986 and DRAP order No. F.3-5/2020-I & V.I (M-297) of 7th Feb 2022 ***has already been established in CCL whose synchronization with CCL's export orders is very critical, CCL being the 2nd largest exporter of drug products from Pakistan with its footprint in 22 countries.***

We solicit that this sequential completion/implementation of product art work in local and international Regulatory perspectives will soon be completed, a humble review in this regard may please be considered by the competent authority and oblige as the product is entirely satisfactory as per USP standards tested by DTL Bahawalpur. we hereby verify the names of person nominated in showcause notice.

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-270/2022

Central Medical Store Depot Pessi, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan** through its Director/Proprietor Salman Anwar Malik 2. Salman Anwar Malik — Director/Proprietor 3. Safder Ali Bhatti — Production Manager 4. Muhammad Fiaz — Quality Control Manager 5. Shahid Mashhood — Warrantor of M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Central Medical Store Depot, Pessi reported that: -

i. He, on 05-10-2022 inspected the Central Medical Store Depot, Pessi, Lahore, took 14 different drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 143423 dated 05-10-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Film coated Tablet Tacavir 0.5mg [Entecavir 0.5mg] **Mfg**. **Date**: 08-2022 **Exp**. **Date**: 07-2024 **Regn**. **No**: 055321	J178	M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan	01-10097000532/DTL dated: 03-12-2022	**Result of test/ analysis with specifications applied: US**P 2022 **COMPOSITION:** Each film coated tablet contains: Entecavir monohydrate eq. to Entecavir …….0.5mg **DESCRIPTION**: Ligh pink color, round, biconvex film coated tablets, which is plain on both sides. packed in Alu-Alu blister pack (primary packing) of 10 tablets. three blisters are packed in outer hard carton. (Secondary packaging). **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 "**Product Spec.: CCL pharmaceuticals**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "**Entecavir tablets**" 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, t**he product is Misbranded** **DISSOLUTION TEST (USP)**: Tolerance limit: NLT 80% release of Entecavir in 30 mins.

ACCEPTANCE CRITERIA						Avg
Each unit is not less than 80% (Q) Entecavir in 30 mins						
1	2	3	4	5	6	
94.69%	95.05%	96.66%	96.49%	96.49%	96.592%	95.99%

IDENTIFICATION (USP): Entecavir is identified

ASSAY (USP): Entecavir

Stated: 0.5mg/tab

Determined: 0.46875mg/tab

Percentage: 93.75%

Limit: 90-105%

RESULT: The sample is declared **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. CMSD, Pessi, provided invoice/ warranty No. 22091703 dated 30-09-2022 issued by M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan.

iv. Warrantor Portion of subject drug sample was sent to M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan.

v. A Copy of Test/ Analysis report was sent to M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore 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 Misbranded Drug.**
ii. **Issuance of false warranty.**

3. Showcause notice(s) issued to the accused dated 20-01-2023

Firm submitted reply of Show cause notice vide ref: CCL/23/R-213 dated 25-01-2023

Please refer to your letter no. PQCB/R-270/2022 dated 20th January, 2023 on the captioned subject wherein DTL Bahawalpur report declares TACAVIR tab 0.5mg batch no. J178 as MISBRANDED on account of Pharmacopeial specs as not mentioned on the product pack, however, the said product COMPLIES with the quality parameters in terms of Dissolution tests, identification and Assay, as specified in USP 2022.

1. Reference to the letter, point 3. It is humbly submitted that:

The DTL has tested the product against USP 2022 and the product complies, the packaging component alignment w.r.t. Pharmacopeia, Drug labelling Rules 1986 and DRAP order No. F.3-5/2020-I & V.I (M-297) of 7h Feb 2022 **has already been established in CCL whose synchronization with CCL's export orders is very critical, CCL being the 2nd largest exporter of drug products from Pakistan with its footprint in 22 countries**. We solicit that this sequential completion/implementation of product art work in local and international Regulatory perspectives will soon be completed, a humble review in this regard may please be considered by the competent authority and oblige as the product is entirely satisfactory as per USP standards tested by DTL Bahawalpur.

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD;

Case No. 67

PQCB/R-547/2020

Services Hospital, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Searle IV solutions Pvt Ltd., 1.5km Manga Raiwind Road, Manga Mandi, District Lahore-Pakistan,** through its Chief Executive Yasir Usman. 2. Yasir Usman — Chief Executive 3. Khawaja Asad Aslam — Production Incharge 4. Zia ul Haq — Quality Control Manager 5. Abdul Rasheed — Warrantor (as per warranty) Of M/s Searle IV solutions Pvt Ltd., 1.5km Manga Raiwind Road, Manga Mandi, District Lahore-Pakistan.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Services Hospital, Lahore reported that:

i. Her predecessor, on 20-08-2020, inspected the Main medicine store of Services Hospital, Lahore and took drug sample 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 **Lahore**, as detailed below:

Name of drug	Batch no.	Name of Manufacturer	DTL Report TRA No. & Date
Suspension cyzit (dry powder for suspension) [Azithyromycin (as dihydrate) …200mg/5ml]	20E023	M/S Searle IV solutions Pvt Ltd., 1.5km Manga Raiwind Road, Manga Mandi, District Lahore	TRA No. 01-149001608/DTL dated: 19-10-2020

Specifications Applied: USP 2019

DETAIL RESULT OF TEST/ANALYSIS:

PHYSICAL DESCRIPTION: White to off white powder in amber glass bottle with a sealed metal screw cap and a stopper upon reconstitution with water formed a uniform suspension.

LABELING: **The label of the product (both inner and outer carton) does not bear "Maximum retail price". (Misbranded)**

IDENTIFICATION: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (AZITHROMYCIN IDENTIFIED.)

ASSAY OF AZITHROMYCIN:

Stated: 200mg/5ml

Determined: **166.6mg/5ml**

Percentage: 83.3% (**Does not Comply**)

Limit: 90-110%

RESULT: The sample is **Substandard** on the basis of Assay performed as per USP and **Misbranded**, as per The Drugs (Labelling And Packing) Rules, 1986 [3 (i)].

iii. Store keeper Main Medicine store, Services Hospital, Lahore, provided Invoice/Warranty No. 3590-PHR-6-20 dated 30-06-2020 issued by M/S Searle IV solutions Pvt Ltd., 1.5km Manga Raiwind Road, Manga Mandi, District Lahore-Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Searle IV solutions Pvt Ltd., 1.5km Manga Raiwind Road, Manga Mandi, District Lahore -Pakistan.

v. A copy of test/analysis report was sent to M/S Searle IV solutions Pvt Ltd., 1.5km Manga Raiwind Road, Manga Mandi, District Lahore-Pakistan with directions to explain their position and provide requisite information in this regard.

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

i. **Manufacturing/stocking/selling of Substandard & Misbranded drug**
ii. **Issuance of false invoice/warranty**

Summary:

Manufacturing Date: 05-2020

Expiry Date: 04-2022

Sampling Date: 20-08-2020

Form 6 date: 22-08-2020

Date of Receipt in DTL: 25-08-2020

DTL Report Date: 19-10-2020

1ST DI Communication with firm on dated: 12-12-2020

Date of Retesting Request of Firm: No (but in response to show cause notice)

Investigation Report Dated: 04-08-2021

3. Showcause notice issued to accused person(s)

Firm's Reply Of showcause Notice:

We further inform you that we have performed the entire test etc. of our keeping samples of Batch #20E023 and found the accurate so that **we challenge this report/Result to NIH, Laboratory, Islamabad.**

That above letter is based upon the alleged recovery and seizure of a single Unit out of substandard Cyzit 200mg Dry Suspension, 15ml, manufactured by Ms Searle IV Solutions (Pvt.) Ltd. Lahore by the Drug Inspector, Services Hospital, Lahore from the Main Medical Store of the hospital. and the Drug Testing Laboratory Punjab, issued the Analysis Report.

The following submissions are made as an INTERIM REPLY

1. That Searle Iv Solutions (Pvt.) Ltd. 1.5km Manga Raiwind Road Manga Mandi Dist. Lahore is a Company established with a vision to deliver the goods to the society by producing high quality healthcare products at affordable prices so that the basic human right to be treated can be guarded. The company is one of well reputed, well equipped & leading pharmaceutical guarded. companies of Pakistan, best known for its quality products and lifesaving/ essential drugs available & used with trust in domestic as well as international markets. The company works globally, within the legal framework of the all applicable and rules framed thereunder. Its firm Commitment to Quality and adherence to high standards cGMP guideline is vital to meet the high expectations of patients as well as health care providers. The products bring a promise of QUALITY, and ensure smooth and flawless operations at its facility with local manufacturing in Compliance with global quality standards which are strict/y maintained and followed meticulously at every level in the process of manufacturing trough the latest European Technology for the manufacturing of huge range of pharmaceutical products, Suspension, Tablets, Capsules, Injections, Intravenous Infusion & other pharmaceutical products.

2.That the company has taken upon an ambitious venture to manufacture lifesaving drugs including Suspension Cyzit 200mg 15ml by employing a highly sophisticated production process; the Technology imported from Europe. This manufacturing facility has the capacity of manufacturing more than 260,000 bottle per month. Quality Assurance comes first, a fact evident through our highly sophisticated and fully integrated production process, where in one continuous operation the container is blown, formed, filled with the powder and sealed. The entire process takes place in a completely sterile environment within the machine, untouched by human hands which eliminates any risk of contamination. The Quanty Control laboratory at the plant ensures intensive quality control checks at all the stages of production process, There ls no likelihood of any entry of any foreign body in any suspension manufactured by Searle Iv Solutions (pvt.) Ltd. 1.5km Manga Raiwind Road Manga Mandi Dist. Lahore.

3. That the "A COMMUNI OBSERVANTIA NON EST RECEDENDUM" is a well cited maxim applicable to all proceeding under the Drugs Act 19/6 and Rules Framed thereunder, where a thing is provided to be done in a particular manner, It has to be done in that manner, and if not so done, the same would not be lawful. It is mandatory provisions prescribed under sections 11, 18, 19, 22 & 32. It is regretted that the special procedure.

4.That company has great respect with highest possible level of compliance for all the prevailing law regulating Pharmaceutical Industry and has always worked within the legal framework of the DRAP Act 2012, The Drug Act 1976 and Rules framed thereunder in order to ensure delivery of high quality effective and safe drugs to the patients. Regulatory advices related to uplifting quality and safety of medicines are always welcome with l00% intention to compliance

5. In the light of above evidence, it is crystal clear that the above report of Government Analyst, DTL, are unlawful and NOT CONCLUSIVE now. **The PQCB's portions of the samples may please be sent to Appellate Laboratory, NIH, Islamabad, in Punjab for appropriate Retesting by applying manufacturer's approved method of analysis. Please note the company is grievances against the matter.**

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

Case is placed before the Board for Decision

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 **234th meeting** held on **28-10-2021.** Mr. Hassan Saeed Secretary DQCB, Lahore was present along with original case record. Among the nominated accused persons Yasir Usman (CEO), Zia ul Haq (Quality Control Manager) along with of Subh-e-Nasib (Advoacte High Court) **of M/s Searle IV solutions Pvt Ltd., 1.5km Manga Raiwind Road, Manga Mandi, District Lahore-Pakistan** appeared before the Board**.**

6. Counsel person stated that as per report of Govt Analyst, that the product is misbranded as the label of the product (both inner and outer carton) does not bear "Maximum retail price". The firm rectified the label of said drug and start mentioning maximum retail price on label. The sample was also declared substandard on the basis of Assay percentage 83.3% i.e., less than 90% and requested retesting of the sample. Counsel person stated that the Govt Analyst applied specifications of USP 2019 instead of USP 2020. The firm stated that dry powder for suspension was reconstituted by adding 7.5ml freshly boiled and cooled water with the help of enclosed plastic measure and shake the bottle.

7. Government Analyst apprised the Board that assay of the subject drug sample was found to be 83.3% when using measuring cups provided by firm. Sample was prepared by reconstituting the powder for suspension in replicate manner. Measuring cups available in outer carton for reconstitution were verified for their graduation volume and it was revealed that there is significant variation in volume of cups provided by the firm. The results of volume of measuring cups were found to be 7.7ml, 7.9ml, 8.2ml and 8.3ml respectively.

8. The Board, after detailed scrutiny of the case record and statement of the accused person observed that firm requested for retesting in reply of show cause issued to firm, so the subject retesting request was time barred. Moreover, USP 2020 was officially available after 6months of publication and at the time of test/analysis by the DTL, the most recent edition available was USP 2019. So, the stance of the firm regarding specification applied is baseless.

9. In view of the forgoing facts the Board was of the view that in order to dig out the root cause of this defect the Production and Quality Control & Assurance for subject drug need to be evaluated. Therefore, the Board decided to **pend** the case and constituted a committee comprising of the followings members in order to conduct Product Specific Inspection (PSI) of **M/s Searle IV solutions Pvt Ltd., 1.5km Manga Raiwind Road, Manga Mandi, District Lahore-Pakistan** and submit report for consideration by the Board:

1.	**Prof Dr. Mehmood Ahmad** Member PQCB	Convenor
2.	**Mr. Muhammad Umair Chaudhary** Provincial Quality Control Board, Punjab	Facilitator

10. Committee submitted PSI report of M/s Searle IV solution Pvt Ltd., Manga Raiwind Road, Lahore

PRODUCT SPECIFIC INSPECTION REPORT OF M/S SEARLE IV SOLUTIONS (Pvt.) Ltd. 1.5 Km MANGA RAIWIND ROAD, MANGA MANDI, DISTRICT, LAHORE-PAKISTAN.

Members of inspection committee:

Prof. Dr. Mahmood Ahmad	**(Member PQCB)**	**(Convener)**
Muhammad Umair Choudhary	**Scrutiny Officer, PQCB**	**(Facilitator)**

Date of Inspection:

Inspection was conducted on 28-09-2022 with reference to PQCB order No. PQCB/R-547/2020 dated 28-10-2021.

No. PQCB/R-5472020

Details of Test/Analysis by the DTL:

The sample CYZIT (DRY POWDER FOR SUSPENSION) is a suspension containing (AZITHROMYCIN AS DIHYDRATE……. 200mg/5ml) Batch No. 20E023. The sample was declared Substandard by the Drug testing laboratory, Lahore on the basis of Assay performed as per USP & Misbranded as per THE DRUGS (Labelling & Packaging) Rules, 1986 [3(i)] test performed under TRA No.01-149001608/ DTL dated 19-10-2020.

The tested sample does not comply the stated limit of acceptance criteria for AZITHROMYCIN, wherein the stated limit was 200mg/5ml and the determined limit was **166.6 mg/5ml**, which accounts to the percentage of **83.3%,** whereas, the stated percentage was **90.0-110.0%** of the labelled amount.

Whereas, the label of the product both (inner & outer carton) does not bear the Maximum retail price, which according to the labelling & packing rules 3(i) 1986 was declared Misbranded.

Premises Detail:

The manufacturing unit was established in 2005. Total area of the premises is 200,000 sq. ft with covered area of about 57805sq. ft. The firm has approved GMP certification on 24-03-2021 and valid for 2 years.

Current Technical Staff:

Designation	**Name**
Chief Executive	Yasir Usman
Manager Quality Control	Zia ul Haq
In-charge Production	Khawaja Asad Aslam
Director Regulatory Affairs	Khalid Munir

Detail of Product:

Letter No.	**PQCB/R-547/2020**
Name of Product	**Suspension CYZIT 200mg/50ml**
Batch No.	**20E023**
Date of Mfg.	05-2020
Exp. Date	04-2022
Sample Taken by	Inspector of Drugs Services Hospital, Lahore.
Sampling Date	20-08-2020
Date of Memorandum to Government Analyst	22-08-2020
Date of Report of Government Analyst	19-10-2020

Detail of Inspection / Observations:

1. During the Product Specific inspection, the members of inspection team has discussed the report of Drug testing laboratory with the technical team of the firm. The technical team presented the drug registration certificate of the dry powder suspension CYZIT 200mg/50ml having DRAP registration **080665** which showed the drug manufacturing & testing specifications as of Manufacturer specifications.

2. The technical team presented the Standard Operating Procedures for CYZIT (Dry Powder) Suspension (200mg/50ml) vide Doc. No. QAD/III/0044, issued date: 24-12-2021 & Effective date: 26-12-2021, of the Quality Control Department which depicted the Vendor Evaluation of the Raw Material & Packaging Material, Quality & On-Site Audit Report, In-process Controls Program, Supplier Evaluation Form & Packaging Material Certificate, followed for the manufacturing of the above said batch of Suspension CYZIT (200mg/50ml). The specifications showed the following parameters:

Sr. No.	Parameters	Reference	Specifications
1	Description	USP	White to off white powder White to off white suspension after reconstitution.
2.	pH	USP	9.93
3.	Identification	USP	Positive
4.	Test of leakage	USP	Complies
5	Assay Azithromycin	USP	95-110% of the label Claim
6	Composition	USP	Each 5ml volume of the syrup contain: Azithromycin (as dihydrate) ……200mg. (Product complies with U.S.P Specifications)
7	Drug Registration Number	Reg. letter	080665
8	Manufacturing License Number	Reg. letter	000586
9	Batch No., Mfg. Date, Exp. Date		20E023, May-2020, Apr- 2022
10.	Batch Size		1,000 Bottles
11.	Commercial Packing		Dry powder for 15 ml suspension

3. **Acceptance criteria for Suspension Azithromycin as Dihydrate (USP)**

   The requirements are met if the Assay of Azithromycin falls within the limit prescribed by the United States Pharmacopeia;

   Stated = 200mg/5ml

   Limit = 90.0 – 110% of the labelled amount

4. **Certificate of Analysis of the Finished Product**:

   The certificate of analysis of the finished product for suspension CYZIT has shown the Doc# QCF-4-01, Batch Number 20E023 (Batch size of 1,000 Bottles) performed on 19-06-2020 according to USP specifications. The parameters tested includes pH, Test of leakage, Deliverable Volume after reconstitution, Identification & Assay and Printing material specifications.

5. The reconciliation sheet of the Batch Manufacturing Record showed the Batch Yield Calculation well within acceptable percent yield of **95%**.
6. The request for analysis report No. QC/5/03 dated 16-05-2020 showed result of the Assay which falls well within the acceptable limit of **96.04%.**

OBSERVATIONS BY THE INSPECTION COMMITTEE:

A: Specific Observations

While carefully analysing the report of Analyst of the Drug testing Laboratory, Lahore, it was found that the embossed measuring cups provided by the manufacturer with every individual bottle have various graduations on it ranging from 2.5ml, 5ml, 7.5ml & 10ml, respectively.

For preparing the syrup, reconstitution of dry powder with 7.5 ml of water is required to be poured in the bottle.

Four different measuring cups were taken and 7.5 ml of water was poured in each cup but the final volume of all the four cups were different ranging as:

1. Cup no. 1 = 7.7 ml
2. Cup no. 2 = 8.2 ml
3. Cup no. 3 = 7.9 ml
4. Cup no. 4 = 8.3 ml

This variation in the deliverable volume for making the reconstitution of dry powder could definitely have the impact on the final volume and thereby determining the limit of Assay of active ingredient which fell to **83.3%** whereas the acceptable limit is 95.0—110.0%.

With respect to the product being declared as Misbranded due to MRP missing on both the inner & outer carton. The technical team of the firm has accepted their mistake and explained the committee that the batch was made for Govt. supply so the MRP was missed while printing the label.

B**: General Observations**

Raw Material Store:

- Raw material store was found properly cleaned. The demarcation for passed & rejected material was also labelled appropriately.
- Temperature of the area was 25.4 degrees and log book were maintained.
- Standard Operating Procedures were properly laid down with the help of flow chart.
- Material receiving area was found serviceable for performing De-dusting etc..
- Raw-material store was equipped with the electronic digital weighing scale.
- Passed material was separately quarantined under proper labeling.

Production:

- The pre-formulation & formulation area is properly designated.
- HVAC system was operational under proper SOP's.
- Flow charts ensuring the processes were laid down.

Quality Control & Quality Assurance

- The Quality Control laboratory is well equipped with HPLC, U.V spectrophotometer, HPLC with RI detector, Karl Fischer, stability chambers, Automatic polarimeter & HPLC Gradient.
- Digital thermometer & hygrometer was present. Temperature & humidity log was maintained.
- HVAC system was installed in laboratory and was operational with HEPA filters.
- The calibration record of the instruments were available and updated.
- Reference standards were available.

Finished Goods Store

i). Thermometer was installed & temperature record log was available.

ii). Hygrometer was installed and humidity record log was updated.

iii). The finished goods were placed under quarantine with proper segregation.

iv). Fire-extinguishers were updated and installed properly according to ISO requirements.

v). Cartons with proper labeling were placed on the racks/ pallets.

Conclusion:

The technical team of the firm has accepted and promised to change their source/vendor of measuring cups in compliance to the observations recorded by the PSI committee. The committee also proposed to opt for the measuring spoon with graduations on the outer side of the spoon for accurate and better patient benefit.

The report of the vendor evaluation for Raw material & Packaging material is also submitted by the manufacturer.

The report is submitted to the honourable Board for final decision

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 68

PQCB R-541/2021

Tehsil Rojhan, District Rajanpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan** through its Chief Executive officer, Mr. Shaukat Hayat Khan 2. Shaukat Hayat Khan Chief Executive Officer/ Warrantor 3. Fwad Ali Khan Production Manager 4. Ahtesham ul Haq Quality Control Incharge of M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Rojhan, District Rajanpur reported that: -

i. He, on 27-01-2021, inspected the business premises of M/S Kaleem Medical store/Hall, Thana Road, Tehsil Rojhan and took 4 different types of drug samples on Form No. 4 for the purpose of test and analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memo no. 83973 dated 27-01-2021.

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
Pwder for Ijection Cefocef 500mg (Ceftriaxone as Sodium 500mg) **Mfg. date**: Oct 2019 **Exp. Date**; June 2021 **Regs. #** 086272	278	M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan	01-89002585/DTL dated: 02-04-2021	**Result of test/ analysis with specifications applied:** USP 2019/PQCB Approved Method **DESCRIPTION**: White to off white color fine powder for reconstitution in transparent labeled glass vial closed with a rubber stopper and blue color flip off cap sealed with aluminum, in an ampoule of Lignocaine 1% (Lacain). The product does not contain Finished Drug Product Specifications on vial as well as on outer carton. **(Misbranded) (Does Not Comply)** **IDENTIFICATION USP:** Ceftriaxone as Sodium identified **ASSAY:** Ceftriaxone Stated 500mg/vial Determined 493.96mg/vial Percentage 98.79**%** Limit: 90-110% **(Complies)** **Sterility:** It conforms to Sterility test. **(Complies)** **RESULT:** The sample is **Misbranded** as defined under clause (vi) of subsection (s) of section 3 of the Drug Act 1976.

iii. M/S Kaleem Medical store/Hall, Thana Road, Tehsil Rojhan, District Rajanpur provided invoice/warranty No. 1025805 dated 03-01-2021 issued by M/S "City Pharma" Adda Fatehpur, Rajanpur.

iv. Warrantor Portion was sent to M/S City Pharma" Adda Fatehpur, Rajanpur with directions to explain their position and provision of requisite information.

v. M/S City Pharma" Adda Fatehpur, Rajanpur.in turn provided the invoice warranty No. SOB-0000723 dated 19-02-2020 issued by M/S Marketing Services, 759-Naqashband Colony, Chowk Rashidabad , Multan.

vi. M/S Marketing Services, 759-Naqashband Colony, Chowk Rashidabad, Multan provided Invoice/warranty No. 7035 dated: 06-02-2020 issued by M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan.

vii. Copy of test/analysis report was sent to M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan with directions to explain their position and provision of 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)/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.

Reply to Show Cause Notice:

This is with reference to your letter No PQCB/R-541/2021, Dated 10-02-2023, received on 17-02- 2023, regarding the misbranded drug cefocef injection 500mg in which product specification was not mention either on label and unit carton of injection, it was a printing mistake which is rectified. Copy of corrected unit carton and label is attached for record.

We would like to informed that Cefocef injection 500mg Batch # 278, expired in 06/2021 and no stock is available in market.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 69

PQCB/R-435/2019

Tehsil Renal Khurd District Okara

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan. Lahore** through its Managing Director Muhammad Imran Asghar. 2. Muhammad Imran Asghar Managing Director 3. Junaid Zafar Manager Quality Control 4. Muhammad Adnan Jamil Manager Production 5. Ghulam Murtaza Warrantor Of **M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Renala Khurd, District Okara reported that: -

i. He, on15-01-2019, inspected the business premises of M/S New Life Medical Store, Situated at Old Kachary Road, Anwaar Shaheed Colony, Tehsil Renala Khurd, District Okara and took samples of two different types of drug samples on Form.04 for the purpose of test and analysis.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Film Coated Tablet. Axifen SR (Diclofenac Sodium 100mg in sustained release formulation)	381	M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan	TRA No.01-25002569/DTL dated:22-05-2019	**Analysis with specifications applied:** MS/BP 2018. **Identification:**Diclofenac Sodium identified. **Assay (BP):Per Tablet:**

Determined	**101.06mg/tab**
Percentage	**101.06%**
Limit	95-105%

Dissolution Test (MS): Does not comply with the specifications of MS as detailed below:

Tolerance Limit: Dissolution should be**:**

After 01 Hour	After 03 Hour	After 05 Hour	After 10 Hour
NMT 10%	20-50%	20-50%	NLT 80%

Level	Numbr tested		Acceptance Criteria						Average	Remarks
L1 & L2			No individual value lies outside each of stated ranges, no individual value is less than stated range and is not less than the stated amount as the final test time (1,2)						L1 & L2	
Time	Limit or range		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		Average of 12 units is less than the stated amount after 10 hours and is less than the stated amount at the final test time
After 01 hour	NMT 10%	L1	1.79%	2.09%	2.09%	1.49%	2.09%	1.19%	1.67%	
		L2	4.49%	0.29%	0.59%	0.59%	1.49%	4.49%		
After 03 Hour	10-30%	L1	23.27%	21.07%	18.31%	22.40%	28.82%	22.43%	22.40%	
		L2	22.51%	20.48%	23.81%	27.41%	20.23%	18.01%		
After 05 Hour	20-50%	L1	54.52%	49.76%	44.16%	58.37%	48.84%	58.92%	49.38%	
		L2	39.19%	43.85%	53.33%	42.61%	54.92%	44.08%		
After 10 Hour	NLT 80%	L1	77.73%	75.98%	74.21%	78.09%	78.73%	78.65%	76.89%	
		L2	76.05%	74.48%	78.82%	74.11%	78.31%	77.89%		

Result: The sample is declared **substandard** on the basis of Dissolution test.

Note: The time extension against said sample vide order no. PQCB/Dtl-B/203/2019 dated 29-03-2019 has been granted by PQCB.

iii. M/S New Life Medical Store, Situated at Old Kachary Road, Anwaar Shaheed Colony, Tehsil Renala Khurd, District Okara provided invoice/ warranty No. 42075, dated 07-10-2018 issued by M/S New Shahzaib Pharmacy, 122, Umer Din Town, St No. 3, Okara who inturn provided invoice/warranty No. 24672, dated 26-09-2018 issued by M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan as a proof of its purchase.

iv. Warrantor portion was sent to M/S New Shahzaib Pharmacy, 122, Umer Din Town, St No. 3, Okara.

v. Copy of test report of drug sample was sent to M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan with directions to explain their position and provide requisite information in this regard.

2. Drug Inspector requested to grant 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 (as amended) and Rules framed there under by the way of: -

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

Summary:

Manufacturing Date: 09-2018

Expiry Date: 09-2020

Sampling Date: 15-01-219

Date of Form 6: 21-01-2019

Date of Receipt in DTL BWP: 24-01-2019

DTL Report Date: 22-05-2019

1ST DI Communication with firm on dated: 08-06-2019

Date of Retesting Request of Firm: No

Investigation Report Dated: 30-11-2019

3. Show-cause/personal hearing notice(s) issued to accused person(s) dated 18-12-2019.

Reply of show cause notice dated 27-12-2019

We have not yet received any manufacturer's sample portion of subject batch of drug Axifen so we are not in a position to cross verify the said product from market.

Furthermore, to cross examine the result of DTL mentioned in the report, we have conducted analysis of retained sample of subject batch of product which was stored as per storage instructions mentioned on our product packaging and to our fullest satisfaction of Dissolution are well within limits.

Therefore, as per test results of the retained sample of the same batch of our product in our quality control laboratory, we are confident in stating that our product is of standard quality. If manufacturer portion was provided to us, it could have been easier for us to further clarify the situation. Moreover,

i. All the test results shown in above mentioned report clearly shows the compliance of our product in all areas except for deviation in dissolution at 10th hour with quite a minor change and such minor difference may be due to some uncertainty factor.
ii. Since the subjected product is sustained release, so by using this product there will be no adverse impact on patients as per declared results of DTL report. We hereby request you to ignore the matter and quash the show cause notice.

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 **216th meeting held on 28-12-2019**. Zaheer-ud-Din Babar Secretary DQCB District Okara & Mr Adnan Yaqoob Drug Inspector Tehsil Renala khurd were present along with original record of the case. Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons involved in the subject case.

5. Accused Persons Junaid Zafar (Manager Quality Control) appeared before the Board on the behalf of M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala, Sahianwala Road, Faisalabad. Pakistan and submitted that the product is declared substandard merely on the basis of dissolution test which does not affect the efficacy of the product and the difference in values of dissolution test may occur due to manual sampling of the sample instead of using Auto-sampler which are minorly deviated from its stated limit in four steps. Moreover, conditions in which dissolution test is performed is not mentioned in DTL Bahawalpur report. pH of the buffer and sample taking point from dissolution apparatus can also affects the results of dissolution test. He requested for lenient view in the subject case.

6. The Board, after detailed scrutiny of the case record, due deliberation and discussion and considering statement of the accused persons was of unanimous opinion that the Production and Quality Control/Assurance processes and the procedures regarding said drug need to be evaluated. Therefore, the Board decided to constitute a **committee comprising of following members to conduct Product Specific Inspection (PSI)** of **M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan** and submit report for consideration by the Board.

1	**Prof. Dr. Sajid Bashir** Professor of Pharmacy, Dean, Faculty of Pharmacy, University of Sargodha, Sargodha.	**Convener/Member**
2	**Mr Muhammad Umair Chaudhary** PQCB, Punjab, Lahore	**Facilitator**

7. Committee submitted its Product Specific Inspection report received in PQCB dated 24-08-2022

PRODUCT SPECIFIC INSPECTION REPORT OF M/S AXIS PHARMACEUTICALS 3-B, VALUE ADDITION CITY, 1.5 Km KHURRIANWALA-SAHIANWALA ROAD, FAISALABAD, PAKISTAN.

Members of inspection committee:

Prof. Dr. Sajid Bahir	**(Member PQCB)**	**(Convener)**
Muhammad Umair Choudhary	**Scrutiny Officer, PQCB**	**(Facilitator)**

Date of Inspection:

Inspection was conducted on 18-09-2020 with reference to PQCB order No. PQCB/R-435/2019 dated 28-12-2019.

No. PQCB/R-435/19

Details of Test/Analysis by the DTL:

The sample Axifen SR is a film coated tablet containing {Diclofenac sodium 1mg in sustained release formulation}. Batch No. 381. The sample was declared Substandard by the Drug testing laboratory, Bahawalpur on the basis of dissolution test performed under TRA No.01-1252569/ DTL dated 22-05-2019.

The tested sample does not comply the stated limit of acceptance criteria which is, that, NO individual value lies outside each of stated ranges, no individual value is less than stated amount (L1) and Average of 2 units lies within each of the stated range and is not less than the stated amount at the final test time (L2). However, at the final test time after 10 hours the stated NLT percentage should be 80% but the reported value is 76.89%. Thus, the sample is declared Sub-standard on the basis of Dissolution test performed.

Premises Detail:

The manufacturing unit was established in 2009. Total area 72,000 sq. ft with the covered area of about 46,800 sq. ft. The firm has approved sections **(GMP Certificate)**.

Current Technical Staff

Designation	**Name**
Managing Director	M. Imran Asghar
Manager Quality Control	Junaid Zaffar
Manager Production	M. Adnan Jamil
Plant Manager	Ghulam Murtaza

Detail of Product:

No. PQCB/R-435/2019	
Name of Product	**AXIFEN-SR TABLETS**
Batch No.	**381**
Date of Mfg.	05-09-2018
Exp. Date	04-09-2020
Sample Taken by	Inspector of Drugs, Tehsil Renala Khurd, OKARA.
Sampling Date	15-01-2019
Date of Memorandum to Government Analyst	21-01-2019
Report of Government Analyst	22-05-2019

Detail of Inspection / Observations:

1. The inspection team has done the Product Specific Inspection and discussed the report of the Drug testing laboratory with the technical team which declared the specific product as of Sub-standard on the basis of dissolution test performed which didn't comply the standard limits. The technical teams presented the drug registration certificate of the Tablet Axifen SR (100mg) having DRAP registration No. 059648 which showed the drug manufacturing & testing specifications as of Manufacturer specifications.
2. The technical team presented the Standard Operating Procedures for AXIFEN SR Tablet (100mg) vide Doc. No. AP/QC/PSF/TAB-009, issued date: 06-02-2019 & Issue status: 04 of the Quality Control Department which depicted the Objective, Scope, Responsibility, Specifications & Procedure followed for the manufacturing the above said batch of AXIFEN SR. The specifications showed the following parameters;

Sr. No	Parameters	Reference	Specifications
1	Description	MS	Light pink, rounded, film coated tablets filled in blister "Alu-Pvc" packed in carton with leaflet
2.	Average Weight/ Weight variation	MS	285 mg/tablet 285 + 5% Limit: 270.75—299.95 --
3.	Identification Diclofenac Sodium	MS	Must Comply
4.	Dissolution Test	MS/ B. P	After 1 Hour NMT 10% (as labeled in 0.1N HCL After 3rd (including 1 hr of in acid stage) 10-30% (as labeled) in water After 5th hr (including 1 hr of in acid stage) 20% to 50% as (labeled) in water After 10th hr (including 1 hr of in acid stage) NLT 80% (as labeled) in water
5	Assay	B. P	95-105% of the labeled amount of Diclofenac Sodium
6	Composition	Reg. Letter	Each sustained release Film coated tablet contain: Diclofenac Sodium:……100mg/Tablet (Product complies with B.P Specifications)
7	Drug Registration Number	Reg. letter	059648
8	MRP.	Reg letter	RS.200.00
9	Batch No. Mfg. Date Exp. Date	As BPCR	As BPCR
10.	Pack size	Reg. Letter	3 *10's
11.	Blister Seal Test	MS.	Must Comply
12.	No. of Packs	MS	246 U/C per shipper

3. **The dissolution test followed the details as;**

Apparatus: II

RPM: 50

Medium: 0.1 N Hydrochloric acid 900 ml

Temperature: 37 C +/- 0.5 C

Sampling Interval: After 1 hour

4. **Acceptance criteria prolonged-release dosage forms (B.P)**

The requirements are met if the quantities of active substance dissolved from the dosage units tested conform to below mentioned criteria in table. Continue testing through the 3 levels unless the results conform at either L1 or L2. Limits on the amounts of active substance dissolved are expressed in terms of the percentage of labelled content. The limits embrace each value of Qi, the amount dissolved at each specified fractional dosing interval. Where more than one range is specified, the acceptance criteria apply individually to each range.

Level	Number Tested	Acceptance Criteria
L1	6	No individual value lie outside each of the stated range and no individual is less than the stated amount at the final test time
L2	6	The average value of the 12 units (L1 +L2) lies with in each of the stated ranges, and is not less than the stated amount at the final test time; none is more than 10% of the labeled content outside each of the stated range; and none is more than 10% of the labeled content below the stated amount at the final test time.
L3	12	The average value of the 24 units (L1+L2+L3) lies with in each of the stated ranges, and is not less than the stated amount at the final test time; not more than 2 of the 24 units are more than 10% of the labeled content outside each of the stated ranges; and none is more than 2 of the 24 units are more than 10% of the labeled content below the stated amount at the final test time, and none of the units is more than 20% of the labeled content outside each of the stated ranges or more than 20% of the labled content below the stated amount of the final test time.

5. The certificate of analysis of the finished product for AXIFEN SR (100mg) has shown the Q.C # 695/18, Batch Num. 381 & Batch size of 400,000 Tabs. performed on 14-09-2018 under B.P specifications followed by all the parameters after the production of the tablets which included the physical tests, Weight Variation, Average weight/ tablet, Assay & Dissolution respectively.
6. The instrument Dissolution apparatus No. AP/QC/INS-011 was used. The standard limit (NMT;10%) at the Acid stage after 1st hour showed the average result of 1.67% with the Max range of 2.59 % and Min range of 0.64%, which complies with the standard limit. At the 3rd hour of water stage (including 1 hr. of acid stage) the standard limit (NMT; 30%) where, the average result range to 23.05% with the Max. 0f 25.90% and Min. of 20.42, which complies with the standard limit.
7. At the 7th hour of water stage (including 1 hr. of acid stage) the standard limit (NMT; 60%) where, the average result range to 65.78% with the Max. 0f 75.45% and Min. of 60.42, which again complies with the standard limit.
8. At the 10th hour of water stage (including 1 hr. of acid stage) the standard limit (NLT; 80%), where the average result range between 87.65% to 95.42% which complies with the standard limit.

Re-testing of Retained Sample:

1. The certificate of analysis of the Re-tested retained sample has been observed, which showed that the testing was performed on 14-06-2019. The dissolution test was performed with 6 tablets with following protocols:

i) Medium Used = 0.1 M HCL

ii) Apparatus = No.2, at 50rpm

iii) Time = 60 minutes

The standard (Limit: NMT 10%) and the average result have shown the 2.10 %, such that the maximum value attained was of 3.66 % and the minimum value attained was of 0.66 % and therefore, complied the standard limit.

After 1st hour, all the 6 tablets have complied with the standard limit that marked within the standard limit of 10%. After 3rd hour, those 6 tablets have shown again the standard limit range between (10%- 30%). At the 5th hour, all the 6 tablets marked within the standard range of (20%-50%). At the 10th hour the standard range which marks the range of NLT (80%), none of the tablet fell below the 80%.

Raw Material Store:

- Raw material store area is properly cleaned & proper demarcation for passed & rejected material was labelled.
- Temperature of the area was 25.4 degrees and log book were maintained.
- Standard Operating Procedures were properly laid down with the help of flow chart.
- Material receiving hood was functional for performing the Dusting & De-dusting.
- Raw-material store was equipped with the electronic digital weighing scale.
- Passed material was separately quarantined under proper labeling.

Production:

- The pre-formulation & formulation area is properly designated.
- HVAC system was operational under proper SOP's.
- SOPs of the tablet manufacturing were laid down.
- Tablet coating section was operational under SOP's.
- Flow charts ensuring the processes were laid down.

Quality Control & Quality Assurance

- No. of functional HPLCs = 7
- The Quality Control laboratory is well equipped with HPLC, U.V spectrophotometer, dissolution apparatus, potentiometer, stability chambers, particle sizing system & polarimeter.
- Digital thermometer & hygrometer was present. Temperature & humidity log was maintained.
- HVAC system was installed in lab and was operational with HEPA filters.
- The calibration record of the instruments was available and updated.
- Three stability chambers were available and stability studies were being carried out.
- Reference standards were available.
- Testing of water is operational.

Finished Goods Store

i). Thermometer was installed & functional and temperature record log is available.

ii). Hygrometer was installed and humidity record log was updated.

iii). The finished goods were placed under quarantine with proper segregation.

iv). Fire-extinguishers were updated and installed properly according to ISO requirement.

v). Cartons with proper labeling were placed on the racks/ pallets.

Each film coating contains, Diclofenac Sodium (B.P) …….. 100 mg

Batch Processing Record of specific product: AXIFEN-SR TABLETS (100mg)

D. Reg # 059648 **BPCR: TB-15**

Batch # 381 **Batch Size**: 4,00,000 Tabs

MFG. Date: 05-09-2018 **EXP. DATE**: 04-09-2020

Process	SR#	INGREDIENTS	EACH TABLET CONTAINS	4,00,000 TABLET CONTAINS (KG)
MIXING	1	Diclofenac sodium	101.00	40.400
	2	Lactose	131.00	52.400
	3	Methocel k-15	35.00	14.000
	4	IPA	0.075 ml	30.00 Lit
	5	Purified Water	0.045 ml	18.00nLit
LUBRICATION	1	Magnesium Stearate	3.00	1.200
	2	Talcum	10.00	4.000
TOTAL			280.00mg	112.000 Kg
COATING	1	EUDRAGIT	3.00	1.200
	2	PVP K-30	1.00	0.400
	3	PEG-6000	1.00	0.400
	4	TITANIUM DIOXIDE	3.25	1.300
	5	TALCUM	3.00	1.200
	6	RED COLOR (Lake)	0.310	0.124
	7	SUN SET YELLOW COLOR (Lake)	0.250	0.100
	8	ISOPROPYL ALCOHOL	0.15 ml	60.000 Lit.

Conclusion:

During the inspection, the batch process & control record was observed for the respective batch # 381. The batch size was consisted of 4,00,000 Tabs. The process of mixing & lubrication was being performed according to the SOP's undersigned by Production In-charge & Quality Assurance In-charge. The stock book record has shown the release of 40.400kg of Diclofenac sodium for the production of respective batch no.381 of Tab. AXIFEN-SR (100mg).

According to the DTL report where, all the criteria of the dissolution testing were complied except the last one where "**after 10th Hour the average of the 12 units is less than the stated amount after 10 Hour and is less than the stated amount at the final test time which has to be Not Less Than 80% and showed up to be 77%".** This difference could be achieved at another 1 hour as the release profile of the product is satisfied. However, the testing protocol would have to be shifted to L3 as the criterion of the L2 was not met in the DTL Bahawalpur's report and for that purpose this minor difference at the 10th hour could be achieved. This is because the release profile of the tablet shown was satisfactory. The overall, inspection of the BMR, testing protocols & the inspection of the Re-testing of that specific batch has found to be satisfactory.

PSI report provided to the firm M/s Axis Pharmaceuticals, Faisalabad on dated 30-08-2022.

CORRECTIVE & PREVENTIVE ACTIONS (CAPA)

Firm submitted Corrective & Preventive Actions (CAPA) vide letter Ref no. Axis/AP/RA/6092 dated 06-09-2022

With reference to Product Specific Inspection Report No. 42340, received to us on 30-08-2022 against PQCB order No. PQCB/R-435/2019 dated 28-12-2019, we hereby submit CAPA plan.

The following areas were visited and found satisfactory.

1. Premises
2. Raw material store and record related to Batch
3. Production
4. Quality control
5. Documents BMR, testing protocols

Moreover, equipment used by us for tests bears internationally traceable calibration and verified frequently with proficiency test standards Pharmassure UK & LGC London to ensure equipment performance. Axis Pharmaceutical is a responsible law-abiding company, which not only maintain GMP standard but also has an independent well-equipped Testing & Research Quality Control laboratory accredited from PNAC for ISO/IEC 17025:2017.

We requested the honorable authority to take lenient view in the subject case as there is a very minor difference in Dissolution results, all other parameters are well within limits.

CAPA # 1

Description:

Testing of retain sample of Axifen-SR 100mg performed and results were found satisfactory.

Action plan	Status of Actions taken	Evidence attached
Retain sample of Axifen-SR 100mg (Batch No. 381) to be tested on 14th June 2019 & on 17th June 2019.	Retained sample was tested on **14th June 2019** and results were found satisfactory as stated below: v. 1st hour 0.1N HCl: NMT 10% Results: complies avg. 2.10% v. 3rd hour (in water including 1 hour in 0.1NHCl) between 10-30% Result: Complies avg. 24.33% v. 5th hour (in water including 1 hour in 0.1NHCl) between 20-50% Result: Complies avg. 45.22% v. 10th hour (in water including 1 hour in 0.1NHCl) NLT 80% Result: Complies None of the tablet fell below avg. 85.16% Retained sample was tested on **17th June 2019** and results were found satisfactory as stated below: v. 1st hour 0.1N HCl: NMT 10% Results: complies avg. 2.04% v. 3rd hour (in water including 1 hour in 0.1NHCl) between 10-30% Result: Complies avg. 24.93% v. 5th hour (in water including 1 hour in 0.1N HCl) between 20-50% Result: Complies avg. 46.65% v. 10th hour (in water including 1 hour in 0.1NHCl) NLT 80% Result: Complies None of the tablet fell below avg. 85.07%	Both reports submitted

CAPA # 02

Description:

In DTL test Report average results are 77% which after 10th hour (limit: NLT 80%) this minor difference can be achieved at another 1 Hour as the release profile of product is satisfactory.

Action plan	Status of Actions taken	Evidence attached
We have reviewed our standard Analytical Procedure according to BP and specification to be revised as below: v. 1st hour 0.1NHCl NMT 10.0% v. 3rd hour (in water including 1 hour in 0.1N HCl) between 10-30% v. 5th hour (in water including 1 hour in 0.1N HCl) between 30-70% v. 12th hour (in water including 1 hour in 0.1N HCl) NLT 80%	Standard Analytical Procedure has been revised according to BP specification with the following limits: v. 1st hour 0.1NHCl NMT 10.0% v. 3rd hour (in water including 1 hour in 0.1N HCl) between 10-30% v. 5th hour (in water including 1 hour in 0.1N HCl) between 30-70% v. 12th hour (in water including 1 hour in 0.1N HCl) NLT 80%	Approved copy of SAP submitted

CAPA # 03

Description:

Testing of retain sample of Axifen-SR 100mg performed and results were found satisfactory**.**

Review of results of other batches included in Annual Product Review 2021.

Action plan	Status of Actions taken	Evidence attached
APR review of Dissolution results of 2021	Annual product review of Axifen SR 100mg tablet has been carried out from Batch # 544 to 580 (total batches: 36) and Dissolution results found satisfactory.	report submitted

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 70

PQCB/R-441/2020

Tehsil & District Pakpattan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore** through its Managing Director Salman Shahid 2. Salman Shahid Managing Director 3. Hafiz Tariq Mehmood Production In-charge/Warrantor 4. Nuzhat Kousar Mumtaz Quality Control Manager of M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Pakpattan, District Pakpattan reported that: -

i. He, on 06-06-2020 inspected the medicine Store O/o CEO DHA Pakpattan, District Pakpattan and took sample of the six different types of drugs on Form No. 4 for the purpose of test and analysis.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Gauze Curay Gauze Swab [Absorbent cotton gauze swab 10cm*10cm, 8ply]	75B20	M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore	01-25005732/DTL dated: 27 Jul 2020	**Result of test/ analysis with specifications applied** BP 2020/BPC 1973 **DESCRIPTION** (**MS**): Absorbent cotton gauze consists of cloth of plain weave, bleached to good white odorless clean, reasonably free from weaving defects. **WEIGHT/UNIT AREA (BPC):** **Limit:** Average 15gm/m^2 (SD 0.33) **Determined:** 14.84gm/ m^2 **WARP (BPC):** **Limit:** Average 73/10cm (SD 1.33) **Determined:** 73.5/10cm **WEFT (BPC):** **Limit:** Average 57/10cm (SD 1.33) **Determined:** 56.0/10cm **SINKING TIME (BPC):** **Limit:** Not more than 10sec **Determined:** 1.47sec **ACIDITY/ ALKALINITY (BPC):** **Limit:** No pink color with Phenolphthalein and Yellow color with Methyl orange. **Determined:** Phenolphthalein: No pink color Methyl orange: yellow color **SURFACE ACTIVE SUBS (BPC)** **Limit:** Not more than a ring of froth **Determined:** Ring of froth appeared **STERILITY (BP):** **Limit:** Must be sterile **Determined: Non-sterile** **(Does not comply with the specifications)** **RESULT:** The sample is declared Sub-Standard on the basis of sterility Test.

iii. The Storekeeper Medicine Store, District Pakpattan provided invoice/ warranty No. 0812 dated 04-06-2020 issued by M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore.

iv. Warrantor Portion was sent to M/s Cotton Craft (Pvt) Ltd., Plot No. 407, 408 Sunder Industrial Estate, Raiwind Road, Lahore.

v. A copy of Test/ Analysis report was also sent to M/s Cotton Craft (Pvt) Ltd., Plot No. 407- 408 Sunder Industrial Estate, Raiwind Road, Lahore 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: 02-2020

Expiry Date: 01-2023

Sampling Date: 06-06-2020

Sent to DTL (Form 6): 06-06-2020

Date of receipt in DTL: 08-06-2020

DTL Report Date: 27-07-2020

1ST DI Communication with firm on dated: 21-08-2020

Date of Retesting Request of Firm: No (**but in reply of Show cause notice**)

Investigation Report Dated: 06-11-2020

3. Showcause notice(s) issued to the accused dated 20-04-2021

Firm submitted reply of Show cause vide letter Ref: 786/0735/2021 dated 26-05-2021

We would like to bring to your kind notice that the sample of the same Batch No. 75B20 of the same item has also been taken from the Jampur and tested by the DTL Punjab Multan and declared as "Pass of Standard Quality". In the light of above DTL report we are unable to understand that how the analyst DTL Punjab Bahawalpur declared the same batch 75B20 as "Sub-standard", whereas the other DTL Multan is declaring the same Batch as "Pass of Standard Quality". It is stated that the same batch was supplied at the same time to the consignees including CE0, DHA Pakpattan.

As regards the test results reported in the DTL Report No. TRA-01-25005732/DTL dated 27.05.2020, it is observed that all chemical and other test of the Drug/ Medical Device under reference mentioned here under has been complies the specifications. But the Analyst declared it sub-standard based on Sterility, whereas we tested the warrantor portion as well as retained sample at our Microbiological Lab and confirm the sample is sterile.

Hence our submissions are as under:-

We are very much conscious about the quality and quantity of the products, especially in sterility process, which is done through Ethylene Oxide (ETO) Sterilization process over the best equipment that has been calibrated and for which IQ and 0Q processes have been completed and we have no doubt about sterilization of this drug / Medical Device under reference.

It is stated that the stock under reference supplied to the Medicine Store CEO (DHA) Pakpattan was very small in quantity, shipped through local transport and maybe it damaged during the transportation or mishandling during loading/ unloading by the untrained laborers, due to which the sum of stock captured and loss its sterility or otherwise all other test complies the specification.

It is worthwhile to mention here that the Surgical Bandages (Gauzes/Gauze Swabs) is meant for external use only and it has many commercial usages other than medical purposes like Cleaning of Machinery, Polishing, Sanitary and Rexene are two major industries for used of Gauze Cloths / Gauzes called as Mulmul).

In the light of above said explanation it is stated that the Product (Medical Device) under reference is complies all test according to the BPC specifications and observations made by the Analyst for declaring sub-standard are unfortunate. Even though if the authority feel it necessary we are ready to replace the seized stock with the fresh stock of standard quality or otherwise **forward the sample of the same product under reference to the NIH for re-testing.**

Hence, It is submitted that we have not contravened the provisions of Section 23/72 of the Drug Act 1976 (as amended)/DRAP Act 2012 and Rules framed there under by the way of (a) Manufacturing for sale/ Selling of Substandard drug (b) Issuance of false warranty.

Keeping in view the above said explanation it is stated that the product (Medical Device) under reference is complies all test according to the BPC specifications and observations find by the Analyst for declaring sub-standard is unfortunate, which may kindly be ignored and consider our request as under:

i. Stock under reference may be accepted.
ii. Allow to return "out of specification" seized stock to us with the conditions of replacement by fresh stock of standard quality to settle this issue at your level.
iii. Forward the sample of the same product (Medical Device) under reference to the NIH for re-testing purposes.

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

Case is placed before the Board for Decision

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 **247th meeting** held on **21-07-2022** under the chairmanship of Vice Chairperson, in the presence of Board members as mentioned above. Mr. Sarfraz Ali, Secretary DQCB Pakpattan, Mr. Aqeel Ahmed Provincial Inspector of Drugs, Tehsil Pakpattan was present along with the original case record. No one among the nominated accused persons of M/s Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind road Lahore was present. Firm submitted written request for adjournment that Managing Director of the firm was suffering from old flu and fever and unable to attend meeting dated 21.7.2022.

5. The Board after discussion decided to **adjourn** the case on the request of the firm in the best interest of justice. The Board further decided to provide another opportunity of hearing to the accused persons.

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD

Case No. 71

PQCB R-162/2022

Tehsil and District Rajanpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Shawan Pharmaceuticals, Plot 37 Roads NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan** through its Director Operations, Amir Iqbal 2. Amir Iqbal Director Operations 3. Ziad Hussain Quality Control Manager/Warrantor 4. Usha Talat Toosi Production Manager of M/S **Shawan Pharmaceuticals, Plot 37 Road NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Jampur, District Rajanpur reported that: -

i. He, on 27-05-2022, inspected the business premises of M/S Punjab Medicine Store, Opposite THQ Hospital, Tehsil Jampur, and took 2 different types of drug samples 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. 128105 dated28-05-2022, 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 Mixcef (Cefixime Trihydrate eq. to Cefixime: 400mg) **Mfg. date**: Oct-2021 **Exp. Date**; Sep-2023 **Regs. #** 056783	097	M/S Shawan Pharmaceuticals, Plot 37 Roads NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan	01-94003959/DTL dated: 18-07-2022	**Result of test/ analysis with specifications applied:** MS **DESCRIPTION**: Off-white to light yellow granular powder filled in hard gelatin capsules of blue color cap & body packed in ALU-ALU blister of 5 units in a labeled outer hard carton. Each outer carton contains1 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)** **IDENTIFICATION USP:** Cefixime as Trihydrate identified **ASSAY:** Cefixime Stated 400 mg/capsule Determined 393.43 mg/capsule Percentage 98.35**%** Limit: 90-105% **(Complies)** **DISSOLUTION TEST:** **Acceptance Criteria**: NLT 80% of labeled amount of Cefixime is dissolved in 60 minutes. **(Complies)** **RESULT:** The sample is **Misbranded** as defined under clause (iv) of subsection (s) of section 3 of the Drug Act 1976.

iii. M/S Punjab Medicine Store, Opposite THQ Hospital, Tehsil Jampur provided invoice/warranty No. 9388 dated 26-05-2022 issued by M/S Hamas Pharma, Shop #12, Block# L, Near National Saving Bank#2, DG Khan, as a proof of purchase.

iv. Warrantor Portion was sent to M/S Hamas Pharma, Shop #12, Block# L, Near National Saving Bank#2, DG Khan.

v. M/S Hamas Pharma, Shop #12, Block# L, Near National Saving Bank#2, DG Khan, in turn provided invoice/warranty No. 10061, dated: 06-01-2022, issued by M/S Biogen Life Sciences, Plot No. 260, Industrial triangle, Kahuta Road, Rawalpindi, Pakistan as a proof of purchase of subject drug sample.

vi. M/S Biogen Life Sciences, Plot No. 260, Industrial triangle, Kahuta Road, Rawalpindi, Pakistan, provided invoice/warranty No. 191, dated: 27-12-2021, issued by M/S Shawan Pharmaceuticals, Plot 37 Road NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan, as a proof of its purchase.

vii. Copy of test/analysis report was sent to M/S Shawan Pharmaceuticals, Plot 37 Road NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan, with directions 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)/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.

Reply to Show Cause Notice:

Please refer your letter No. PQCB/R-162/2022 Dated: 10/02/2023 received at our office 21/02/2023 to the captioned subject regarding Mis-Branded Mixcef 400mg Capsule B#097 Mfg. Date 10-21 Exp 09-23.

It is to bring into your kind notice that as per decision of DRAP Minutes of Meeting Conducted on 16-18th November 2021, new revised specification for Cefixime 400mg Capsule have been approved.

DRAP issued a Letter No F.14-1/2022-PEC Dated 14th March 2022 for implementation of revised specification within 6 months. We have implemented the same for all batches manufactured after decision of the DRAP.

We are attaching herewith Minutes of 313th Meeting of Registration Board Conducted on November 2021, DRAP Letter No F.14-1/2022-PEC Dated 14th March 2022 and Artwork of Mixcef 400mg Capsule with revised Shawan's Specification along with this letter for your kind perusal.

As our Product was manufactured on 10-2022 before issuance of DRAP letter. Hence your kind cooperation and kindness based on DRAP Letter No F.14-1/2022-PEC Dated 14th March 2022 & within 6 months time frame relaxation, which shall be highly appreciated.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 72

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore** through its Chief Executive Officer Ali Ahmad Khan 2. Ali Ahmad Khan Chief Executive Officer 3. Nabila Shaheen Production Manager 4. Faiza Rashid Quality Control Manager/Warrantor of M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs Tehsil Jampur District Rajanpur reported that: -

i. His predecessor, on 26-01-2021, inspected the business premises of M/s Madina Medical Store, Store at Adda Charagh Shah Tehsil Jampur and took two different types of Drug samples on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Multan.

ii. 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 TRA No. & Date	DTL Test Report Result
Powder for Reconstitution Ceffest 30ml [Cefixim as Trihydrate Eq. to Cefixime 100mg/5ml]	0973	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore	01-89002557/DTL Dated 24-05-2021	**Analysis with specifications applied: USP 2019** **Description**: Light yellow to lemon color suspension after reconstitution in a labeled white plastic bottle sealed with Aluminum and covered with Red screw cap packed in a labeled outer hard carton along with water for suspension. **Identification**: Cefixime as Trihydrate identified. **Analytical Technique: HPLC** **Assay (**Cefixime)

Stated	100mg/5ml
Determined	**81.10mg/5ml**
Percentage	**81.10%**
Limit	90-120

(Does not comply)

Result: The above sample is **Substandard** on the basis of Assay Test.

iii. M/s Madina Medical Store, Store at Adda Charagh Shah Tehsil Jampur provided Invoice/warranty No. 275 Dated 05-01-2021 issued by M/s Al-Shifa Enterprises, Jampur who in turn provided invoice/warranty No. 0307 Dated 10-12-2020 issued by M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore as a proof of its purchase.

iv. A copy of test/analysis report was sent to M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore and they were asked to provide the requisite information in this regard.

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

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 Results
Ceffest Dry Suspension 30ml	0973	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Lahore	0263-P/2021 dated: 15-12-2021	**Analysis with specifications applied: USP 39** **Description:** Slightly off white powder contained in white labeled plastic bottle along with a bottle containing purified water packed in an outer carton produces off white suspension after reconstitution with water provided along with the pack. **Identification: Cefixime trihydrate identified.** **Assay:**

Cefixime (as trihydrate)	Stated	Found	Limit	Percentage
	100mg/5ml	**72.29mg/5ml**	**90-120%**	**72.29%**

Does not comply with USP-39.

Result: The sample is of **Substandard** quality on the basis of tests performed.

vii. Copy of NIH report was sent to M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore.

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

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

3. Show cause notice(s) issued to the accused vide 28-06-2022.
4. Personal Hearing notice(s) issued to accused person(s) on 19-12-2022.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 255th Meeting held on 29-12-2022:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **255th meeting held on 29-12-2022** under the Chairmanship of Secretary Primary and Secondary Healthcare Department Punjab. Mr. Adil Jameel, Secretary DQCB District Rajanpur and Mr. Kaleem Bhutta, Drug Inspector, tehsil Jampur, were present along with original case record. No one among the nominated accused persons was present on behalf of **M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore** was present.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case due to absence of the firm in best interest of justice. The Board further decided to provide another/ final opportunity of personal hearing to the accused persons.

Personal Hearing notice(s) issued to accused person(s) on 17-02-2023.

Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 05-2020

Expiry Date:04-2022

Sampling Date (Form 4): 26-01-2021

Sent to DTL (Form 6): 28-01-2021

Date of receipt in DTL: 30-01-2021

DTL Report Date (Form 7): 2 4 - 0 5 - 2 0 2 1

1ST DI Communication with firm on dated: 07-08-2021

Date of Retesting Request of Firm: 20-08-2021

Fate of Retesting Request: Allowed, NIH Substandard

Investigation Report Dated: 12-04-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 73

Tehsil Jampur, District Rajanpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan** through its Managing Director Amir Siddique 2. Amir Siddique Managing Director 3. Muhammad Uzair Bhatti Production Manager 4. Muhammad Aslam Quality Control Manager 5. Aamir Siddique Warrantor of M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Jampur, District Rajanpur reported that: -

i. His predecessor, on 31-12-2020, inspected the premises of M/S Irfan Medical Store, Near THQ Hospital Jampur and took 3 different types of drug samples on Form No.04 and sent to Drug Testing Laboratory Multan for the purpose of test/analysis. The subject sample was sent vide memorandum no. 82506 dated 06-01-2021.

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

iii. M/S Irfan Medical Store, Near THQ Hospital Jampur provided invoice/ warranty 349 dated 01-12-2020 issued by M/S Gul Brothers, Block #5, New College Road, D.G. Khan as a proof of its purchase.

iv. Warrantor portion was sent to M/S Gul Brothers, Block #5, New College Road, D.G. Khan with direction provide requisite information in this regard.

v. M/S Gul Brothers, Block #5, New College Road, D.G. Khan provided invoice/ warranty no. Oct/01001 dated: 13-10-2020 issued by M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan as a proof of its purchase.

vi. A copy of test/analysis report was sent to M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan, with directions to explain their position and provide requisite information in this regard.

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

viii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

ix. Copy of NIH report was sent to M/s British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan.

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Manufacturer</th><th>DTL Report
TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Syrup Beroline 60ml (Salbutamol as Sulphate 2mg/5ml)

Mfg. Date: Sep-2020

Exp. Date: Sep-2022

Regs # 094671</td><td>20280</td><td>M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan</td><td>01-89002252/DTL

Dated: 08-03-2021</td><td>Analysis with specifications applied: BP 2019

<u>Description:</u>

Clear, Colorless solution in amber plastic bottle of 60ml sealed with white Aluminum cap packed in a labelled outer hard carton

<u>Identification:</u> Salbutamol as Sulphate identified.

<u>Assay:</u> (Salbutamol)

Analysis Method: HPLC
<table>
<tr><td>Stated</td><td>2mg/5ml</td></tr>
<tr><td>Determined</td><td>3.86mg/5ml</td></tr>
<tr><td>Percentage</td><td>192.81%</td></tr>
<tr><td>Limit</td><td>90-105%</td></tr>
</table>
<u>(Does not comply)</u>

<u>pH:</u>
<table>
<tr><td>Range</td><td>3.3-4.0</td></tr>
<tr><td>Determined</td><td>4.88 at 25^{o}C</td></tr>
</table>
<u>(Does not comply)</u>

<u>Result:</u> The above sample is “Substandard” on the basis of Assay and pH.</td></tr>
</table>

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>NIH Test Report No. & Date</th><th>NIH Test Report Results</th></tr>
<tr><td>Syrup Beroline 60ml (Salbutamol as Sulphate 2mg/5ml)
Mfg. Date: Sep-2020
Exp. Date: Sep-2022
Regs # 094671</td><td>20280</td><td>M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan</td><td>021-P/2022
dated: 10-06-2022</td><td>Analysis with specifications applied: BP 2017
<u>pH</u>:
<table><tr><td>Determined</td><td>4.9</td></tr><tr><td>Limit</td><td>Not available in BP2017</td></tr></table>
<u>Assay:</u>
<table><tr><td>Stated</td><td>2mg/5ml</td></tr><tr><td>Determined</td><td>3.9mg/5ml</td></tr><tr><td>Percentage</td><td>195.47%</td></tr><tr><td>Limit</td><td>90-105%</td></tr></table>
(Does Not Comply with BP2017)
<u>Result:</u> The sample is of <u>Substandard</u> quality on the basis of tests performed.</td></tr>
</table>

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

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

3. Show cause notice(s) issued to the accused vide 14-12-2022.

Reply to Show Cause:

With reference to letter no. PQCB/R-492/2022, dated 19-10-2022 received at our factory premises on 29-10-2022 with the subject "SHOW CAUSE NOTICE" regarding "Beroline Syrup 60ml Batch No. 20280" which was allegedly declared substandard from DRUGS TESTING LABORATORY MULTAN on the basis of Assay and pH test vide test report No.TRA-01-89002252/DTL, dated 08-03-2021.

It is submitted that at the time of final release, all the tests were performed and product was found of standard quality.

After receiving of DTL Multan report, we retested our retaining samples of said batch of "Beroline Syrup 60ml (Salbutamol as sulphate)" and all the parameters including assay and pH test were found within specifications. Reports of tests are attached for your kind consideration.

This is submitted with due respect that, according to Drug act 1976 the Drug inspector is bound to send sample to concerned DTL within 7 days. But in this case the sample was send to DTL on 9th day clearly violating the Drug Law.

Also, sir, NIH test report is time barred. According to drug law 1976 NIH is bound to generate the test report of sample within 60 days. But in our case the report was generated after 109th days. It must be noted that the Expiry date of said Product was September 2022(Expired) and NIH perform test in the month of june 2022 so the storage condition of the product will remain suspected and questionable.

Therefore, this is requested that NIH test report may consider as Null & voided. It is also found contradictory that NIH follow's BP2017 specifications while DTL Multan follows BP 2019 specification. BP2017 and BP 2018 do not mention the pH of the product. We follow in-house pH specification range 4.5-5.5 at the time of manufacturing. We have updated product specification following cGMP.

We didn't receive the warrantor portion of the said product another drug rule violated.

As per direction of Provincial Quality control Board we have also recalled the available stock of above product from market detail attached. The Recalled stock of the product was later destroyed as Expiry product (Mfg 9/2020 Exp 9/2022) in the presence of qualified technical staff. all of the recalled stock

4. Personal Hearing notice(s) issued to accused person(s) on 19-12-2022.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 255th Meeting held on 29-12-2022:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **255th meeting held on 29-12-2022** under the Chairmanship of Secretary Primary and Secondary Healthcare Department Punjab. Mr. Adil Jameel, Secretary DQCB District Rajanpur and Mr. Kaleem Bhutta, Drug Inspector, Tehsil Jampur, were present along with original case record. No one among the nominated accused persons was present on behalf of **M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan.**

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case due to absence of the firm in best interest of justice. The Board further decided to provide another/ final opportunity of personal hearing to the accused persons.

Personal Hearing notice(s) issued to accused person(s) on 17-02-2023.

Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 09-2020

Expiry Date:09-2022

Sampling Date (Form 4): 31-12-2020

Sent to DTL (Form 6): 06-01-2021

Date of receipt in DTL: 08-01-2021

DTL Report Date (Form 7): 0 8 - 0 3 - 2 0 2 1

1ST DI Communication with firm on dated: 20-03-2021

Date of Retesting Request of Firm: 29-03-2021

Fate of Retesting Request: Allowed, NIH Substandard

Investigation Report Dated: 06-08-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 74

Tehsil Jampur, District Rajanpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Venus Pharma, 23-km, Multan Road, Lahore, Pakistan** through its Managing Partner Pervaiz Iqbal Siddiqui 2. Pervaiz Iqbal Siddiqui Managing Partner/Warrantor 3. Malik Muhammad Asif Production Incharge 4. Muhamad Adnan Tahir Quality Control Incharge of M/S **Venus Pharma, 23-km, Multan Road, Lahore, Pakistan**.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Jampur, District Rajanpur reported that: -

i. His predecessor, on 17-03-2021, inspected the business premises of M/s Janjua Pharmacy, opposite THQ Hospital Jampur and took two different types of Drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.

ii. Following drug sample, sent vide memo no. 87325 dated: 17-03-2021, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, Multan, as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date
THREEBION [VITAMIN B1 (THIAMINE HCl) 100mg/3mL, VITAMIN B6 (PYRIDOXINE HCl) 100mg/3mL & VITAMIN B12 (CYANOCOBALAMIN) 1000mcg/3mL] INJECTION 3mL	H-26320	VENUS PHARMA, 23-KM. MULTAN ROAD, LAHORE.	TRA 01-89003063 /DTL Multan dated 08-05-2021

Specification applied: MS

Description: Clear red color solution filled in a sealed amber glass ampoule of 3mL with white printed label, white colored neck ring in a labeled outer hard carton. 25 ampoules holding in beehives are packed in a unit outer hard carton (25 * 3 Ampoules).

Extractable Volume

Limit: NLT stated

Determined: 3.28 mL **(Complies)**

pH:

Limit: 3.5-4.5

Determined: 3.70 mL at 25 ºC **(Complies)**

Sterility:

It conforms to sterility test **(Complies)**

Identification:

Vitamin B1 (Thiamine HCl), Vitamin B6 (Pyridoxine HCl) & Vitamin B12 (Cyanocobalamin) Identified.

Assay	Stated	Determined	Percentage	Limit	Result
Vitamin B1 (Thiamine HCl) (HPLC)	100 mg/ 3mL	64.69 mg/ 3mL	**64.69%**	90-115%	**Does Not Comply**
Vitamin B6 (Pyridoxine HCl) (HPLC)	100 mg/ 3mL	112.02 mg/ 3mL	112.02%	90-115%	**Complies**
Vitamin B12 (Cyanocobalamin) (UV-Spectrophotometer)	1000 mcg/ 3mL	958.4 mcg/ 3mL	95.84%	90-115%	**(Complies)**

Result: The above sample is **Substandard**, on the basis of **Tests** Performed.

iii. M/s Janjua Pharmacy, opposite THQ Hospital Jampur provided invoice/ warranty No. 1227 dated 02-01-2021 issued by M/S Venus Pharma, 23-km, Multan Road, Lahore, Pakistan, as a proof of purchase of subject drug sample.

iv. Warrantor portion of drug sample was sent to M/S Venus Pharma, 23-km, Multan Road, Lahore, Pakistan.

v. A copy of test/analysis report was sent to M/S Venus Pharma, 23-km, Multan Road, Lahore, Pakistan and they were asked to explain their position and provide the requisite information in this regard.

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

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

3. Show cause notice(s) issued to the accused vide 20-01-2023.

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

Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 07-2020

Expiry Date:07-2022

Sampling Date (Form 4): 17-03-2021

Sent to DTL (Form 6): 17-03-2021

Date of receipt in DTL: 18-03-2021

DTL Report Date (Form 7): 08-05-2021

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

Date of Retesting Request of Firm: 16-08-2021

Fate of Retesting Request: Allowed, FNA at NIH

Investigation Report Dated: 14-09-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 75

PQCB/R-335/2022

Tehsil Chichawatni, District Sahiwal

ATTENDANCE:

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

BRIEF FACTS OF THE CASE:

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

i. His predecessor, on 14-09-2022 inspected the business premises of M/s Ali Medical store, 90- More Chichawatni, Sahiwal, took following drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug testing Laboratory, Bahawalpur vide memorandum no. 140262 dated 15-09-2022

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Capsule Perl 20mg [Each capsule contains Enteric coated pellets eq to Omeprazole 20mg] **Mfg**. **Date**: 08-2022 **Exp**. **Date**: 09-2024 **Regn**. **No**: 022859	F-914	M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar	01-10097000217/DTL dated: 31-10-2022	**Result of test/ analysis with specifications applied: USP** 2022 **COMPOSITION:** Each capsule contains Enteric coated pellets eq to Omeprazole (BP)…… 20mg **DESCRIPTION**: off white color pellets filled in a pink color hard gelatin capsule. packed in a blister pack (primary packing) of 07 capsules. The capsule blister is 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 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 "**Mfg**. **Stanley specifications**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of "**Omeprazole delayed release 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** **DISSOLUTION TEST (USP)**: ***Tolerance limit***: Each unit is NLT 75% in 45 mins in buffer stage.

ACCEPTANCE CRITERIA						Avg
Each unit is not less than 75% (Q) in 45 mins						
1	2	3	4	5	6	
98.42%	98.4%	99.24%	100.67%	105.20%	107.59%	101.08%

IDENTIFICATION (USP): Omeprazole is identified

ASSAY (USP): Omeprazole

Stated: 20mg/cap

Determined: 20.35mg/cap

Percentage: 101.76%

Limit: 90-110%

RESULT: The sample is declared **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. M/s Ali Medical store, 90- More Chichawatni, Sahiwal, provided Invoice/Warranty No. SDB-0945612 dated 10-09-2022 issued by M/s Al- Noor Medicine Company House no. 15, Gulshan E Raheem Colony Burewala as proof of its purchase.

iv. Warrantor Portion of drug sample was sent to M/s Al- Noor Medicine Company House no. 15, Gulshan E Raheem Colony Burewala who in turn provided invoice/warranty no. 789 dated 24-08-2022 issued by M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar.

v. A copy of Test/ Analysis report was sent to M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar, 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. Showcause notice(s) issued to the accused

Firm submitted reply to show cause notice dated 16-02-2023

We rectified both unicarton and innermost aluminum foil of capsule Perl immediately *where product specification Stanley spec replaced with* ***USP Specifications****.*

As per DRAP Order F.3-5/2020-I & V-II (M-297) dated 7th February 2022. We M/s Stanley Pharma immediately rectified both uni-carton and innermost Al. foil of capsule Perl 20mg

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD;

Case No. 76

PQCB/R-576/2021

Punjab Health Facilities Management Company, District Sahiwal

ATTENDENCE

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

BRIEF FACTS OF THE CASE

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

i. He, on 06-09-2021, inspected premises of PHMC Medicine Store (Store inside District Office PHFMC Ganj Shakar Colony Chak No. 89/6-R District Store PHFMC Sahiwal) and took sample of drug on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 0000106016 dated 09-09-2021.

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

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

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

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

<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>Syrup Broxol DM (Dextromethorphan 6.25mg + Diphenhydramine HCl 5mg/5ml)
Mfg.date:
Jul-2021
Exp. date:
Jul-2023
Regn No.
022854</td><td>E-509</td><td>M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan</td><td>TRA No. 01-25008152/DTL
Dated:-27-11-2021</td><td><u>Analysis with specifications applied:</u>
Manufacturer Specification (MS)
<u>Composition:</u>
Each 5 ml contains:
Dextromethorphan HBr…6.25mg
Diphenhydramine HCl…5mg
<u>Description (MS):</u>
Pink color liquid in amber color sealed glass bottle.
(stated volume: 120 ml)
<u>Identification (MS):</u> Dextromethorphan HBr & Diphenhydramine HCl are identified.
<u>Assay (MS):</u>
Dextromethorphan HBr
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>6.25mg/5ml</td><td>5.74mg/5ml</td><td>91.76%</td><td>90.0-110.0%</td></tr>
</table>
Diphenhydramine HCl
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>5.0mg/5ml</td><td>9.97mg/5ml</td><td>199.37%</td><td>90.0-110.0%</td></tr>
</table>
(Does not Comply with Specifications)
RESULT:
The sample is declared <u>SUB-STANDARD</u> on the basis of <u>ASSAY TEST OF DIPHENHYDRAMINE HCL.</u></td></tr>
</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>Syrup Broxol DM</td><td>E-509</td><td>M/s Stanley Pharmaceuticals (Pvt.) Ltd.,, 84-B, Industrial State Hayatabad, Peshawar-Pakistan</td><td>096-P/2022 dated 13-06-2022</td><td>Analysis with specifications applied:
Manufacture Specifications
<u>ASSAY:</u>
<table>
<tr><th><u>ASSAY</u></th><th><u>STATED</u></th><th><u>FOUND</u></th><th><u>LIMIT</u></th><th><u>PERCENTAGE</u></th></tr>
<tr><td>Diphenhydramine HCl</td><td>5mg/5ml</td><td>8.52mg/5ml</td><td>90-110%</td><td>170.4%</td></tr>
<tr><td>Dextromethorphan HBr</td><td>6.25mg/5ml</td><td>5.93mg/5ml</td><td>90-110%</td><td>94.88%</td></tr>
</table>
Does not Comply with the Manufacturer’s specifications.
<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of tests performed.</td></tr>
</table>

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

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 26-10-2022.

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

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

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

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

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

Summary:

- **Manufacturing Date: 07-2021**
- **Expiry Date: 07-2023**
- **Sampling Date (Form 4): 06-09-2021**
- **Sent to DTL (Form 6): 09-09-2021**
- **Date of receipt in DTL: 15-09-2021**
- **DTL Report Date (Form 7): 27-11-2021**
- **Time Extension: Granted in 235th meeting dated 30-11-2021**
- **1ST DI Communication with firm on dated: 06-01-2022**
- **Date of Retesting Request of Firm:10-01-2022**
- **Fate of Retesting: Allowed (241th meeting dated 31-03-2022)**
- **Investigation Report Dated: 29-07-2022**

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

Case is placed before the board for decision.

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. Ahmed Awais, Secretary DQCB, District Sahiwal and Dr. M. Sheeraz, Drug Inspector Punjab Health Facilities Management Company were present along with the original case record. No one among the nominated accused persons of **M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan** appeared before the Board. However, a written request for adjournment was received from the firm vide letter no. Nil dated 09-12-2022 on behalf of the firm. The Board after due deliberation and discussion unanimously decided to **adjourn** the case in best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

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

Case is placed before the board for decision.

CURRENT PROCEEEDINGS & DECISION BY THE BORAD:

Case No. 77

DISTRICT SARGODHA

PQCB/R-213/2022

Tehsil Bhera District Sargodha

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan through its** Chief Executive Officer Amin Notta 2. Amin Notta — Chief Executive Officer 3. Muhammad Rizwan — Production Manager/ Warrantor 4. Umar Farooq — Quality Control Incharge Of **M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Bhera,, District Sargodha reported that: -

i. He on 28-06-2022 inspected the business premises of M/s Adnan Medical Store, Miani, Tehsil Bhera, District Sargodha, took sample of two different types of drugs on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Rawalpindi vide Memorandum No. 0000131879 dated 29-06-2022.

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

Name of drug	Batch no.	Name of manufacturer	DTL Test Report No. & Date	DTL Test Report Results
Film coated tablet Rhizin (Cetirizine Dihydrochloride: 10 mg) **Mfg. date:** Mar-2022 **Exp. Date:** Feb-2024 **Reg.No.** 021752	5046	M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan	TRA No. 01-75004118/DTL dated: 01-09-2022	**Result of Test/Analysis with Specifications applied:** USP 2022 **DESCRIPTION:** White colored, round shaped, biconvex tablet, plain from both sides, packed in Alu-PVC blister of 1*10s, further packed in outer labelled carton containing two blisters (20 Tablets). **Two different Manufacturing Specifications are mentioned on the label; Cibex specs on the blister whereas USP specs and Cibex specs on the outer carton. (DOES NOT COMPLY)** **IDENTIFICATION:** Cetirizine Dihydrochloride identified. **ASSAY:**

Stated	Determined	Percentage	Limit
10mg/tablet	10.703mg/tablet	107.03%	90-110%

RESULT: The above sample is Misbranded as defined under clause (iv) of subsection (s) of section 3 of The Drugs Act 1976.

iii. M/s Adnan Medical Store, Miani, Tehsil Bhera, District Sargodha provided invoice/ Warranty No. 210,271 dated 18-06-2022 issued by M/s Moeen Enterprises, House No. 102/2 Old Civil Lines Shamsher Road Sargodha as proof of their purchase.

iv. Warrantor Portion was sent M/s Moeen Enterprises, House No. 102/2 Old Civil Lines Shamsher Road Sargodha who in turn submitted Invoice/ Warranty No. 54588 dated 30-04-2022 issued by M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan as proof of their purchase.

v. A copy of Test/ Analysis report was sent to M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan and they were asked to provide requisite information in this regard.

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

i. **Manufacturing for Sale /Sale of Misbranded Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 05-01-2023.

Reply of firm to show cause notice vide letter no. nil dated nil

With reference to the show cause notice no. PQCB/R-213/2022 dated 05-01-2023, on the above noted subject the undersigned would like to explain as under;

As your kind self has mentioned in vour letter that the drug testing report dated 01-09-2022 of sample of our product Tab., RHIZIN 10mg, Batch No.S046. was declared Misbranded by Drug Testing Laboratory on the basis of misprinting / different specifications on the immediate and outer label.
That according to the report of analvst on the sample two different manufacturing specification were mentioned. *Cibex Specifications" was printed on blister whereas USP Specifications and Cibex Specs"
1as printed on the outer carton.
That the printing Mistake has now been rectified and corrected in accordance with law and labeling Rules. Copy of the Rectified Label of Outer Carton and blister are annexed herewith for ready reference.
That all the legal formalities and remedial measures have been taken in this regard and further, do hereby undertalke to be more careful in future. An undertaking to this effect is also annexed.
Regarding your queries mentioned in your letter referred above, copy of our Manufacturing License and Registration Certificate of the subject drug is annexed. It is also submitted that we have recalled almost 80% stock from the market.
The documents related to the subject case, as inquired by your kind self, are attached herewith for your kind perusal. Names of CEO/warrantor, Production Incharge and QC, already sent to you, are hereby verified as true.
Under the circumstances explained above it is most respectfully prayed that as the remedial measures had already been taken therefore the case may kindly be dropped or the warning may kindly be issued.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 03-2022**
- **Expiry Date: 02-2024**
- **Sampling Date (Form 4): 28-06-2022**
- **Sent to DTL (Form 6): 29-06-2022**
- **Date of receipt in DTL: 04-07-2022**
- **DTL Report Date (Form 7): 01-09-2022**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 15-09-2022**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 25-11-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 78

PQCB/SM-24-11/2022

Tehsil Ferozewala, District Sheikhupura

Form-

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Neutro Pharma, 9.5 km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Zia-ud-din 2. Zia-ud-din Chief Executive Officer 3. Muhammad Faheem Production Incharge 4. Zartash Gul Production Manager 5. Muhammad Ahsan Quality Control Manager/ Warrantor of **M/S Neutro Pharma, 9.5 km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. He, on 29-12-2021, along-with other team members inspected the manufacturing premises of M/s Neutro Pharma situated at 9.5 km Lahore Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API on Form 5:

Sr.NO.	Name of drugs	Batch No.	Expiry Date	Quantity
1.	Powder (Raw material) Tropisetron HCl	200601	01-05-2022	500 gms (Approx.)
2.	Powder (API) Tramadol HCl	TM2106002	10-06-2024	500 gms (Approx.)

ii. Accused present could not produce any documents regarding the sale/ consumption of APIs at the time of inspection. One cabinet was sealed under the provision of 18(1) of The Drugs Act 1976.

iii. He also took sample of four different types of drugs on Form 4 for the purpose of test/ analysis. These sample were declared of standard Quality from Drug Testing Laboratory, Lahore as detailed below:

Sr. No.	Name of Drug	Batch No.	TRA No.	Status
1	Inj. Indrop D	HP947	01-177000042/DTL dated 01-02-2022	Standard
2	Tab Affif 500 mg	2171PO85	01-171000353/DTL dated 09-02-2022	Standard
3	Inj. Neupine 1 g	1809PO54	01-177000044/DTL dated 11-02-2022	Standard
4	Tab. Lefoxin	1809PO86	01-171000352/DTL dated 18-01-2022	Standard

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. **Stock of Raw material without documentations**
b. **Violation of GMP conditions**

3. Show-cause was issued to accused person(s) vide dated 21-12-2022.

REPLY OF THE FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

4. M/s Neutro Pharma situated at 9.5 km Lahore Sheikhupura Road, Ferozewala, District Sheikhupura submitted written reply vide reference number Nil dated 07-02-2023 stating that:

*1. that in response to the show-cause Notice No. CB/SM-24-11/2022 dated 21-12-2022 wherein M/s Neutro Pharma Pvt. Ltd. (the **"company"**) has been directed to explain its position vis-à-vis allegations of "Stock of raw material without documentations" and violation of GMP conditions".*

2.At the very outset, company is highly respected and trusted pharmaceutical company in Pakistan engaged in the manufacturing and selling of high quality Pharmaceutical products. The company has consolidated its image by displaying firm commitment to quality and strict adherence to high standards and drug laws as well as GMP Guidelines.

3. In response to the mis-placed baseless allegations levelled in the show-cause notice under reply, we submit as under:

i. By way of background, it is submitted that on 29-12-2021 a team comprising of Drug Controller Sheikhupura, Drug Controller CDC, Provincial Drug Inspector and Deputy Controller Ferozewala conducted a raid on Company's Premises consequently one cabinet of API's at warehouse of the company had been sealed by the area inspector and two API's were seized. The sole reason for seizure of API's by the Provincial Drug Inspector were non-availability of requisite documents and records in hard copy/ form. The technical team of the company provided the Provincial Drug Inspector data of computerized software system (ERP) which was not accepted by the drug inspectors without any rhyme or reason.

ii. subsequently the company approached the Drug Court, Lahore for de-sealing purposes and sealed cabinet of API's was de-sealed vide order dated 09-05-2022.

iii. It is pertinent to mention here that at the time of de-sealing all necessary documents were submitted to the Provincial Drug Inspector. Furthermore, the company has adopted a protocol of keeping all record in physical form along-with the electronic record already being maintained by the same.

iv. *Furthermore, details of the seized API's are as under:*

Sr.NO.	Name of drugs	Batch No.	Expiry Date	Quantity
1.	Powder (Raw material) Tropisetron HCl	200601	01-05-2022	500 gms (Approx.)
2.	Powder (API) Tramadol HCl	TM2106002	10-06-2024	500 gms (Approx.)

It is clarified that 'Tropesetron HCl' was imported from Shandong Qidu Pharma. Co. Ltd. China and Tramodol HCl was imported from Virupaksha Organics Limited India. The purpose for import of Topesterone HCl" and "Tramadol HCl" was to manufacture registered products.

The Provincial Inspector also took sample of four different types of drugs on Form 4 for the purpose of test/ analysis. These sample were declared of standard Quality from Drug Testing Laboratory, Lahore as detailed below:

Sr. No.	**Name of Drug**	**Batch No.**	**TRA No.**	**Status**
1	Inj. Indrop D	HP947	01-177000042/DTL dated 01-02-2022	Standard
2	Tab Affif 500 mg	2171PO85	01-171000353/DTL dated 09-02-2022	Standard
3	Inj. Neupine 1 g	1809PO54	01-177000044/DTL dated 11-02-2022	Standard
4	Tab. Lefoxin	1809PO86	01-171000352/DTL dated 18-01-2022	Standard

Consequently, proceedings further against the company is futile and the captioned proceedings are liable to be dropped. In view of the above-mentioned reports from competent laboratory, it is pertinent to note that the company and its officials have engaged in the manufacturing of standard quality pharmaceutical products by using imported raw materials being purchased from approved vendors. There is no cavil to the fact that the company has always ensured strict compliance with Good Manufacturing Practices by manufacturing Quality Products.

4. In view of foregoing, it is most respectfully requested that the show-cause notice under reply may be withdrawn in the interest of justice, equity and fair-play.

Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 79

PQCB/SM-25-11/2022

Tehsil Ferozewala, District Sheikhupura

Form-

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Irza Pharma Pvt. Ltd., 10.2km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Muhammad Imran Javed S/o Abid Ali Jawa 2. Muhammad Imran Javed Chief Executive Officer/ Warrantor 3. Dr. Iftekhar Masud Plant Manager 4. Dr. Azmat Ali Production Incharge 5. Dr. Asim Khan Quality Control Incharge of **M/S Irza Pharma Pvt. Ltd., 10.2km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that :-

- He, on 13-01-2022, along-with other team members inspected the manufacturing premises of M/S Irza Pharma Pvt. Ltd., 10.2km Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API/ material on Form 5:

Sr.NO.	Name of drugs	Quantity
1.	A polythene bag without label/ information containing white powder	2 kg (Approx.)
2.	A polythene bag without label/ information containing white powder	1.5 Kg (Approx.)
3.	Workers in different sections without wearing hand gloves and safety kits.	

- Person present could not produce any documents regarding the sale/ purchase of raw materials/ drugs/ articles at the time of inspection.
- He also took sample of four different types of drugs on Form 4 for the purpose of test/ analysis. These sample were declared of standard Quality from Drug Testing Laboratory, Lahore as detailed below:

Sr. No.	**Name of Drug**	**Batch No.**	**TRA No.**	**Status**
1	E/D Chloramphenicol 0.5%	1ASI1	01-171000495/DTL dated 22-02-2022	Standard
2	Tablet Irzacip 500 mg	1CYK2	01-171000494/DTL dated 11-02-2022	Standard
3	Tablet Famosib	1CL1	01-171000497/DTL dated 22-02-2022	Standard
4	Drops Jaxcil 125 mg	1ETL1	01-171000496/DTL dated 22-02-2022	Standard

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. **Stock of Raw material without Sale Purchase Record**
b. **Stock without Labellings- Misbranded**
c. **Violation of GMP conditions**

3. Show-cause was issued to accused person(s) vide dated 21-12-2022.

REPLY OF THE FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

4. M/S Irza Pharma Pvt. Ltd., 10.2km Sheikhupura Road, Ferozewala submitted written reply vide reference number IP/01/2023 dated 07-02-2023 stating that:

Sr. No.	*Name of drugs*	*Justification*
1	*A polythene bag without label/ information containing white powder. Quantity 2.0 Kg (approx.)*	*A polythene bag containing white powder (2.0 kg) was starch and was placed in PRE DISPENSED AREA waiting for identification tag by the dispensing pharmacist as the procedure was in progress.* *Rest of the materials were properly tagged along-with the name of the product under dispensing on dated 13.01.2022 (Invoice of material attached)*
2	*A polythene bag without label/ information containing white powder.* *Quantity 1.5 Kg (approx.)*	*A polythene bag containing white powder (1.5 kg) was Magnesium Stearate and was placed in PRE DISPENSED AREA waiting for identification tag by the dispensing pharmacist as the procedure was in progress.* *Rest of the materials were properly tagged along-with the name of the product under dispensing on dated 13.01.2022 (Invoice of material attached)*
3	*Workers in different sections without wearing hand gloves and safety kits.*	*The blisters were packing in both sections in their respective unit cartons (Secondary Packing stage) where the gloves and safety kits are not mandatory because the product is not directly exposed at secondary packaging level.*

Different dosage forms of the finished products were also sampled by the authority and all found of STANDARD QUALITY declared by the DRUG TESTING LABORATORY LAHORE as detailed below,

Sr. No.	***Name of Drug***	***Batch No.***	***TRA No.***	***Status***
1	*E/D Chloramphenicol 0.5%*	*1ASI1*	*01-171000495/DTL dated 22-02-2022*	*Standard*
2	*Tablet Irzacip 500 mg*	*1CYK2*	*01-171000494/DTL dated 11-02-2022*	*Standard*
3	*Tablet Famosib*	*1CL1*	*01-171000497/DTL dated 22-02-2022*	*Standard*
4	*Drops Jaxcil 125 mg*	*1ETL1*	*01-171000496/DTL dated 22-02-2022*	*Standard*

We M/s Irza Pharma (Pvt.) Ltd. Always step ahead to meet the quality standard as the above REPORTS of the DTL revealed. We assure to the honourable board about our commitment to provide the good quality medicines to our valuable customer. We assure our best co-operation and services to maintain the quality of the product and shall not leave any stone unturned to get compliance of GMP.

4. Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 80

PQCB/SM-14-06/2022

Tehsil Ferozewala, District Sheikhupura

Form-

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Intervac Pvt. Ltd. 18-km, Sheikhupura Road, Ferozewala** through its Chief Executive Officer/ Warrantor Ashfaq Ahmad S/o Mumtaz Ahmad 2. Ashfaq Ahmad S/o Mumtaz Ahmad Chief Executive Officer/ Warrantor 3. Qasim Aziz S/o Abdul Aziz Production Incharge 4. Ammar Yasir S/o Amjad Baig Quality Control Incharge of **M/S Intervac Pvt. Ltd. 18-km, Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. He, on 09-06-2022, along-with other team members inspected the manufacturing premises of M/s Intervac Pvt. Ltd. Situated at 18-km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API/ material on Form 5:

Sr.NO.	Name of drugs	Batch No.	Expiry Date	Quantity
1.	Powder Oxyclozanide vet BP 85	OX3191221	11-2026	20 Kg (Approx.)
2.	Powder API Sulpha-chlorpyridazine	Svd.21080401	03-2023	5 kg (Approx.)
3.	Material Vitamin B-12	HS181216	09/2023	500 g (Approx)

ii. Accused present could not produce any documents regarding the sale/ consumption of APIs at the time of inspection. Raw Material store was sealed under the provision of 18(1) of The Drugs Act 1976 (as amended) and the rules framed thereunder.

iii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis. These samples were declared of standard Quality from Drug Testing Laboratory, Lahore as detailed below:

Sr. No.	Name of Drug	Batch No.	TRA No.	Status
1	Powder Negafus	NGF-184	01-17700610/DTL dated 28-07-2022	Standard
2	Liqued Leva-15	LV-241	01-171001611/DTL dated 03-08-2022	Standard

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. **Stocking of Raw material/ articles without sale purchase record**
b. **Stocking of Raw material/ articles without labellings- Misbranded**
c. **Violation of GMP**

3. Show-cause was issued to accused person(s) vide dated 21-12-2022.

Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 81

PQCB/SM-19-03/2018

Tehsil Ferozewala, District Sheikhupura

Form-

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Paradise Pharma, 23-Km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura** through its Managing Partner Muhammad Shahzad Khan 2. Muhammad Shahzad Khan — Managing Partner 3. Muhammad Sheraz Khan — Managing Partner 4. Mian Tariq Mehmood — Managing Partner 5. Muhammad Sajid Manzoor — Quality Control Manager 6. Muhammad Ali — Production Incharge of **M/S Paradise Pharma, 23-Km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. His Predecessor, on 20-02-2018, inspected the manufacturing premises of M/S Paradise Pharma, 23-Km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API/ material on Form 5:

Sr.No.	Name of drugs	Batch No.	Manufacturer	Quantity	Reason for Seizure
1.	Adult Glycerol Suppositories 12's 70% w/v	GS017	Paradise Pharma	10x06=60 Suppositories	Manufacturing under unhygienic conditions in the room established in the backyard of factory premises
2.	Ammonia solution strong 10 x 50 ml	AM-012	Paradise Pharma	10 x 04=40 packs	Manufacturing under unhygienic conditions in the room established in the backyard of factory premises
3.	Material Vitamin B-12	GV-016	Paradise Pharma	07 bottles	Manufacturing under unhygienic conditions in the room established in the backyard of factory premises
4.	Tincture Iodine 450 ml (as said by M. Sajid Manzoor) filled in plastic bottles capped with white screwable lid without label			08 bottles	Misbranded Drugs
5.	Adult Glycerol Suppositories 70% w/v	GS-017		50 Approx.	filled in plastic jar capped with green lid bearing label without unit carton
6.	Adult Glycerol Suppositories 70% w/v	GS-017		300 Suppositories	Plastic jar bearing label without cap
7.	A suppository making mold (punch & dye) approx. 12 x 12 inches being used to manufacture suppositories in a room established in a backyard of the factory premises under unhygienic condition without Good Manufacturing Practices (GMP)				
8.	Green screwable cap embossed with company logo			500 caps	
9.	Unit cartons of Adult Glycerol Suppositories	GS-017		200 unit cartons Approx.	
10.	Parapipe Elixer 30 ml	PE006	Paradise Pharma	25 packs	Non-compliance of GMP

ii. Person present could not produce any documents regarding the sale/ purchase of raw materials/ drugs/ articles at the time of inspection. Raw Material store and the rooms where the drugs manufacturing was carried out and elixir packing area were locked and sealed under the provision of 18(1) of The Drugs Act 1976 (as amended) and the rules framed thereunder.

iii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis. These samples were declared of standard Quality from Drug Testing Laboratory, Lahore.

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 of Misbranded Drugs**
b. **Manufacturing/ manufacturing for sale under unhygienic conditions.**
c. **Poor compliance/ violations of Schedule B-II (GMP) of Drugs (Licensing, Registration and Advertising) Rules.**

3. Show-cause was issued to accused person(s) vide dated 27-12-2022.

REPLY OF THE FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

4. M/S Paradise Pharma, 23-Km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura submitted written reply vide reference number Nil dated 03-02-2023 stating that:

a. Manufacturing/ Stocking of Misbranded Drugs	The drug was considered misbranded because of the missing primary packing material, i.e., without a label. The concerned drug were in the intermediate stage of the production processes at that time and was held due to shortage of packing material, which were filling and sealing of bottles (In-Process stage). After this stage, the drug was tested for in-process quality Check (IPQC) and released to the next stage of labeling and packing where the label adhered and the drug packed to final packing in shippers.
b. Manufacturing/ manufacturing for sale under unhygienic conditions.	The inspection team considered the area of plant used for storage of miscellaneous tools and objects which would be subjected to maintenance or discarded after thorough investigation as unhygienic conditions. The dubious areas were solely used for storage purposes for unnecessary tools and parts and not for manufacturing of any kind of product.
c. Poor compliance/ violations of Schedule B-II (GMP) of Drugs (Licensing, Registration and Advertising) Rules.	The organization responded to the team's concerns about non-compliance with Schedule B-II of GMP by reviewing and upgrading all relevant documents, processes, and records. This was done after an inspection by a panel of the DRAP (Drug Regulatory Authority of Pakistan), which revealed the guidelines and areas that needed improvement. The thorough inspection led to the decision to improve compliance with Schedule B-II GMP. The central Licensing Board (CLB) allowed to restart the production activities at the premises after reviewing the inspection report from the DRAP team. This decision was communicated in the letter, F.8-3/2019-QA (M-271-CLB), dated on October 1st, 2019. The team also collected samples of two different types of drugs on Form 4 for testing and analysis. After providing the method of analysis and necessary documents to the drug testing laboratories in Lahore, the samples were deemed to be of standard quality according to the results from the Laboratories.

Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 82

PQCB/R-283/2022

Allama Iqbal Memorial Teaching Hospital, Sialkot

Misbranded

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan** through its Chief Executive Officer Bilal Ajmal 2. Bilal Ajmal — Chief Executive Officer 3. Muhammad Shahid Iqbal Khan — Production Manager 4. Muhammad Basit — Quality Control Incharge/Warrantor of **M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Allama Iqbal Memorial Teaching Hospital, Sialkot reported that: -

i. She, on 01-04-2022 inspected the premises of Medicine Store of Allama Iqbal Memorial Teaching Hospital, Sialkot, took following drug sample on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memo no. 121724 dated 01-04-2022.

ii. The following 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
Film coated tablet Demxet [Each film coated tablet contains: Fexofenadine HCl eq. to Fexofenadine…120mg] **Mfg. Date:** 01-2022 **Exp. Date:** 12-2023 **Regn. No:** 092561	T32014	M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.	01-68014904/DTL dated: 03-06-2022	**Result of test/ analysis with specifications applied:** Manufacturer's Specifications **DESCRIPTION**: Sea green colored oblong shaped biconvex tablet, engraved "DEMONT" on one side and scored line on reverse, contained in ALU-PVC packing of 10's, packed in outer hard carton. **Uniformity of Weight (Mass):** Comply the acceptance criteria of Uniformity of weight as per MS. (Average weight of Tablet: 355.20 mg). **Tolerance Limit:** ± 5% of Average weight. (Manufacturer's Specifications) **Reference Limit:** 337.4 -373.0 mg **Determined Limit:** 346.7-359.8 mg (Complies) **Identification:** Fexofenadine HCl is identified. **ASSAY:** Stated: 120 mg Fexofenadine/ Tablet (As per label Claim) Determined: 119.696 mg Fexofenadine / Tablet Percentage: 99.746 % (Complies) Limit: 93-107% (Manufacturer's Specifications) **Disintegration Test:** (Complies) **Labelling Requirements:** **Stated:** According to Drugs Act, 1976 Section 3 (s)(iv), Misbranded means: "it's label or container or anything accompanying which, bears any statement or design or device which makes any false claim for the drug or which is false or misleading in any particular." **Observed:** Product specs of given sample is printed as," USP Specs" According to USP 2022, "Fexofenadine Hydrochloride tablets contain NLT 93.0% and NMT 107.0% of the labelled amount of Fexofenadine Hydrochloride" whereas manufacturer specify label claim as "Each film-coated tablet contains: Fexofenadine Hydrochloride eq. to Fexofenadine…120 mg" which is contradictory to the statement of United States Pharmacopeia and is misleading and in violation to Drugs Act 1976. **(Does not Comply).** **RESULT:** Given sample is **Misbranded** with regards to Labelling (as per Section 3 (s)(iv) of The Drugs Act 1976).

iii. Storekeeper of Medicine Store of Allama Iqbal Memorial Teaching Hospital, Sialkot, provided invoice/ warranty No. Fac-22-03-012473 dated 18-01-2022 issued by M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.

iv. Warrantor Portion of the drug sample was sent to M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.

i. A copy of Test/ Analysis report was sent to M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan with directions to explain the 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: -

i. **Manufacture for Sale /Sale of Misbranded Drug**
ii. **Issuance of false warranty**

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

Note: Firm has submitted rectified label of the product

4. Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 83

PQCB/R-284/2022

Allama Iqbal Memorial Teaching Hospital, Sialkot

Misbranded

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan** through its Chief Executive Officer Bilal Ajmal 2. Bilal Ajmal — Chief Executive Officer 3. Muhammad Shahid Iqbal Khan — Production Manager 4. Muhammad Basit — Quality Control Incharge/Warrantor of **M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Allama Iqbal Memorial Teaching Hospital, Sialkot reported that: -

i. She, on 14-05-2022 inspected the premises of Medicine Store of Allama Iqbal Memorial Teaching Hospital, Sialkot, took following drug sample on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memo no. 126297 dated 14-05-2022.

ii. The following 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
Sustained release capsule Flowset-SR [Each capsule contains Tamsulosin HCl sustained release pellets eq. to Tamsolusin… 0.4mg] **Mfg. Date:** 02-2022 **Exp. Date:** 02-2024 **Regn. No:** 085175	C10018	M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.	01-68015851/DTL dated: 06-07-2022	**Result of test/ analysis with specifications applied:** Manufacturer's Specifications **DESCRIPTION**: off-white pellets filled in orange colored hard-gelatin capsule contained in ALU-PVC blister of 10's, packed in outer hard carton. **Identification:** Tamsulosin HCl is identified. **ASSAY:** Stated: 0.4mg mg Tamsulosin / Capsule (As per Label Claim) Determined: 0.368 mg Tamsulosin / Capsule Percentage: 92 % (Complies) Limit: 90-110% Dissolution Test: Complies Labelling Requirements: According to Drugs Act, 1976 Section 3 (s)(iv), Misbranded means: Stated: "it's label or container or anything accompanying which, bears any statement or design or device which makes any false claim for the drug or which is false or misleading in any particular." Observed: Product specs of given sample is printed as," USP Specs" According to USP 2022, "Tamsolusin Hydrochloride capsules contain NLT 90.0% and NMT 110.0% of the labelled amount of Tamsolusin hydrochloride" whereas manufacturer specify label claim as "Each capsule contains: Tamsolusin HCl sustained release pellets eq. to Tamsolusin… 0.4mg" which is contradictory to the statement of United States Pharmacopeia and is misleading and in violation to Drugs Act 1976. (Does not Comply). **RESULT:** Given sample is **Misbranded** with regards to Labelling (as per Section 3 (s)(iv) of The Drugs Act 1976).

iii. Storekeeper of Medicine Store of Allama Iqbal Memorial Teaching Hospital, Sialkot, provided invoice/ warranty No. Fad-22-04-012906 dated 18-04-2022 issued by M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.

iv. Warrantor Portion of the drug sample was sent to M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan with directions to explain the 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: -

i. **Manufacture for Sale /Sale of Misbranded Drug**
ii. **Issuance of false warranty**

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

Note: Firm has submitted rectified label of the product

4. Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 84

PQCB/R-217/2022

Tehsil & District Vehari

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan** through its Managing Director Syed Saleem Asghar 2. Syed Saleem Asghar — Managing Director 3. Sajjad Hussain — Production Manager/Warrantor 4. Muhammad Mudassir — Quality Control Manager of M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan**.**

BRIEF FACTS OF THE CASE:

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

i. She, on 25-08-2022, inspected the Main medicine store of Chief Executive Office (DHA) Vehari, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan vides memorandum no. 138113 dated 26-08-2022.

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

iii. Store Keeper, medicine store of Chief Executive Office (DHA) Vehari, provided invoice/warranty No. IP-6813 dated 02-08-2022 issued by M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan.

iv. Warrantor Portion was sent to M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan, with directions to provide the requisite information.

v. Copy of test/analysis report was sent to M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan. with directions to explain their position in this regard.

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Dispersible Tablet Orazinc 20mg (Each tablet contain: Elemental zinc (as Zinc Sulphate Monohydrate 20mg) **Mfg. date**: 07-2022 **Exp. Date**; 06-2024 **Regn. No.** 066593	268	M/S Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan	01-94005667 /DTL dated: 29-09-2022	**Result of test/ analysis with specifications applied:** MS **DESCRIPTION**: White colored, oval shaped tablet, engraved "AMSON" on one side & line of bisection on other side, in ALU-ALU blister of 10 units packed in a labelled outer hard carton. Each outer carton contains 3 blisters i.e., (3x10=30) tablets per pack. Product claims USP Finished Drug Product Specifications. According to USP monograph of Zinc Sulfate Tablets, under labeling **"Label the tablets 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/Tablet" which is false and misleading. **Misbranded (Does Not Comply)** **IDENTIFICATION** Elemental Zinc identified **ASSAY:** Elemental Zinc Stated 20mg/ Tablet Determined 19.30mg/ Tablet Percentage 96.48**%** Limit: 95-105% **(Complies)** **DISINTEGRATION TEST:** NMT 60 seconds **(Complies)** **RESULT:** The sample is **Misbranded** as defined under section 3 s (iv) of the Drug Act 1976.

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. Showcause notice(s) issued to the accused dated 22-12-2022

Firm submitted rectified label

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

CURRENT PROCEEDINGS & DECISION BY THE BOARD;

Case No. 85

PQCB/R-384/2020

Tehsil & District Vehari

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore** through its Managing Director Salman Shahid 2. Salman Shahid Managing Director 3. Hafiz Tariq Mehmood Production Incharge/Warrantor 4. Nuzhat Kausar Mumtaz Quality Control Incharge of M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore.

BRIEF FACTS OF THE CASE:

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

i. He, on 21-09-2020 inspected the premises of Main Medicine Store of CEO (DHA) Office Vehari and took samples of seven different types of drugs on Form No. 4 for the purpose of test/analysis.

ii. One out of seven drug samples, 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
Bandages. Elastocraft 10cm*4.5m [Cotton Crepe Bandage 10cm*4.5m]	30B20	M/s COTTON CRAFT, Plot No. 407, 408 SUNDER INDUSTRIAL ESTATE RAIWIND ROAD LAHORE.	01-89000336/DTL dated 26 Oct 2020	**Result of test/ analysis with specifications applied:** BPC 1973 **DESCRIPTION:** Cotton crepe bandage consists of characteristic fabric of plain weave, in one continuous length containing no joints, clean and reasonably free from weaving defects, cotton leaf, and shell having fast edges. **(Comply)** **Warps:** Limits: Avg NLT 17 / cm Determined: 15.68/ cm **(Does Not Comply)** **Wefts:** Limits: Avg NLT 78 / 10 cm Determined: 82.7/ 10 cm **(Comply)** **Weight g / m^2:** Limit: NLT 140 g / m^2 Determined: 126.67 g/ m^2 **(Does not Comply)** **RESULT:** The above sample is **Sub-standard** on the basis of tests performed.

iii. Storekeeper, CEO DHA Vehari, provided Invoice/Warranty bearing No. 0105 dated 12-08-2020 issued by M/s Cotton Craft, Plot No. 407, 408 Sunder Industri Estate Raiwind Road Lahore, Pakistan as a proof of its purchase.

iv. Warrantor Portion of drug sample was sent to M/s Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind Road Lahore, Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind Road Lahore, Pakistan with direction to expla 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 drug**
ii. **Issuance of false warranty**

Summary:

Manufacturing Date: 02-2020

Expiry Date: 01-2025

Sampling Date: 21-09-2020

Sent to DTL (Form 6): 21-09-2020

Date of receipt in DTL: 24-09-2020

DTL Report Date: 26-10-2020

1ST DI Communication with firm on dated: 07-11-2020

Date of Retesting Request of Firm: No

Investigation Report Dated: 11-02-2021

3. Showcause notice(s) issued to the accused dated 24-02-2021

Firm submitted reply of Show cause vide letter Ref: 786/0458/2021 dated 09-03-2021

We would like to bring to your kind notice that the sample of the same batch No. 30B20 of the same item has also been taken from the Medicine Store CEO DHA Bahawalpur and tested by the DTL Bahawalpur and declared as "Pass of Standard Quality".

In the light of above DTL report we are unable to understand that how the analyst of the DTL Multan declared the same batch 30B20 as "Sub-standard", whereas the other DTL declared it as "Pass of Standard Quality. It is stated that the same batch was supplied at the same time to the consignees including CE0, DHA Vehari.

It is mentioning that as per Revised Specification Notification No.F.6/2005-Reg-II (South) dated 13.09.2006 issued by the Ministry of Health, Government of Pakistan Islamabad, a variation in the threads and weight is allowed ±5%.

We do understand that if the Thread count complies the specification, then it is understood that weight per unit area is also complies. And there is no question of any shortfall in the weight, hence we confirm the sample under reference is complies the required standards. We understand it might be happened in weighing the sample casually and ensure it is up-to the required limit.

other than the two test all necessary parameters (Weft, Width, Length, Elasticity etc.) required under the BPC specification also complies as per DTL Multan vide his report No. TRA-01-89000336/DTL dated 26.10.2020 and confirms it is up-to the standards.

Hence our submissions are as under: -

We are very much conscious about the quality and quantity of the products and do not compromise on the quality of our product in any case.

It is positive to mention here that we tested the retained sample of the said Batch No. 30B20 of Cotton Crepe Bandage BPC 10cm x 4.5m at our Quality Control Lab and observe it is of "Standard Quality" and there is no such shortfalls in the sample as reported by the Analyst in his report.

Further, it is worthwhile to mention here that the Surgical Bandages (Cotton Crepe Bandage) is meant for external use only and it has many commercial usages other than medical purposes like Cleaning of Machinery, Polishing etc. Further stated that the Product (Medical Device) under reference is complies all test according to

the BPC specifications and observations find by the Analyst for declaring sub-standard are of minor nature, unfortunate, ignorable and we understand has no such effect in externally use on human body. Even though if the authority feels it necessary, we are ready to replace the seized stock with fresh stock of standard quality.

In the light of above said facts it is submitted that we have not contravened the provisions of Section 23/72 of the Drug Act 1976 (as amended)/DRAP Act 2012 and Rules framed there under by the way of (a) Manufacturing for sale/Selling of Substandard drug (6) Issuance of false warranty.

Keeping in view the above said explanation it is stated that the Drug / Medical Device under reference is complies all test according to the BPC specifications and observations find by the Analyst for declaring sub-standard is unfortunate, which may kindly be ignored and stock under reference may be accepted or otherwise allow to return "out of specification'" seized stock to us with the conditions of replacement by fresh stock of standard quality for which we shall be highly obliged.

3. Personal Hearing notice(s) issued to accused person(s) dated 06-07-2022

Case is placed before the Board for Decision

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 **247th meeting** held on **21-07-2022** under the chairmanship of Vice Chairperson, in the presence of Board members as mentioned above. Mr. Imran Rasheed, Secretary DQCB Vehari, was present along with the original case record. No one among the nominated accused persons of M/s Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind road Lahore was present. Firm submitted written request for adjournment that Managing Director of the firm was suffering from old flu and fever and unable to attend meeting dated 21.7.2022.

5. The Board after discussion decided to **adjourn** the case on the request of the firm in the best interest of justice. The Board further decided to provide another opportunity of hearing to the accused persons.

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD: