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

260 Meeting of PQCB

Date: 04-05-2023

Time: 10:00 AM

Venue

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

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ITEM No. 1

COURT CASES

Case No. 1

PQCB/ R-711/2019

Government Medical Store Depot, Punjab

ATTENDENCE

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

ORDER SHEET

IN THE LAHORE HIGH COURT

LAHORE

JUDICIAL DEPARTMENT

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

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

Date of Order: 09-02-2023

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

BRIEF FACTS OF THE CASE

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

i. He, on 06-07-2019 inspected the premises of IRMNCH warehouse, Maraka, Lahore, and took drug samples of eighteen different types of drugs on Form No. 4 for the purpose of test/analysis.
ii. Three out of eighteen drug samples after test/ analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, Bahawalpur as detailed below: -

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

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

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

v. A copy of Test/ Analysis report was sent to M/S Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan and they were directed to provide requisite information in this regard.

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

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

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

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

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

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

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

ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s)

Reply of the Firm to the Show Cause Notice:

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

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

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

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

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

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

1) Nadeem Panjatan (Managing Director)

CNIC # 42101-1397557-5

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

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

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

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

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **235th meeting** held on **30-11-2021**. Mr. Hassan Saeed, Secretary DQCB, District Lahore and Mr. Ubaid Ullah Anwer, Provincial Inspector of Drugs, Government Medical Store Depot, Punjab was present along with the original case record. Among the nominated accused persons, Dr.

Zamir-ul-Hassan (COO/Managing Director) along with Sohail Aslam, Representative of M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan appeared before the Board. Representatives of the firm presented following arguments in their case:

i. Global pharmaceuticals (Pvt) limited also recalled all three batches as a gesture of Goodwill through a public notice in Newspaper dated 20-01-2020 keeping in view the patient safety and in compliance with directions of PQCB.
ii. These batches are manufactured for Punjab Government only and supplied to IRMNCH Maraka. These are still under custody of said warehouse.
iii. These batches were not supplied to the private market, so all stock is placed under government custody as a case property.
iv. All batches have been expired and will be disposed of. It is added that no payment has been received against these three batches.

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

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

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

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

For the offences of:

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

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

REVIEW PETITION:

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

Brief facts of the case are as under;

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

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

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

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

a) if samples taken conform to the stated specifications chemically do not fall within the definition of the substandard drugs.
b) That the learned single Judge rightly held the term (substandard Drug with particles is not known to the Drug Act and that is true.
c) There was nothing on the record to show, as to what is the nature of the particles found in the samples, and what are its consequences? (Whether injurious to health).
d) That Analyst's report in question, when considered within meaning of the definitions of "Adulterated Drug", spurious and substandard drug as given in section 3 of Drug Act 1976, the drugs tested and reported, fell outside the category of definitions of substandard, spurious and adulterated drugs.
14- That the above results have shown in a crystal clear manner that the sample of Injection a) Transolide 500mg/5ml (Tranexamic Acid\ Batch no. 19C051 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 99.03% which is with in pharmacopoeia limit of 90-105%. *A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 02 out of 20 ampoules containing undissolvable visible particulate matter" without stating its nature/composition and consequence in terms of "injurious to health'. Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183.
b) Transolide 500mg/5ml (Tranexamic Acid) Batch no. 19C053 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 98.25% which is within pharmacopoeia limit of 90-105%. “A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 04 out of 20 ampoules containing stating its undissolvable visible without matter* particulate nature/composition and consequence in terms of "Injurious to health". Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183.

c) Transolide 500mg/5ml (Tranexamic Acid) Batch no 19A038 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 102.96%o which is within pharmacopoeia limit of 90-105%. “A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 01 out of 20 ampoules without matter" stating it’s containing undissolvable visible particulate nature/composition and consequence in terms of "Injurious to health". Reliance on 1992 MLD 481 1992. 1996 PCr. LJ I183.
15. That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic
acid) Batch no. 19C051 had been declared as of standard quality by the report dated 21- 08-2019 of DTL Rawalpindi, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.
That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19C053 had been declared as of standard quality by the report dated 10- 08-2019 of DTL Rawalpindi, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.
That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19A038 had been declared as of standard quality by the report dated 06- 05-2019 of DTL Multan, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.
16. That the absence of the full protocols of test in the above is crystal clear violation of Drug Laws. Reports of Analyst have to be conclusive and must disclose the protocols of tests applied to formulate opinion of Government Analyst. The description of the testing procedure must be crystal clear whenever report would be disputed.
Reliance on PLD 2003 Lahore

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

19. That not a single unit of said drug has been supplied in the market, even then we recalled all batches through a public notice in newspaper dated 20-01-2020.
20. That no adverse consequence about said drug is on record.
21. That the drug in question is of standard quality with regards to assay, sterility test, and other physical parameters and thus there is no risk on the use of drug for patients.
22. That in the impugned order has been passed contravene to 1992 MLD 481 Lahore title PQCB and others versus Irza pharma and others in which Hon'ble Court has declared such report against the law which is on the basis of on physical observation o undissolved visible particles. In the reliance Hon'ble Lahore High Court has observed that the size of the particle would have been determine that whether it may be injurious to health or not. In this context. It is further necessary to mention here that Board itself has directed to Director DTL Punjab through written letter in the year 1990.
23. That the said test reports are incomplete, non-conclusive and illegal and thus the same are not admissible evidence in the eye of Law.

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

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

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

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

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

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

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

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

Case is placed before the Board for decision.

Summary:

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

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

Sampling Date: 06-07-2019

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

Date of receipt in DTL: 13-07-2019

DTL Report Date: 26-08-2019

Time Extension: N/A

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

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

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

Investigation Report Dated: 22-11-2021

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 2

PQCB/ R-712,713/2019

Government Medical Store Depot, Punjab

ATTENDENCE

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

ORDER SHEET

IN THE LAHORE HIGH COURT

LAHORE

JUDICIAL DEPARTMENT

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

Date of Order: 09-02-2023

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

BRIEF FACTS OF THE CASE

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

i. He, on 06-07-2019 inspected the premises of IRMNCH warehouse, Maraka, Lahore, and took drug samples of eighteen different types of drugs on Form No. 4 for the purpose of test/analysis.
ii. Three out of eighteen drug samples after test/ analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, Bahawalpur as detailed below: -

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

iii. Store Incharge, IRMNCH warehouse, Maraka provided Warranty bearing No. 501874 dated 03-06-2019 issued by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle,

Kahuta Road, Islamabad, Pakistan as proof of its purchase.

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

v. A copy of Test/ Analysis report was sent to M/S Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan and they were directed to provide requisite information in this regard.

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

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

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

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

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

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

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

ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s)

Reply of the Firm to the Show Cause Notice:

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

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

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

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

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

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

1) Nadeem Panjatan (Managing Director)

CNIC # 42101-1397557-5

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

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

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

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

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

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

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

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

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

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

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

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

For the offences of:

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

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

REVIEW PETITION:

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

Brief facts of the case are as under;

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

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

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

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

a) if samples taken conform to the stated specifications chemically do not fall within the definition of the substandard drugs.
b) That the learned single Judge rightly held the term (substandard Drug with particles is not known to the Drug Act and that is true.
c) There was nothing on the record to show, as to what is the nature of the particles found in the samples, and what are its consequences? (Whether injurious to health).
d) That Analyst's report in question, when considered within meaning of the definitions of "Adulterated Drug", spurious and substandard drug as given in section 3 of Drug Act 1976, the drugs tested and reported, fell outside the category of definitions of substandard, spurious and adulterated drugs.
14- That the above results have shown in a crystal clear manner that the sample of Injection a) Transolide 500mg/5ml (Tranexamic Acid\ Batch no. 19C051 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 99.03% which is with in pharmacopoeia limit of 90-105%. *A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 02 out of 20 ampoules containing undissolvable visible particulate matter" without stating its nature/composition and consequence in terms of "injurious to health'. Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183.
b) Transolide 500mg/5ml (Tranexamic Acid) Batch no. 19C053 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 98.25% which is within pharmacopoeia limit of 90-105%. “A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 04 out of 20 ampoules containing stating its undissolvable visible without matter* particulate nature/composition and consequence in terms of "Injurious to health". Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183.

c) Transolide 500mg/5ml (Tranexamic Acid) Batch no 19A038 is standard quality because it has been determined in chemical assay that therapeutic ingredient Tranexamic Acid is 102.96%o which is within pharmacopoeia limit of 90-105%. “A drug could not be declared as substandard when it meets the chemical specification." Nevertheless, he has erroneously declared the sample as substandard because of the observation "solution, filled in transparent glass printed ampoule (stated volume 5ml). 01 out of 20 ampoules without matter" stating it’s containing undissolvable visible particulate nature/composition and consequence in terms of "Injurious to health". Reliance on 1992 MLD 481 1992. 1996 PCr. LJ I183.
15. That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic
acid) Batch no. 19C051 had been declared as of standard quality by the report dated 21- 08-2019 of DTL Rawalpindi, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.
That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19C053 had been declared as of standard quality by the report dated 10- 08-2019 of DTL Rawalpindi, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.
That the sample of drug of same batch of Injection Transolide 500mg/5ml (Tranexamic acid) Batch no. 19A038 had been declared as of standard quality by the report dated 06- 05-2019 of DTL Multan, which was a very strong evidence for retesting, but unfortunately Board did not take it into consideration.
16. That the absence of the full protocols of test in the above is crystal clear violation of Drug Laws. Reports of Analyst have to be conclusive and must disclose the protocols of tests applied to formulate opinion of Government Analyst. The description of the testing procedure must be crystal clear whenever report would be disputed.
Reliance on PLD 2003 Lahore

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

19. That not a single unit of said drug has been supplied in the market, even then we recalled all batches through a public notice in newspaper dated 20-01-2020.
20. That no adverse consequence about said drug is on record.
21. That the drug in question is of standard quality with regards to assay, sterility test, and other physical parameters and thus there is no risk on the use of drug for patients.
22. That in the impugned order has been passed contravene to 1992 MLD 481 Lahore title PQCB and others versus Irza pharma and others in which Hon'ble Court has declared such report against the law which is on the basis of on physical observation o undissolved visible particles. In the reliance Hon'ble Lahore High Court has observed that the size of the particle would have been determine that whether it may be injurious to health or not. In this context. It is further necessary to mention here that Board itself has directed to Director DTL Punjab through written letter in the year 1990.
23. That the said test reports are incomplete, non-conclusive and illegal and thus the same are not admissible evidence in the eye of Law.

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

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

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

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

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

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

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

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

Case is placed before the Board for decision.

Summary:

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

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

Sampling Date: 06-07-2019

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

Date of receipt in DTL: 13-07-2019

DTL Report Date: 26-08-2019

Time Extension: N/A

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

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

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

Investigation Report Dated: 22-11-2021

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 3

PQCB/ R-198/2021

Punjab Institute of Neurosciences, Lahore

(Court Direction Case)

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan** through its COO/Managing Director, Dr. Zamir-ul-Hassan 2. Dr. Zamir-ul-Hassan COO/Managing Director 3. Umair Ahmed Production Manager 4. Muhammad Ibrahim Quality Control Manager 5. Waheed Shah Warrantor of M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan.

Order dated 09-02-2023 in W.P. No. 55855/2022

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

BRIEF FACTS OF THE CASE

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

i. She, on 23-06-2021, inspected the Main Medicine Store of Punjab Institute of Neurosciences, Lahore and took sample of following drug on Form No.04 for the purpose of test/analysis.
ii. The drug sample after test/analysis was declared as **Misbranded** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report
TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Powder for Injection. Merem 1g [Meropenem USP….1g/ Vial)</td><td>21E098</td><td>M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan</td><td>01-156001510/DTL
dated
26-08-2021</td><td>
Analysis with specifications applied: USP 2021

<u>PHYSICAL DESCRIPTION:</u> White coloured powder for injection in transparent glass vial with rubber stopper, aluminium seal and brown flip off cover.

<u>Observation:</u> Out of 25 units received, 07 units are found with label claim of “Merem 500mg (Meropenem) USP” on outer carton, whereas label on immediate container, i.e., vial of these 07 units bear “Merem 1g (Meropenem) USP”.

The inner and outer label of these 07 units are different in label claim strength.

(MISBRANDED DRUG)

<u>pH:</u>

Limit: 7.3 – 8.3

Determined: 8.08 at 23.6 °C

<u>IDENTIFICATION:</u> The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (MEROPENEM identified)

<u>ASSAY OF MEROPENEM:</u>

(On basis of immediate label claim on vial)
<table>
<tr><td>Stated</td><td>1 g/ Vial</td></tr>
<tr><td>Determined</td><td>1.1 g/ Vial</td></tr>
<tr><td>Percentage</td><td>110.0%</td></tr>
<tr><td>Limit</td><td>90% - 120% of the labelled amount</td></tr>
</table>
<u>STERILITY:</u> The product is sterile.

<u>RESULT:</u> The above sample is <u>MISBRANDED</u>, on the basis of THE DRUGS ACT 1976 3{s (iv)}
</td></tr>
</table>

iii. Storekeeper of Punjab Institute of Neurosciences, Lahore provided warranty bearing No. 6203811 dated 21-06-2021 issued by M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan as a proof of its purchase.

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

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

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

a. **Manufacturing/ Stocking /Selling of Misbranded drug**

b. **Issuance of false warranty**

3. Showcause was issued to accused person(s) dated 09-11-2021

Reply of the Firm to the Show Cause Notice:

We did complete investigation, and we are assure on the basis of investigation ***there may be only 20-30 cartons mixed from the Printer (Supplier) in the consignment,*** *which if you allow, can be sorted out to remedied the consignment supplied to Punjab Institute of Neurosciences, Lahore.*

Reply of the Firm to the Drug Inspector:

- *We checked all the documents including BMR, QC testing reports of all components including Packaging material testing reports and also inspect the Packaging material store to sort out the root cause of this discrepancy. During inspection of packaging material store,* ***we observed that this mixing of Unit Carton of Merem Inj 500mg in Unit Carton of Merem Inj 1gm was by mistake done at the Supplier end****; we could not observe this issue during testing and sampling of the said lot due to very low percentage (only 20-30 cartons) in whole lot.*
- *The investigation reveal that* ***only 1-2 sheets of Merem 500mg containing 20-30 cartons may be mixed with Merem 1gm carton.***
- *So we assure on the basis of investigation there may be only 20-30 cartons in the consignment, which if you allow, can be sorted out to remedied the consignment supplied to Punjab Institute of Neurosciences, Lahore.*
- ***We took a strict action against the supplier, also performed detailed audit of the said printing press, they have proper system and they are following the system including line clearance before starting the printing of any lot.*** *Supplier committed that in future they must sort and verify the quality of the supply before sending to Global Pharma.*
- *Moreover, we have revised our system for ordering of packaging material and instructed the procurement department to follow the below mentioned advices*
- ***If any product range have same dimension for two different strengths, then order of both strengths will be given to two different suppliers.*** *This will make zero chance of mixing of the packaging material of two different strength of the same product.*
- *QA and Production staff will also check more vigilantly the packaging components during packaging process.*

4. Personal Hearing notice(s) issued to accused person(s) dated 22-11-2021

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

235th meeting held on 30-11-2021

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

i. We checked all the documents including BMR, QC testing reports of all components including Packaging material testing reports and also inspected the Packaging material store to sort out the root cause of this discrepancy. During inspection of packaging material store, we observed that this mixing of Unit Carton of Merem Inj 500mg in Unit Carton of Merem Inj 1gm was by mistake done at the Supplier end as we could not observe this issue during testing and sampling of the said lot due to very low percentage (only 20-30 cartons) in whole lot.

ii. So, our investigation reveals that there may be only 20-30 cartons which may be mixed with Merem 1gm carton from the Printer (Supplier) in the consignment.

iii. We took a strict action against the supplier, also performed detailed audit of the said printing press.

iv. Moreover, we have revised our system for ordering of packaging material. If any product range have same dimension for two different strengths, then order of both strengths will be given to two different suppliers. This will make zero chance of mixing of the packaging material of two different strength of the same product.

6. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample has been declared Misbranded by the Drug Testing Laboratory, Lahore as per The Drugs Act 1976 3 (s) (iv) on the basis that out of 25 units received, 07 units were found with label claim of "Merem 500mg (Meropenem) USP" on outer carton, whereas label on immediate container, i.e., vial of these 07 units bear "Merem 1g (Meropenem) USP" which means that the inner and outer label of these 07 units are different in their label claim strength.

7. The Board was highly perturbed on this gross negligence on part of firm as it could result in serious consequences. The Board was of the view that the batch was supplied to Punjab Institute of Neurosciences Lahore and if this error was unnoticed as the firm admitted that 20-30 cartons were mixed with Injection Merem 1gm, it could have led to wrong administration of dose to already debilitated and ailing patients.

8. Considering the facts of the case, the Board after due deliberation and discussion, unanimously decided to grant **permission for prosecution** against the following accused persons **M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan** in the drug court due to this major lapse of non-compliance to GMP by the firm:

1. **M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan** through its COO/Managing Director, Dr. Zamir-ul-Hassan
2. Dr. Zamir-ul-Hassan COO/Managing Director
3. Umair Ahmed Production Manager
4. Muhammad Ibrahim Quality Control Manager
5. Waheed Shah Warrantor

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

For the offences of:

a. **Manufacturing/ Stocking/ Selling of Misbranded drug**
b. **Issuance of false warranty**

9. The Board further directed to initiate a **regulatory recall** of batch 21E098 of Powder for Injection. Merem 1g [Meropenem USP….1g/ Vial) manufactured by M/s Global Pharmaceuticals, (Pvt.) Ltd., Plot No. 204-205 Industrial Triangle Kahuta Road, Islamabad Pakistan, through Chief Drug Controller Office may be done under The Drugs Act 1976 and rules framed thereunder in order to safeguard the public from potential adverse effects of this mixing. The Board further directed that:

i. Recall will be conducted at Level 2 i.e. from market, distributors, hospitals and retailers.
ii. Provincial Government may advertise Public Awareness Notice through newspaper regarding recall of above-mentioned batch of the drugs.

Furthermore, firm will recall the drug in intimation to Chief Drug Controller Office and also carry out the comprehensive investigation in the subject case and submit root cause analysis report.

10. Firm **submitted Review Petition** against the above mentioned orders in the office of the PQCB on 10-01-2022 which was **referred back to the firm** on 14-01-2022, in compliance to the Drug Court Lahore directions dated 25-08-2021.

Firm **re-submitted the subject review petition** in the office of the PQCB on 02-02-2022 and then filed a **writ petition No. 55855/2022 in Lahore High Court** in which the Honorable Lahore High Court passed above mentioned orders.

Subject: Review petition against the orders no. POCB/R-1982021 dated 30-11-2021 in case of Misbranded powder Injection Merem lgm (Meropenem USP 1gm) Batch No. 21E098

Respectfully submitted as under,

a. *That Drug inspector of Punjab Institute of Neurosciences (PINS) Lahore took the sample of subject Drug from main Medicine store of Punjab Institute of Neurosciences, Lahore on form 4 for the purpose of test/analysis.*
b. *That the drug sample after test analysis was declared as MISBRANDED by the Government Analyst DTL, Lahore vide test report # TRA 01-156001510 dated 26-8-202 1 and the reason of Misbranded mentioned on the test report are "out of 25 units received, 07 units are found with label claim of "Merem 500mg (Meropenem) USP" on outer carton, whereas label on immediate container, i.e., vial of these 07 units bear Merem lgm (Meropenem) USP". **The inner and outer labels of these 07 units are different in label claim strength."***
c. *That after the receipt of test report from Drug inspector, we submitted our reply vide letter no. REF/GP/065/DTLI21 dated 27-9-202, wherein **we guaranteed you that such type human error will be strictly prohibited in future**. However, the **product meets the Pharmacopoeial limit (90 - 120.0%) of active ingredient along with other parameters**, hence inference is that the drug is effective and safe for use on patients.*
d. *That in response to your show cause notice no. PQCB/R-198/2021 dated 08-11-2021. We submitted our reply vide letter no. REF/GP/073/DTL/21 dated 20-11-202.*
e. *That in response to personnel hearing notice no. POCB/R-198/2021 dated 22-11-202 1; we attended the 235th meeting of the Board held on 30-11-2021.*
f. *That PQCB, Punjab **granted permission for prosecution** against us vide order no. PQCB/R198/2021 dated 30-11-2021 in its 235th mecting held on 30-11-2021 received in Global Pharmaceuticals on 10-01-2022.*

We intend to submit;

g. *That the drug sample had been declared as Misbranded **due to mixing of outer carton of different strength, whereas the label on immediate container/vial was of correct strength in bold letter**. This happened due to **un-intended human error at the part of printer**. The gravity of mixing is up to 20-30 units in 3538 packs.*
h. *That whole batch of said drug sample was supplied to Punjab Institute of Neurosciences, Lahore and **not a single unit of the injection had been used by the institution**. All supplied injections are lying in the main Medicine store of Punjab Institute of Neurosciences, Lahore.*
a. *That **not a single unit of said drug has been supplied in the market**.*
j. *That the drug in question is of **standard quality with regards to assay, sterility test**, and other physical parameters and thus there is no risk on the use of drug for patients.*
k. *That the offence of **Misbrand is a rectifiable offence** as per section 18(t) of the Drug Act 1976 and it is a generalized policy of the DRAP/Board that the Misbranded offences, being rectifiable, are not prosecuted.*
ax. *That the **said test report (issued after 63 days) is time barred**, illegal and in violation of section 22(2) of the Drug Act 1976 and rules framed there under. Hence the same is not admissible evidence in the eye of Law.*

Reliance 1984 Pcr LJ 1580

1985 Pcr LJ 281

PRAY

*That in the light of above submissions, you are **requested to review the prosecution dated 30-11-2021 and set aside the case** in the best interest of justice, by exercising the powers orders of review under the Drug Act 1976 and rules frame there under.*

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

11. Personal Hearing Notice issued to accused dated 26-04-2023.

12. Case is placed before the Board for decision.

Summary:

Manufacturing Date: May-2021

Expiry Date: Jan-2024

Sampling Date (Form 4): 23-06-2021

Sent to DTL (Form 6): 24-06-2021

Date of receipt in DTL: 25-06-2021

DTL Report Date (Form 7): 26-08-2021

Time Extension: Granted in 18th Committee Meeting dated 13-09-2021

1ST DI Communication with firm on dated: 16-09-2021

Retesting Request of Firm: NA

Investigation Report Dated: 15-10-2021

Previous Decision of Case: Prosecuted in 235th meeting dated 30-11-2021

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 4

COURT CASE

M/s Amson Vaccines and Pharma (Pvt) Ltd. Versus Province Quality Control Board and Others.

Tehsil and District Sahiwal

PQCB/R-546/2019

Tehsil and District Sahiwal

Substandard (Dissolution Test)

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 Industrial Triangle Kahuta Road, Islamabad, Pakistan** through its managing director Syed Saleem Asghar 2. Syed Saleem Asghar Managing Director 3. Sajjad Hussain Production Incharge/Warrantor 4. Muhammad Mudassir Quality Control Incharge Of **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 Industrial Triangle Kahuta Road, Islamabad, Pakistan.**

The firm filed **Writ Petition** No. 10009 of 2022 and Lahore High Court, Lahore Orders dated 09-02-2023, received in the office of PQCB on 21-02-2023.

ORDER SHEET

IN THE LAHORE HIGH COURT, LAHORE.

JUDICIAL DEPARTMENT

W.P. No. 10009 of 2022

M/s Amson Vaccines and Pharma (Pvt) Ltd. Versus Province Quality Control Board and Others.

09.02.2023

Presence same as in W.P. No.54146 of 2021

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

BRIEF FACTS OF THE CASE

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

i. She, on 11-10-2019, inspected the business premises of M/s Matloob Medical Store, 99/6- R Adda Bootipal Tehsil & District Sahiwal and took sample of below-mentioned drug on Form-4 for the purpose of test/analysis, drug sample, after test/ analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

Name of drug	Ba tch no.	Name of manufa cturer	DTL Report TRA	DTL Test Report Results

<table>
<tr><td></td><td></td><td></td><td>No. & Date</td><td></td></tr>
<tr><td>Film-coate d tablet, Famot id [Famo tidine 20mg]

<u>DESCRIPTION (MS)</u>

<u>IDENTIFICATION (USP)</u></td><td>037</td><td>M/s Amson Vaccine s & Pharma (Pvt.) Ltd., 154, Industri al Triangle Islamab ad.</td><td>TRA No. 01-2500458 0/DTL dated:1 0-12-2019</td><td>Analysis with specifications applied:
USP 2018
<u>COMPOSITION</u>: Each Film Coated tablet contains:
Famotidine USP……...…….20mg
yellow color, round, biconvex tablet which is plain on both sides and packed in a blister pack of 10 tablets.
Famotidine is identified.
<u>ASSAY (USP)</u> <u>Stated</u> <u>Determine</u> <u>Percentage</u>
Famotidine 20 mg/Tab. 19.70 mg/Tab. 98.52% LIMIT: 90-110%
<u>DISSOLUTION TEST (USP):</u> Does not Comply with the specifications of USP as detailed below:
Tolerance Limit: Not less than 75% (Q) of the labeled amount of Famotidine.
<table>
<tr><th>STAGE</th><th>NUMBER TESTED</th><th colspan="6">ACCEPTANCE CRITERIA</th><th>AVERAGE</th><th>REMAR</th></tr>
<tr><td rowspan="2">S1</td><td rowspan="2">06</td><td colspan="6">Each unit is not less than Q+5% and not more than 2 units are less than Q-15% and no unit is less than Q-25%.</td><td rowspan="2">S1</td><td rowspan="2">Does N Comply v specifica</td></tr>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit 5</td><td>Unit 6</td></tr>
<tr><td>Stage 1</td><td>Famotidine</td><td>35.55%</td><td>42.28%</td><td>55.30%</td><td>40.81%</td><td>49.45%</td><td>43.30%</td><td>44.45%</td><td></td></tr>
</table>
<u>Note:</u> All Six units are less than Q-15%, moreover Five out of Six Units (i.e., unit no. 01, 02, 04, 05 & 06) are less thar Q-25%.
<u>RESULT</u>: The sample is declared <u>SUB-STANDARD</u> on the basis of DISSOLUTION TEST.</td></tr>
</table>

ii. M/s Matloob Medical Store, 99/6-R Adda Bootipal Tehsil & District Sahiwal provided invoice/ warranty no. 60207 dated 22-09-2019 issued by M/s Ghazi Pharma, building Peshawary Nan Shop Karbala Road Sahiwal as a proof of its purchase.

iii. Warrantor portion of the drug sample was sent to M/s Ghazi Pharma, building Peshawary Nan Shop Karbala Road Sahiwal.

iv. A copy of test report was sent to M/s Ghazi Pharma, building Peshawary Nan Shop Karbala Road Sahiwal with directions to explain their position and provide requisite information in this regard, who in-turn provided invoice/ warranty no. 69516 dated 29-07- 2019 issued by M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad.

v. A copy of test report was sent to M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty.**

3. Show-cause notice(s) issued to accused person on dated 23.06.2020

REPLY OF THE FIRM TO THE DRUG INSPECTOR:

2. M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad submitted written reply stating that:

Reference to your letter No. PQCB/R-546/2019 dated 23rd June 2020; received at AMSON on dated 29-6-2020 through UMS-Pakistan Post. The letter states that our product Famotid Tablets (Famotidine 20mg) Batch No 037 is found substandard on the basis of Dissolution Test by Drug Testing Laboratory, Bahawalpur.

In this regard following documents to justify our product quality standard on technical ground:

1. Test report of other Drug Testing Laboratories (attached)
2. Test report done at Amson with chromatograms (attached)
3. Valid Drug Manufacturing and valid drug product registration certificates (attached)
4. Appointment letters of technical staff, copy of job certificate and national identity card (attached)
5. Respected sir, on the basis of above-mentioned technical facts it can be confirmed that our product Famotid Tablets (Famotidine 20mg) Batch No. 037 is declared standard quality by DTL Karachi as well as internal testing results.
6. So, we humbly request you to withdraw the show-cause notice against us or send samples of our product to Appellate Laboratory for retest as per procedure.

4. Personal hearing notice served earlier for 229th Meeting on dated 20-01-2021.

Case was placed before the Board for Decision.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board (PQCB), Punjab under section

11 of the Drugs Act 1976 in its **229th meeting held on 02-02-2021.** Ms. Atia Nawaz Secretary DQCB District Sahiwal and Mr. M. Irfan Munir Drug Inspector Tehsil & District Sahiwal were present. Among nominated accused persons Muhammad Muddassir (Quality Control Incharge) of M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad was present along-with representative from the firm Tahir Hameed Gill. They submitted their grievance on the report of Government Analyst Drug Testing Laboratory, Bahawalpur. They stated that the Specifications supposed to be applied was of U.S.P. 19, whereas, Government Analyst has applied the specifications of U.S.P 2018. The Columns and flow rate are different in both U.S.P.'s. They also requested to send their sample to Appellate Laboratory, National Institute of Health Sciences, Islamabad for retest/ analysis.

6. The Board after keen perusal of the Report of Government Analyst, Drug Testing Laboratory, Bahawalpur, reply of the firm submitted in response to show-cause notice issued to them and the arguments of the accused persons observed that the Product Film-coated tablet Famotidine was declared Substandard from Drug Testing Laboratory, Bahawalpur on the basis of dissolution test. All the six units tested were out of the specified range. Dissolution testing measures the extent and rate of solution formation from a dosage form. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. The product failed to comply the dissolution test would result in lesser bioavailable drug and would not be able to provide optimal therapeutic response. Furthermore, the Board also observed that the request of re-testing of the drug sample was not made within the stipulated time. The firm requested for retesting of the drug sample in response to the show- cause notice issued to them. Hence, the report of Government Analyst Drug Testing Laboratory, Bahawalpur is considered as the conclusive evidence of the facts stated therein.

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

1. **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad**

   through its Managing Director Syed Saleem Asghar

2. Syed Saleem Asghar Managing Director
3. Sajjad Hussain Production Incharge/ Warrantor
4. Muhammad Muddassir Quality Control Incharge

Of **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad.**

For the offences of:

a) **Manufacturing/ Stocking/ Selling of Substandard Drug**

b) **Issuance of false warranty.**

REVIEW PETITION

The firm filed review petition in PQCB against the prosecution orders of PQCB dated 02.02.2021s, received in the office of PQCB on 06.05.2021, stated that;

Grounds

1. That the Honorable Board in the impugned order dated,2/2/21, failed to consider the additional grounds of the Petitioner.

2. That no warrantor portion was sent to the Petitioner Company by the Drug Inspector, hence this was a mandatory for the Drug Inspector to send collected sample to the Petitioner Company, hence failure goes to the roots of the case, a valid ground for the review of order dated,2/2/21.

3. That Honorable Board did not consider the ground that the Drug Testing Laboratory Karachi Declared the same batch of medicine standard quality, which rise the question on the credibility of Drug Testing Laboratory Bahawalpur and investigation conducted by that Drug Inspector.

4. That the Honorable Board failed to consider establish principle of law, when law required a thing to be done in a particular manner then it should be done in such particular manner, if it is not followed then the proceedings become invalid and illegal.

5. That the Honorable Board turned down the retesting request by not providing opportunity to the Petitioner to prove its innocence.

6. That Honorable Board even discussed one of the contentions raised by the Petitioner in its Additional grounds while the other grounds were not even considered which is also error floating on the record.

7.That the Govt Analyst Report was not of with protocol hence liable to be rejected.

8. That no Govt Analyst laboratory report was sent to Petitioner Company which was mandatory and obligatory on the part of Drug Inspector or The Prosecution and failure to fulfill this mandatory provision of law provides opportunity to this Honorable Board to review its decision dated, 2/2/21 and drop the proceeding against the Petitioner.

9. That the dissolution test conducted by the Govt Analyst is not required by the law. Hence not acceptable and liable to be rejected.

Under the submission above it is requested that by accepting the instant review petition case against company may please be dropped.

11. Personal Hearing notice(s) issued to accused person(s) dated 27-04-2023.

Summary:

- **Manufacturing Date: 07.2019**
- **Expiry Date: 06.2022**
- **Sampling Date (Form 4): 11.10.2019**
- **Sent to DTL (Form 6): 12.10.2019**
- **Date of receipt in DTL: 12.10.2019**
- **DTL Report Date (Form 7): 10.12.2019**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 07.01.2020**
- **Date of Retesting Request of Firm: N/A**
- **Fate of Retesting: N/A**
- **Investigation Report Dated: 10.06.2020**
- **Prosecution granted against firm: 229st meeting dated 02-02-2021**
- **Review Petition submitted by firm: Dated 06.05.2021.**
- **Status of Review Petition: Pending**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 5

PQCB/R-40/2020

Tehsil and District Sahiwal

Substandard (Dissolution Test)

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 Industrial Triangle Kahuta Road, Islamabad, Pakistan** through its managing director Syed Saleem Asghar 2. Syed Saleem Asghar Managing Director 3. Sajjad Hussain Production Incharge/Warrantor 4. Muhammad Mudassir Quality Control Incharge Of **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 Industrial Triangle Kahuta Road, Islamabad, Pakistan.**

The firm filed **Writ Petition** No. 58154 of 2021 and Lahore High Court, Lahore Orders dated 09-02-2023, received in the office of PQCB on 21-02-2023.

ORDER SHEET

IN THE LAHORE HIGH COURT, LAHORE.

JUDICIAL DEPARTMENT

W.P. No. 58154 of 2021

M/s Amson Vaccines and Pharma (Pvt) Ltd. Versus Province Quality Control Board and Others.

09.02.2023

Presence same as in W.P. No.54146 of 2021

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

BRIEF FACTS OF THE CASE

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

i. She, on 09-11-2019, inspected the business premises of M/s Rashid Pharmacy, 30-W Scheme No. 2, Farid Town, Tehsil & District Sahiwal and took sample of four different types of drugs on Form-4 for the purpose of test/analysis.

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

Name of drug	Ba tch no.	Name of manufa cturer	DTL Report TRA No. & Date	DTL Test Report Results

Film- coated tablet, Famotid [Famotidine 20mg]	035	M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamab ad.	TRA No. 01-2500466 2/DTL dated:14-01-2020	**Analysis with specifications applied:** USP 2018 **Description:** Yellow colour, round, biconvex tablet plain on both side packed in a blister pack of 10 tablets. **Assay (Famotidine):** Complies **Dissolution Test:** Does not comply with the specifications of USP as detailed below: **Tolerance limit:** Not less than 75% (Q) of the labelled amount of Famotidine

Stage	**No. tested**	**Acceptance criteria**						**Average**	**Remarks**
S1	06	Each unit is not less than Q +5% and not more than 2 units are less than Q -15% and no unit is less than Q-25%						S1	**Does not comply with the specific atio**
		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
Stage 1	famotidine	**58.69 %**	**53.17 %**	62.76 %	**44.74 %**	**43.73 %**	61.16 %	54.04%	

				Note: Four units (Unit No. 01, 02, 04 & 05) are less than Q-15% moreover among those four units two units (Unit nc & 05) are less than Q-25%. **Result:** The sample is declared **Substandard,** on the basis of dissolution test.

iii. M/s Rashid Pharmacy, 30-W Scheme No. 2, Farid Town, Tehsil & District Sahiwal provided invoice/ warranty no. 67879/1 dated 29-04-2019 issued by M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent to M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad.

v. A copy of test report was sent to M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty.**

3. Show-cause notice(s) issued to accused person on dated 23.06.2020

REPLY OF THE FIRM TO THE DRUG INSPECTOR:

4. M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Islamabad submitted written reply stating that:

Reference to your letter No. PQCB/R-40/2020 dated 23rd June 2020; received at AMSON on dated 29-6-2020 through UMS-Pakistan Post. The letter states that our product Famotid Tablets (Famotidine 20mg) Batch No 035 is found substandard on the basis of Dissolution Test by Drug Testing Laboratory, Bahawalpur.

In this regard following documents to justify our product quality standard on technical ground:

1. Test report of other Drug Testing Laboratories (attached)
2. Test report done at Amson with chromatograms (attached)
3. Valid Drug Manufacturing and valid drug product registration certificates (attached)
4. Appointment letters of technical staff, copy of job certificate and national identity card (attached)
5. Respected sir, on the basis of above-mentioned technical facts it can be confirmed that our product Famotid Tablets (Famotidine 20mg) Batch No. 035 is declared standard quality by DTL Faisalabad as well as internal testing results.
6. So, we humbly request you to withdraw the show-cause notice against us or send samples of our product to Appellate Laboratory for retest as per procedure.

4. Personal hearing notice served earlier for 229th Meeting on dated 25-01-2021.

Case was placed before the Board for Decision.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board (PQCB), Punjab under section 11 of the Drugs Act 1976 in its **229th meeting held on 02-02-2021.** Ms. Atia Nawaz Secretary DQCB District Sahiwal and Mr. M. Irfan Munir Drug Inspector Tehsil & District Sahiwal were present. Among nominated accused persons Muhammad Muddassir (Quality Control Incharge) of M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad was present along-with representative from the firm Tahir Hameed Gill. They submitted their grievance on the report of Government Analyst Drug Testing Laboratory, Bahawalpur. They stated that the Specifications supposed to be applied was of U.S.P. 19, whereas, Government Analyst has applied the specifications of U.S.P 2018. The Columns and flow rate are different in both U.S.P.'s.

They also requested to send their sample to Appellate Laboratory, National Institute of Health Sciences, Islamabad for retest/ analysis.

6. The Board after keen perusal of the Report of Government Analyst, Drug Testing Laboratory, Bahawalpur, reply of the firm submitted in response to show-cause notice issued to them and the arguments of the accused persons observed that the Product Film-coated tablet Famotidine was declared Substandard from Drug Testing Laboratory, Bahawalpur on the basis of dissolution test. Four among the six tested units were out of the specified range. Dissolution testing measures the extent and rate of solution formation from a dosage form. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. The product failed to comply the dissolution test would result in lesser bioavailable drug and would not be able to provide optimal therapeutic response. Furthermore, the Board also observed that the request of re-testing of the drug sample was not made within the stipulated time. The firm requested for retesting of the drug sample in response to the show- cause notice issued to them. Hence, the report of Government Analyst Drug Testing Laboratory, Bahawalpur is considered as the conclusive evidence of the facts stated therein.

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

1. **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad**

   through its Managing Director Syed Saleem Asghar

2. Syed Saleem Asghar Managing Director
3. Sajjad Hussain Production Incharge/ W arrantor
4. Muhammad Muddassir Quality Control Incharge

Of **M/s Amsons Vaccines & Pharma (Pvt.) Ltd. 154 industrial Triangle Islamabad.**

For the offences of:

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

REVIEW PETITION

The firm filed review petition in PQCB against the prosecution orders of PQCB dated 02.02.2021s, received in the office of PQCB on 03.05.2021, stated that;

Grounds

1. That the Honorable Board in the impugned order dated,2/2/21, failed to consider the additional grounds of the Petitioner.
2. That the report of the Govt analyst is time barred which is not considered by the Honorable Board as

   the impugned order is silent in respect of any extension taken by Govt analyst from the board hence the strong presumption is in favor of Petitioner Company that the Govt analyst has not taken any permission for extension from the Board, hence, it is error floating on the record, confirming that the report of the Govt analyst is time barred, thus on this solely ground proceedings are to be dropped or quashed.
3. That Honorable Board did not consider the ground that the Drug Testing Laboratory Faisalabad Declared the same batch of medicine standard quality, which rise the question on the credibility of Drug Testing Laboratory Bahawalpur and investigation conducted by that Drug Inspector.
4. That the Honorable Board failed to consider establish principle of law, when law required a thing to be done in a particular manner then it should be done in such particular manner, if it is not followed then the proceedings become invalid and illegal.
5. That the Honorable Board on the one hand turned down the request for retesting on the ground of time barred and other hand did not turn down the time barred Govt analyst report, hence committed the error floating on the record.
6. That Honorable Board even discussed one of the contentions raised by the Petitioner in its Additional grounds while the other grounds were not even considered which is also error floating on the record.
7. That the Govt Analyst Report was not of with protocol hence liable to be rejected.
8. That even the Govt Analyst Report is manifested that there is no extension is sought by the Govt Analyst for the extension of time hence it is liable to be rejected.
9. That the dissolution test conducted by the Govt Analyst is not required by the law. Hence not acceptable and liable to be rejected.

Under the submission above it is requested that by accepting the instant review petition case against company may please be dropped.

11. Personal Hearing notice(s) issued to accused person(s) dated 27-04-2023.

Summary:

- **Manufacturing Date: 01.2019**
- **Expiry Date: 12.2021**
- **Sampling Date (Form 4): 09.11.2019**
- **Sent to DTL (Form 6): 11.11.2019**
- **Date of receipt in DTL: 11.11.2019**
- **DTL Report Date (Form 7): 14.01.2020**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 07.02.2020**
- **Date of Retesting Request of Firm: N/A**
- **Fate of Retesting: N/A**
- **Investigation Report Dated: 10.06.2020**
- **Prosecution granted against firm: 229st meeting dated 02-02-2021**
- **Review Petition submitted by firm: Dated 03.05.2021.**
- **Status of Review Petition: Pending**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 6

COURT CASE

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

PQCB/ R-730/2019

Nishtar Hospital, Multan

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi** through its Chief Executive Officer Amin Muhammad Notta 2. Amin Muhammad Notta — Chief Executive Officer 3. Waseem Ahmed — Production Officer/Warrantor 4. Muhammad Hanif — Quality Control Head of M/s Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi

The firm filed **Writ Petition** No. 52668 of 2022 and Lahore High Court, Lahore Orders dated 09-02-2023, 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 Cibex Pharmaceuticals (Pvt) Ltd., v/s Province of Punjab

WRIT PETITION:

The firm filed writ petition No. 52668/2022 in Lahore High Court. Following is the order sheet Dated: 09-02-2023, issued by the Lahore High Court, to direct the board further in this case.

Ordre Sheet

Presence same as in W.P. No 54146 of 2021

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

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Nishtar Hospital, Multan reported that: -

i. She, on 07-01-2019, inspected the premises of Main Drug Store Nishtar Hospital, Multan and took six different types of Drug samples on Form No. 04 for the purpose of test and analysis and sent to Drug Testing Laboratory, Multan.

ii. Following 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>Enteric/ delayed release Tablet Voltagesic (Diclofenac Na) 50mg</td><td>5023</td><td>M/s Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi</td><td>TRA No.01-56003937/DTL

dated:25-02-2019</td><td>
Analysis with specifications applied: USP 2015

<u>Description</u>:

Dark brown color, round enteric coated tablet plain on both sides packed in blister of 10 units packed in outer carton

<u>Dissolution Test:</u>

Does not comply with specifications as described below:

Tolerance Limit:

Acid Stage: NMT 10%

Buffer Stage: NLT Q+5% Where Q is 75% of labeled amount of Diclofenac Sodium.
<table>
<tr><th>Level</th><th>Units</th><th>% Release</th><th>Average</th><th>Remarks</th></tr>
<tr><td></td><td></td><td>Acceptance criteria Acid Stage
No individual value exceeds 10% dissolved.</td><td>0.50%</td><td>Complies</td></tr>
</table>
<table>
<tr><td>A1</td><td>6</td><td>U1</td><td>U2</td><td>U3</td><td>U4</td><td>U5</td><td>U6</td><td></td><td></td></tr>
<tr><td>Determined</td><td></td><td>0.29</td><td>0.29</td><td>0.64</td><td>0.58</td><td>0.58</td><td>0.64</td><td></td><td></td></tr>
<tr><td>B1</td><td rowspan="2">6</td><td colspan="6">Acceptance criteria Buffer Stage
Each Unit is not less than Q+5%</td><td>40.17%</td><td>Does not comply</td></tr>
<tr><td></td><td>U1</td><td>U2</td><td>U3</td><td>U4</td><td>U5</td><td>U6</td><td></td><td></td></tr>
<tr><td>Determined</td><td></td><td>32.50</td><td>40.14</td><td>22.55</td><td>44.40</td><td>54.88</td><td>46.53</td><td></td><td></td></tr>
</table>
The criteria for B2 and B3 stage met on B1 stage therefore the sample was not proceeded to next stage.

The quantity Q is specified amount of dissolved active substance, expressed as percentage on the label claim.

<u>Assay:</u> Diclofenac Sodium
<table>
<tr><td>Stated</td><td>50mg/Tab</td></tr>
<tr><td>Determined</td><td>49.58mg/Tab</td></tr>
<tr><td>Percentage</td><td>99.16%</td></tr>
<tr><td>Limit</td><td>90-110%</td></tr>
</table>
(Complies)

<u>Result</u>: The above sample is <u>Sub-standard</u> on the basis of Test performed.
</td></tr>
</table>

iii. Store keeper of Main Drug Store Nishtar Hospital, Multan provided invoice/ Warranty No. 42966/43134 dated 02-01-2019 issued by M/s Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi as a proof of its purchase.

iv. Warrantor portion was sent to M/s Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi with directions to explain their position in this regard.

v. A copy of test report was sent to M/s Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi with directions to provide relevant information in this regard. and they were asked to provide the requisite information in this regard. 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:

<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>Voltagesic Tablets 50mg</td><td>5023</td><td>M/s Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi</td><td>0138-P/2019
dated: 27-06-2019</td><td>
Analysis with specifications applied: USP-39
<u>Description:</u>
Brown colored, circular, biconvex coated tablets packed in blister packing further contained in an outer carton.
<u>Identification:</u> Diclofenac Sodium identified.
<u>Weight Variation:</u> Complies with USP-39
<u>Dissolution Test:</u>
<table>
<tr><td>Acid Stage</td><td>Determined</td><td>Nil</td></tr>
<tr><td>Buffer Stage</td><td>32.90%</td><td>All the six tablets deviated from the limit.</td></tr>
<tr><td>Limit</td><td colspan="2">Not less than 75% Q of the labeled amount.</td></tr>
</table>
Does not comply with USP-39.
<u>Assay:</u>
<table>
<tr><th></th><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td>Diclofenac Sodium</td><td>50mg/Tab</td><td>45.76mg/Tablet</td><td>90-110%</td><td>91.53%</td></tr>
</table>
Complies with USP-39.
<u>Result:</u> The sample is of <u>Substandard</u> quality on the basis of tests performed.
</td></tr>
</table>

vii. Copy of NIH report was sent to M/s Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi

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

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

b. **Issuance of false warranty**

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

Written Reply Submitted by the Firm:

With reference to the show cause Notice number and dated mentioned above, it is most respectfully submitted as under;

1. That our product tablet Voltagesic 50mg, batch No.5023 was declared by Drug testing Lab / NIH as substandard on the basis of tests performed.

2. That it is hereby most respectfully submitted that the drug test report was not in accordance with law therefore the said report cannot be the basis of prosecution.

3. That the Govt., Analyst did not mention the full details of protocols of the tests applied, therefore, the report was not to be relied upon being not admissible in evidence.

4. That it is important to mention here that NIH did not ask for any testing method from the answering respondent / manufacturer, therefore the report of NIH was inadmissible in evidence hence, not reliable.

5. That the Govt., Analyst failed to mention the weight of each tablet and also failed to mention any supportive evidence of the tests and analysis which made the said test report as a void document.

6. That the reference sample of the same batch was analyzed by the quality control staff of the company who found the reference sample of standard quality in all respect.

7. That the storage condition such as temperature etc at the time of seizure of the product from the premises or at the time of analysis by the Govt., Analyst were not mention or observed which might affect the result or analysis

8. That no notice under section 32(3)(b) of the Drugs Act, 1976 was given to the manufacturer / answering respondent without which the plea of warranty cannot be availed

9. That it is important to mention here that other three batches No.5022, 5024 and 5025 of the same drug were declared of standard quality by the DTL, Multan and Lahore which were manufactured immediately before and after of this this batch No.5023, therefore it could safely be inferred that this batch was also of standard quality.

10. The documents required by your kind self, are attached herewith for your kind perusal Names of CEO/warrantor. Production Incharge and QC Incharge are hereby mentioned below,

Amin Muhammad Notta. Managing Director, Waseem Ahmed Production Incharge, Muhammad Hanif Quality Control Incharge

Under the circumstances explained above it is most respectfully prayed that as the case is based upon the tests report which was not conclusive for the reasons mentioned above, hence the same is not a legal therefore the said cannot be prosecuted, therefore the case may kindly be dropped or the warning may kindly be issued

4. Personal hearing notice(s) issued to accused person(s) dated 26-04-2022.

PREVIOUS PROCEEDINGS OF THE CASE:

PQCB 243rd Meeting Held on 12-05-2022:

5. 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. Ms Irum Kokaub Secretary DQCB District Multan and Mr. M. Nasir Drugs Inspector Nishtar Hospital, Multan were present. No one among the nominated accused persons appeared before the Board, However, Counsel person Sheikh Irfan Saeed appeared before the Board on the behalf of M/s Cibex Pharmaceuticals, Karachi. Counsel of the firm stated that subject batch was manufactured in 2018 and analysis was performed after 10 months of manufacturing, So the environmental factors like fluctuation in storage conditions can affect the stability of the product. He further stated that Government analyst did not perform the dissolution test on advance stages like S2 and S3. He further argued that NIH Islamabad did not ask for the testing method of the analysis in subject case and its report is also time barred.

6. The Board after careful perusal of the case record and scrutiny of Drugs Testing Laboratory, Multan report observed that the product Enteric/ delayed release Tablet Voltagesic batch no. 5023 Manufactured by M/s Cibex Pharmaceuticals was declared as Substandard on the basis of its dissolution test. The firm requested for retesting of sample and product was sent to NIH Islamabad for retesting where it was again declared as Substandard on the basis of dissolution test. The Board observed that according to invoice/warranty issued by the firm, the subject batch is manufactured on 31-12-2018. Drugs Testing Laboratory, Multan declared Drug sample of substandard quality on 25-02-2019 and NIH Islamabad declared it as Substandard quality on 27-06-2019 and both laboratories declared subject drug sample of substandard quality on same grounds, So the point raised by the counsel person regarding testing performed after 10 months of its manufacturing is in-valid. The Board considered firm's argument that Government analyst did not perform the dissolution test on advance stages, is also invalid because there is no need to perform dissolution test on advance stages if it is failed to comply with specifications at initial stage. The Board also observed that the product was tested on USP specs in NIH Islamabad which was according to the stated specs adopted by the firm. The firm also failed to provide valid scientific justifications against this defect/failure of the formulation.

7. In view of the foregoing facts, the Board after due deliberation and detailed discussion unanimously decided to grant **permission for Prosecution** against the following accused 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 Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi** through its Chief Executive Officer Amin Muhammad Notta
2. Amin Muhammad Notta Chief Executive Officer
3. Waseem Ahmed Production Officer/Warrantor
4. Muhammad Hanif Quality Control Head

of M/s Cibex Pharmaceuticals Pvt Ltd F-405, S.I.T.E, Karachi for the offences of

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

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

Review Petition:

The firm filed review petition against the Prosecution orders of PQCB vide REF No. Nil Dated Nil, received to this office on 25-08-2022, stated that;

Grounds

- That the impugned order of prosecution, without giving proper hearing to the petitioners on merits 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.
- 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.
- That the Govt., Analyst did not mention the full protocols of the tests applied, therefore, the reports were not to be relied upon being not admissible in evidence. Reliance was placed on PLD 2003 Lahore 115.
- That it is hereby most respectfully submitted that the drug test report was not in accordance with law therefore the said report cannot be the basis of prosecution.
- That the Govt., Analyst did not mention the full details of protocols of the tests applied, therefore, the report was not to be relied upon being not admissible in evidence.
- That it is important to mention here that NIH did not ask for any testing method from the answering respondent / manufacturer, therefore the report of NIH was inadmissible in evidence hence, not reliable.
- That the Govt., Analyst failed to mention the weight of each tablet and also failed to mention any supportive evidence of the tests and analysis which made the said test report as a void document.
- That the reference sample of the same batch was analyzed by the quality control staff of the company who found the reference sample of standard quality in all respect.
- That the storage condition such as temperature etc at the time of seizure of the product from the premises or at the time of analysis by the Govt., Analyst were not mention or observed which might affect the result or analysis.
- That no notice under section 32(3)(b) of the Drugs Act, 1976 was given to the manufacturer / answering respondent without which the plea of warranty cannot be availed.
- That it is important to mention here that other three batches No.5022, 5024 and 5025 of the same drugs were declared of standard quality by the DTL, Multan and Lahore which were manufactured immediately before and after of this this batch No.5023, therefore it could safely be inferred that this batch was also of standard quality.
- That the drug inspector violates the provisions of section 103 CrPC.
- That Hon'ble High Court had declared that Provincial Quality Control Board should perform their duties fairly, justly without the element of discrimination. Reliance was placed on 2002 YLR 1621.
- That the Hon'ble Supreme Court of Pakistan held in its judgment report in 1996 SCMR 1183 that in a similar circumstance the benefit shall be extended to those who are similarly placed and no discrimination shall be allowed.
- That it would be extremely unjust unfair and illegal to treat two similar cases in two opposite directions such as one is prosecuted and other is issued warning.
- That no notice under section 32(3)(b) of the Drugs Act, 1976 was received which is the mandatory requirement of law, otherwise no one have the plea of warranty.
- That the 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 may kindly be accepted and the impugned order dated 12-05-2022 of prosecution may kindly be set aside and the case against the petitioners may kindly be dropped for the reasons mentioned above. Any other relief which this Honorable Board may deem fit and appropriate in the circumstances of the case may also be allowed.

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

9. The review was Pending in the office of PQCB as the Honorable Drug Court has restrained the Provincial Quality Control Board, Punjab from taking up the review petitions against the orders of Provincial Quality Control Board till further orders.

Personnel Hearing notice(s) issued to accused person(s) on 26-04-2023.

Case is placed before the Board for decision

Summary of the case:

- **Mfg. date: 12-2018**
- **Exp. Date: 12-2020**
- **Sampling date (Form 4):** 07-01-2019
- **Sent to DTL (Form 6):** 07-01-2019
- **Date of receipt in DTL:** 07-01-2019
- **DTL Report Date (Form 7):** 25-02-2019
- **DI 1st intimation to firm:** 28-02-2019
- **Retesting request if any: Yes, allowed in 10th committee meeting dated: 22-07-2019**
- **Fate of Retesting request: NIH Substandard**
- **Investigation report Dated:** 16-12-2021

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 7

PQCB R-557/2018

DHQ Hospital, Rawalpindi

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area North Karachi, Pakistan** through its Chief Executive Officer, Asad Ilyas. 2. Asad Ilyas Chief Executive Officer 3. Ahmed Nadeem Qasmi Quality Control Manager/Warrantor 4. Ekram ud Din Production Manager Of M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area, North Karachi, Pakistan.

ORDER SHEET

IN THE LAHORE HIGH COURT

LAHORE

JUDICIAL DEPARTMENT

Case No: W.P. No.18379/2023.

M/S Epharm Laboratories Pvt. Ltd. Vs Province of Punjab, etc.

Date of Order: 20-03-2023

Learned counsel for the petitioner submits that against the order dated 13.12.2022, petitioner's review petition is pending before respondent No. 2 and he will be satisfied if said review petition be decided in accordance with law. Learned counsel submits that in number of similar writ petitions including W.P No. 32138/2019 direction has already been issued to decide the review petition.

2. Learned Law Officer submits that review petition, if pending, will either way be decided in accordance with law.

3. It is accordingly directed that respondent No. 2 will either way decide the aforesaid review petition of the petitioner, strictly in accordance with law, expeditiously, preferably within two months from receipt of certified copy of this order.

4. Disposed of in above terms.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, DHQ Hospital, Rawalpindi reported that: -

i. His predecessor, on 03-07-2018, inspected the premises of Main Medical Store, DHQ Hospital, Rawalpindi and took samples of the five different types of drugs on Form No. 04 for the purpose of test and analysis.
ii. One of the drug samples after test/analysis, was declared **Sub-standard** 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
Film Coated tablet. Reneph 150mg [Ranitidine:150mg]	RP060	M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area North Karachi, Pakistan	TRA No. 01-13001316/DTL dated:16 Aug 2018	**Result of test/analysis with specifications applied:** MS 0 **PHYSICAL DESCRIPTION:** Light yellow coloured, round shaped, biconvex, film coated tablets, plain from both sides, packed as 1X10s Alu-Alu blister strip. **WEIGHT VARIATION:** **Average weight (20 units):** 220.95mg **Limit:** ±7.5% **Result: Out of 20units, four units deviated from average weight by more than specified limit. (DOES NOT COMPLY)** **Specifications:** Not more than two of the individual masses deviate from the average mass by more than percentage specified and none deviates by more than twice that percentage. **DISINTEGRATION TEST:** Result: All units comply the disintegration test. **Limit**: NMT 30min **IDENTIFICATION:** Ranitidine identified **ASSAY** Stated: 150mg/Tablet Determined: 159.14mg/Tablet Percentage: 106.09% (Complies) Limit: 90-110% **RESULT:** The above sample is **Sub-Standard on the basis of the Weight Variation test performed**.

iii. Store keeper of Main Medical Store, DHQ Hospital, Rawalpindi provided Invoice/warranty/bill/DC No. B-71025, dated 19-06-2018 issued by Muhammad Imran Khan of Imran Traders, B334-5 Iqbal Road, Rawalpindi as a proof of their purchase.

iv. Warrantor portion was sent to Imran Traders, B334-5 Iqbal Road, Rawalpindi who provided Invoice/warranty/bill/DC No. 064-339, dated 13-06-2018 issued by M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area North Karachi, Pakistan.

v. A copy of test report was sent to M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area North Karachi, Pakistan.

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

a. **Manufacture for Sale /Sale of Sub-standard Drug.**

b. **Issuance of false warranty.**

3. Show-cause was issued to accused person(s) vide dated 08-03-2022.

REPLY OF SHOWCAUSE

In response to the Show-cause notice, firm replied vide letter dated 24th March, 2022 stating that

"With reference to your letter No. PQCB/R-557/2018, dated.08/03/2022, received by us on 21/03/2022. The following submissions are made

1. That we have not received yet manufacturer/Warrantor portion from Drug Inspector which is a mandatory provision of Drug act, 1976.

2 We have already submitted a letter on 26/01/2019 for Retesting of product from Appellate labs

3. That the DTL test / report clearly shows that Reneph-150mg Tablet is standard quality because assay result of Active Ingredient is 106.09% (Limit: 90--110 %) and Disintegration Time is within limit of 30 minutes.

4. That we do not agree with Government Analyst Test /analysis report No.TRA.01-13001316/DTL Dated.16/08/2018 related to the sample of Reneph-150mg Tablets B.NO.RP060 which was taken from the M/S Imran Trader, B-334-5 lqbal Road, Rawalpindi for test/analysis by Drug Inspector,Ahmad Ali Khattak on the basis of following evidence in controversion of this report as required under section 22 (4) Of the Drugs Act 1976

a) That "Reference Sample" of the same batch of subject drug Reneph-150mg Tablets B.NO.RP060 retained at Q.C Labs, of the Epharm, Karachi under prescribed condition was tested and found within the specifications.

b) The sample were collected from the Market and tested and Analyzed. These samples conformed to the approved specification in term of assay and all other Tests.

In the light of above adduced evidence, we request you to kindly give us a chance of personnel hearing before the board for defence of case in the best interest of Justice."

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

PREVIOUS PROCEEDINGS AND DECISION OF THE BOARD

5. Case was considered by the Provincial Quality Control Board, under Section 11 of the Drugs Act 1976 in its **247th meeting** held on **21-07-2022** under the Chairmanship of Vice Chairperson, Primary & Secondary Healthcare Department Punjab in the presence of Board members as mentioned above. Secretary Provincial Quality Control Board apprised the Board that Show Cause and Personal Hearing notice was duly served to accused persons. Mr. Talib Hussain, Secretary District Quality Control Board, Rawalpindi and Mst. Uzma Khalid Provincial Inspector of Drugs, DHQ Hospital, Rawalpindi were present along with original case record. No one among the nominated accused persons of M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area North Karachi, Pakistan was present. The firm submitted the written request for adjournment vide letter No. Nil dated 18-07-2022.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.

6. Personal Hearing notice(s) issued to accused person(s) vide dated 12-08-2022.

PREVIOUS PROCEEDINGS AND DECISION OF THE BOARD

7. 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. Uzma Khalid, Provincial Inspector of Drugs, DHQ Hospital, Rawalpindi was present along with original case record. Among the nominated accused persons, Asad Ilyas, Chief Executive Officer and Ahmed Nadeem Qasmi, Quality Control Manager of M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area North Karachi, Pakistan along with Counsel, Rana Maqsood Afzal (Advocate) appeared before the Board. The Board observed that the Secretary District Quality Control Board, Rawalpindi was absent. The Board was of the considerate opinion that presence of Secretary District Quality Control Board was mandatory to hear the case. Therefore, the Board after due deliberation and discussion unanimously decided to **Adjourn** the subject case due to incomplete quorum.

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

PREVIOUS PROCEEDINGS AND DECISION OF THE BOARD

9. 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 & Secondary Healthcare Department Punjab. Mst. Misbah Noreen, Secretary DQCB, Rawalpindi, and Mst. Uzma Khalid Drug Inspector, DHQ Hospital, Rawalpindi, District Rawalpindi were present along with the original case record. No one among the nominated accused persons of M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area North Karachi, Pakistan was present. Secretary PQCB apprised the Board that the firm has submitted its request for adjournment second time through WhatsApp on official cell number.

10. The Board after careful perusal of the case record observed that the subject drug sample, product Film coated Tablet Reneph 150 mg (Ranitidine 150mg) was found substandard by the Drug Testing laboratory, Rawalpindi on the basis of weight variation test performed. Weight variation ensures content uniformity of the active ingredient in tablets and in subject case 04 out of 20 tablets deviated from criteria. If the product does not fall in the prescribed limits of weight variation, it results in uneven distribution of active ingredient that may lead to overdose or under dose of the active pharmaceutical ingredient. As weight of a tablet is directly related to its therapeutic response, failure of a product to comply with weight variation test limits will lead to unreliable therapeutic response, which is unacceptable. The Board further observed that the firm has already given two chances of personal hearing and the case was adjourned on request of the firm. Therefore, the Board decided to turn-down the request of adjournment of the firm and was of considered view that the firm is using delaying tactics and wilfully absents itself from proceedings of the Board.

11. In view of the foregoing facts, the Board after due deliberation and detailed discussion unanimously decided to grant **Permission for Prosecution** against the following accused who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended)/DRAP Act 2012 and Rules framed there under

5. **M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area North Karachi, Pakistan** through its Chief Executive Officer, Asad Ilyas.
6. Asad Ilyas Chief Executive Officer
7. Ahmed Nadeem Qasmi Quality Control Manager/Warrantor
8. Ekram ud Din Production Manager

Of M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E., Super Highway Industrial Area, North Karachi, Pakistan.

For the offences of;

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

12. The Board further directed to launch the complaint against the above-mentioned accused persons before the drug court concerned and submit copy of the same.

13. M/S Epharm Laboratories Pvt. Ltd. filed a review petition against the prosecution order of Provincial Quality Control Board, received on 06.02.2023

REVIEW PETITION:

1. That the petitioner is a Pharmaceutical Company with the name & style of M/s EPharm Laboratories A-40, Industrial Area of North Karachi.
2. That the petitioner is manufacturing and selling a large number of medicines throughout the country and due to its quality products, the petitioner company is increasing its customer day by day.

3. That a sample of drug (tablet) Reneph 150mg (Ranitidine) was taken for test and analysis and sent to the same to the Provincial Drug Testing Laboratory (DTL) followed by the report/ test/ analysis dated 16.08.2018,declaring the samples substandard on the basis of the weight variation which was allegedly not in accordance with law.

4. That the said report was based on self-presumption without analysing the samples and therefore feeling aggrieved the petitioner requested for retesting the sample by the Appellate Laboratory through written application dated 26.01.2019 well within time under Section 22(4) of the Drug Act, 1976 which is reproduced as under:
"Section 22(4) Notwithstanding anything contained in any other law for the time begin in force, any document purporting to be a report signed by a Government analyst shall be admissible as evidence of the facts stated therein without formal proof and such evidence shall be conclusive unless the person from whom the sample was taken or the said warrantor has, within thirty days of the receipt of a copy of the report notified in Writing to the inspector or the Provincial Quality Control Board, or as the case may be, the central Licensing board or the Registration Board or the Drug Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in contravention of the report."

But the application of retesting dated 26.01.2019 was not decided.

5. That the order dated 13.12.2022 was passed without considering all the legal and factual points therefore the same is liable to be reviewed.

6. That the learned Board ignored the law as it is mandatory for the Board to refer the analyst report to Federal Drug Laboratory or any other Laboratory specifies by the Federal Govt of its own motion or upon the request of the party. The section 22(5) of the Drug Act, 1976 is reproduced as under:

"S. 22(5) where a person has, under sub- section (4), notified his intention of adducing in contravention of a Government Analyst's report, Provincial Quality Control Board, or as the case may be, the Central Licensing board or the Registration Board or the Drug Court] may, of its complainant or the accused, cause the sample of the drug lying with the Board concerned under sub-section (3) of section 19 to be sent for test or analysis to the Federal Drug Laboratory specified for the purpose by the Federal Government which shall make the test or analysis and report in writing signed by or under the authority of the person for the time being Incharge of the Federal Drug Laboratory, or, as the case may be, such other laboratory, the result thereof and such report shall be conclusive evidence of the facts stated therein."

But the order was passed without deciding the retesting application.

7. That the Govt. analyst did not mention full protocols of the tests applied, therefore, the report was not to be relied upon being not admissible in evidence.

8. That the Govt Analyst did not declare the product to be injurious to health without which the alleged weight varieties could not from the basis of prosecution of the petitioner.

9. That the petitioner was condemned unheard because the adjournment request of the petitioner was turned down without advancing any reason. Suffice to mention that in previous meeting of the Board held on 23.08.2022, the petitioner was present before the Board along with his counsel but the meeting was postponed due to the absence of the Secretary District Quality Control Board, Rawalpindi. On 13.12.2022, the counsel of the petitioner remained unable to appear due to his engagement before the Honourable High Court, Multan Bench.10. That in many other cases of similar nature where the Govt. Analyst declared the sample as substandard on the basis of weight variations the learned Board was pleased to accept the request of retest and sent the sample for retest by the appellate Laboratory, therefore, refusal from retest in this case is similar to them would cause discrimination which warranted under the law, hence order dated not 13.12.2022 not sustainable.

PRAYER:

Under the circumstances explained above, it is, therefore respectfully prayed that the review petition may kindly be accepted and the impugned order dated 13.12.2022 may be reviewed and the sample of the drug be retested by the appellate laboratory as early as possible in the interest of justice without element of discrimination.

14. M/S Epharm Laboratories Pvt. Ltd. filed Writ Petition No. 18379/2023 with the Lahore High Court, Lahore.

GROUNDS

A. That the petitioner was condemned unheard which is a violation of Article 10-A & 4 of the Constitution of Islamic Republic of Pakistan as well as 11(5) of the ACT, Right of fair trial is the right of every citizen and these rights should be dealt in accordance with law and not otherwise as enshrined in Article 4 of the constitution.

B. The request to retest the samples of the drug in question submitted by the petitioner before the respondent No. 2 was not decided either way is violate of section 22 of sub section 4 of the ACT,

which vitiates the whole proceedings against the petitioner.

C. That it is a settled principal of law that when certain acts or actions are required to do in a prescribed manner, these must be done in the way as law prescribes and not otherwise. In case of the petitioner, respondent Nos 2 and 3 proceeded against the petitioner against the settled principal of law because these respondents ignored the mandatory provisions of law ibid.

D. That the petitioner has also filed a review petition under part viii of Provincial Quality Control Board regulations against the impugned order dated 13/12/2022, which the respondent refused to entertain therefore, the same was filed through post and the same is pending before the respondent No. 2.

E. That in an identical matter in Writ Petition No. 32138 of 2019 His Lordship Mr. Justice Shahid Kareem, Judge Lahore High Court Lahore hold that the PQCB not enjoys the discretionary power to allow or reject the request of retesting rather it is the right of the accused/complainant of getting the disputed samples retested through appellate laboratory. Order dated 11.9.2019 by Lahore High Court.

F. That the petitioner has no other adequate, efficient and speedy remedy available except to invoke the constitutional jurisdiction of the honourable court.

PRAYER:

Under the circumstances explained above it is therefore, humbly prayed that the petition may kindly be accepted and the impugned order dated 12.12.2022 passed by the Provincial Quality Control Board, Lahore respondent No. 2 be set aside and declared as illegal and without lawful authority.

It is further prayed that in alternate a direction to the respondent No. 2 may kindly be issued to decide the review petition pending before the said respondent against the impugned order.

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

15. Personal Hearing notice(s) issued to accused person(s) dated 20.04.2023

Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 05-2018

Expiry Date: 05-2020

Sampling Date: 03-07-2018

Sent to DTL (Form 6): 03-07-2018

Date of receipt in DTL: 12-07-2018

DTL Report Date: 16-08-2018

Time Extension: N/A

1st DI Communication with firm on dated: 21-01-2019

Date of Retesting Request of Firm: 26-01-2019

1st Letter to firm to submit evidence in contravention of Govt. analyst's Report: 27-03-2019

2nd Letter to firm to submit evidence in contravention of Govt. analyst's Report: 12-09-2019

3rd Letter (Final Reminder) to firm to submit evidence in contravention of Govt. analyst's Report: 18-12-2019

Investigation Report Dated: 22-11-2021

Show cause notice issued: 08-03-2022

Prosecution: 254th meeting dated 13-12-2022

Review petition received: 06-02-2023

M/S Epharm Laboratories Pvt. Ltd. filed Writ Petition **No. 18379/2023** with the **Lahore High Court, Lahore**.

Orders dated: 20-03-2023.

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

ITEM No. 2

REGULAR CASES

Case No. 1

PQCB/R-286,287,288/2020

Bahawalpur Saddar

Misbranded & Sub-Standard (Extractable Volume Test

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad through** its Chief Executive Officer Ghulam Jilani. 2. Ghulam Jilani — Chief Executive Officer/Warrantor 3. Muhammad Sheraz Khan — Production Incharge 4. Anam Bhatti — Quality Control Incharge of **M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad.**

BRIEF FACTS OF THE CASE

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

i. He, on 06-07-2020, inspected the premises of Cholistan Live Stock, Tehsil Yazman, District Bahawalpur and took four different types of drugs on Form No. 04 for the purpose of test and analysis.

ii. Two out of these drug samples, after test/ analysis, were declared **Substandard & Misbranded** and one out of these samples was declared **Misbranded** by Government Analyst Drug Testing Laboratory Bahawalpur as detailed below:

<table>
<tr><th>Sr.No.</th><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report
TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>1</td><td>Injection Wagenta 100 [Gentamycin (as sulphate): 100mg/ml</td><td>I-050</td><td>M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad</td><td>01-77002020/DTL
Dated. 28-08-2020</td><td>
Analysis with specifications applied:

USP 2019

<u>Composition:</u>

Each ml contains:

Gentamycin (as sulphate) B.P……100mg

<u>Description:</u>

Colorless liquid in amber glass sealed, vial enclosed in ou carton. (Stated Volume: 100ml) Label of “ Wagenta 1 claims “each ml contains Gentamycin (as sulphate) l However, BP, USP and other pharmacopoeias claim the w “Gentamicin” in monograph instead of “Gentamycin”. (product is misbranded).

<u>Extractable Volume USP:</u>
<table>
<tr><td>Limit</td><td>NLT nominal vol</td></tr>
<tr><td>Determined</td><td>91ml</td></tr>
</table>
Does not comply with specifications.

<u>PH(USP):</u>
<table>
<tr><td>Limit</td><td>3.0-5.5</td></tr>
<tr><td>Determined</td><td>3.677</td></tr>
</table>
<u>Sterility USP:</u>

The Product is sterile.

<u>Identification USP:</u>

Gentamicin is Identified.

<u>Assay:</u>

<u>Gentamicin:</u>
<table>
<tr><td>Stated</td><td>100mg/ml</td></tr>
<tr><td>Determined</td><td>97.044mg/ml</td></tr>
<tr><td>Percentage</td><td>97.044%</td></tr>
<tr><td>Limit</td><td>90-125%</td></tr>
</table>
<u>Result:</u>

The sample is declared <u>Substandard</u>, on the basis of extracta volume test and <u>Misbranded</u> according to the Drugs (Label and Packaging) Rules, 1986 and as defined under sub-section of section 3 of Drugs Act 1976.
</td></tr>
</table>

2	Injection Wagenta 100 [Gentamycin (as sulphate): 100mg/ml	I-051	M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad	01-77002019/DTL Dated. 28-08-2020	**Analysis with specifications applied:** **USP 2019** **Composition:** Each ml contains: Gentamycin (as sulphate) B.P……100mg **Description:** **Colorless liquid in amber glass sealed, vial enclosed in ou carton. (Stated Volume: 100ml) Label of "Wagenta 1 claims "each ml contains Gentamycin (as sulphate) However, BP, USP and other pharmacopoeias claim the w "Gentamicin" in monograph instead of "Gentamycin". (product is misbranded).** **Extractable Volume USP:** Limit: **NLT nominal vol** Determined: **83.5ml** **Does not comply with specifications.** **PH(USP):** Limit: **3.0-5.5** Determined: **3.487** **Sterility USP:** The Product is sterile. **Identification USP:** Gentamicin is Identified. **Assay:** **Gentamicin:** Stated: 100mg/ml Determined: 96.411mg/ml Percentage: 96.411% Limit: 90-125% **Result:** The sample is declared **Substandard**, on the basis of extracta volume test and **Misbranded** according to the Drugs (Label and Packaging) Rules, 1986 and as defined under sub-sectior of section 3 of Drugs Act 1976.

3	Injection Wagenta 100 [Gentamycin (as sulphate): 100mg/ml	I-049	M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad	01-77002018/DTL Dated. 21-08-2020	**Analysis with specifications applied:** **USP 2019** **Composition:** Each ml contains: Gentamycin (as sulphate) B.P……100mg **Description:** **Colorless liquid in amber glass sealed, vial enclosed in ou carton. (Stated Volume: 100ml) Label of "Wagenta 1 claims "each ml contains Gentamycin (as sulphate) However, BP, USP and other pharmacopoeias claim the w "Gentamicin" in monograph instead of "Gentamycin". (product is misbranded).** **Extractable Volume USP:** Limit: NLT nominal vol Determined: 100ml **PH(USP):** Limit: 3.0-5.5 Determined: 3.398 **Sterility USP:** The Product is sterile. **Identification USP:** Gentamicin is Identified. **Assay:** **Gentamicin:** Stated: 100mg/ml Determined: 96.754mg/ml Percentage: 96.754% Limit: 90-125% **Result:** The sample is declared **Misbranded** according to the Dı (Labelling and Packaging) Rules, 1986 and as defined ur sub-section (s) of section 3 of Drugs Act 1976.

iii. Store Keeper of Cholistan Live Stock, Tehsil Yazman, District Bahawalpur provided Invoice/warranty No 1833, dated 07-06-2020 issued by M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad.

v. A copy of test/analysis report was sent to M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad 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: -

Offences for the drugs mentioned at Serial No. 1 & 2:

a. **Manufacturing for sale /Stocking for sale/selling of Substandard & Misbranded drugs**

b. **Issuance of false warranty**

Offences for the drugs mentioned at Serial No. 3

a. **Manufacturing for sale /Stocking for sale/selling of Misbranded drug**

b. **Issuance of false warranty**

3. Show-cause issued to accused person(s) vide dated 25.02.2021

Reply of Show Cause Notice By Firm:

We hereby acknowledge the receipt of Show cause Notice vide Letter No. PQCB/R-286/2020,287/2020/288/2020 dated 25-02-2021 with the following observations.

a) Product is Misbranded due to spelling mistake.

b) Product is Substandard due to low volume.

1. As per DTL Report TRA No. 01-77002018/DTL (Batch # 1-049), dated 21-08-2020

complies the Sterility, Assay and extractable volume up to 100 ml but product is

Misbranded due to spelling mistake.

It is stated respectfully that our firm was granted Registration Letter of the above-mentioned Veterinary Drug, Wagenta 100 Injection with composition as under: Each ml contains gentamycin as sulphate B.P 100 mg (Copy of registration Letter attached).

Now the spelling mistake has been rectified by DRAP (Copy attached).

2. As per DTL Report (s), TRA No. 01-77002019/DTL (Batch # 1-051), and TRA No. 01- 77002020/DTL (Batch # 1-050), dated 28th August 2020 comply sterility and Assay of the drug but the extractable volume deviates from the stated limits.

It is stated that our Quality Control Lab and Quality Assurance department have rechecked and found the filled volume of both batches (Batch # 1-050 and 1-051) within the stated limit of 100ml.

Keeping in view the above-mentioned facts, we humbly request that volume of both the batches i.e. Batch # 1-050 and Batch # 1-051 may please be rechecked by third party.

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

Summary:

Manufacturing Date:05.2020

Expiry Date: 05.2022

Sampling Date (Form 4): 06.07.2020

Sent to DTL (Form 6): 06.07.2020

Date of receipt in DTL: 06.07.2020

DTL Report Date (Form 7): 21.08.2020

Time Extension: N/A

1ST DI Communication with firm on dated: 07.10.2020

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated:23.12.2020

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 2

PQCB/R-635,636,637/2020

Bahawalpur Saddar

Misbranded & Sub-Standard (Extractable Volume Test

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad through** its Chief Executive Officer Ghulam Jilani. 2. Ghulam Jilani — Chief Executive Officer/Warrantor 3. Muhammad Sheraz Khan — Production Incharge 4. Anam Bhatti — Quality Control Incharge of **M/s Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat Islamabad.**

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 08-06-2020, inspected the premises of M/S Store Keeper (Veterinary Medicine) of Director Live Stock Bahawalpur and took samples of three different type of drugs on Form No. 04 for the purpose of test and analysis and sent them to Drug Testing Laboratory, Bahawalpur.

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

<table>
<tr><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>Injection Wagenta 100 [Gentamycin (as sulphate): 100mg/ml]</td><td>I-048</td><td>M/S Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat, Islamabad-Pakistan</td><td>TRA No.01-77001687/DTL

dated: 08-08-2020</td><td>Analysis with specifications applied: USP 2019.

<u>Composition:</u>

Each ml contains:

Gentamycin (as Sulphate) B.P…….100mg

<u>Description</u>:

Colorless to straw color liquid in amber glass sealed vial enclosed in outer carton. (Stated volume:100ml). Label of “Wagenta 100” claims “Each ml contains Gentamycin (as sulphate) “BP” However, BP, USP and other pharmacopoeias claim. The word “Gentamicin” in monograph instead of “Gentamycin” (The Product is misbranded).

Extractable volume (USP):

<table><tr><td>Limit</td><td>NLT Nominal vol</td></tr><tr><td>Determined</td><td>97ml</td></tr></table>
Does not comply with the specifications.

<u>PH (USP)</u>

<table><tr><td>Limit</td><td>3.0-5.5</td></tr><tr><td>Determined</td><td>3.668</td></tr></table>
<u>Sterility (USP):</u> Sterile.

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

Gentamycin is identified.

<u>Assay:</u>

<u>Gentamycin:</u>

<table><tr><td>Stated</td><td>100mg/ml</td></tr><tr><td>Determined</td><td>97.94mg/ml</td></tr><tr><td>Percentage</td><td>97.94%</td></tr><tr><td>Limit</td><td>90-125%</td></tr></table>
<u>Result:</u> The sample is declared Substandard on the basis of extractable volume test and Misbranded according to the Drugs (Labelling and Packaging) Rules, 1986 and as defined under subsection (s) of section 3 of the Drugs Act 1976.</td></tr>
<tr><td>Injection Wagenta 100 [Gentamycin (as sulphate): 100mg/ml]</td><td>I-050</td><td>M/S Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat, Islamabad-Pakistan</td><td>TRA No.01-77001688/DTL

dated: 08-08-2020</td><td>Analysis with specifications applied: USP 2019.

<u>Composition:</u>

Each ml contains:

Gentamycin (as Sulphate) B.P…….100mg

<u>Description</u>:

Colorless to straw color liquid in amber glass sealed vial enclosed in outer carton. (Stated volume:100ml). Label of “Wagenta 100” claims “Each ml contains Gentamycin (as sulphate) “BP” However, BP, USP and other pharmacopoeias claim. The word “Gentamicin” in monograph instead of “Gentamycin” (The Product is misbranded).

Extractable volume (USP):

<table><tr><td>Limit</td><td>NLT Nominal vol</td></tr><tr><td>Determined</td><td>94ml</td></tr></table>
Does not comply with the specifications.

<u>PH (USP)</u>

<table><tr><td>Limit</td><td>3.0-5.5</td></tr><tr><td>Determined</td><td>3.389</td></tr></table>
<u>Sterility (USP):</u> Sterile.

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

Gentamycin is identified.

<u>Assay:</u>

<u>Gentamycin:</u>

<table><tr><td>Stated</td><td>100mg/ml</td></tr><tr><td>Determined</td><td>96.22mg/ml</td></tr><tr><td>Percentage</td><td>96.22%</td></tr><tr><td>Limit</td><td>90-125%</td></tr></table>
<u>Result:</u> The sample is declared Substandard on the basis of extractable volume test and Misbranded according to the Drugs (Labelling and Packaging) Rules, 1986 and as defined under subsection (s) of section 3 of the Drugs Act 1976.</td></tr>
</table>

<table>
<tr>
<td>Injection Wagenta 100 [Gentamycin (as sulphate): 100mg/ml]</td>
<td>I-051</td>
<td>M/S Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat, Islamabad-Pakistan</td>
<td>TRA No.01-77001689/DTL

dated: 08-08-2020</td>
<td>
Analysis with specifications applied: USP 2019.

<u>Composition:</u>
Each ml contains:
Gentamycin (as Sulphate) B.P…….100mg

<u>Description</u>:
Colorless to straw color liquid in amber glass sealed vial enclosed in outer carton. (Stated volume:100ml). Label of “Wagenta 100” claims “Each ml contains Gentamycin (as sulphate) “BP” However, BP, USP and other pharmacopoeias claim. The word “Gentamicin” in monograph instead of “Gentamycin” (The Product is misbranded).

Extractable volume (USP):
<table>
<tr><td>Limit</td><td>NLT Nominal vol</td></tr>
<tr><td>Determined</td><td>94ml</td></tr>
</table>
Does not comply with the specifications.

<u>PH (USP)</u>
<table>
<tr><td>Limit</td><td>3.0-5.5</td></tr>
<tr><td>Determined</td><td>3.5997</td></tr>
</table>
<u>Sterility (USP):</u> Sterile.

<u>Identification (USP):</u>
Gentamycin is identified.

<u>Assay:</u>
<u>Gentamycin:</u>
<table>
<tr><td>Stated</td><td>100mg/ml</td></tr>
<tr><td>Determined</td><td>97.05mg/ml</td></tr>
<tr><td>Percentage</td><td>97.05%</td></tr>
<tr><td>Limit</td><td>90-125%</td></tr>
</table>
<u>Result</u>: The sample is declared Substandard on the basis of extractable volume test and Misbranded according to the Drugs (Labelling and Packaging) Rules, 1986 and as defined under subsection (s) of section 3 of the Drugs Act 1976.
</td>
</tr>
</table>

iii. Store Keeper of M/S Store Keeper (Veterinary Medicine) of Director Live Stock Bahawalpur provided invoice/ Warranty No. 21507 dated 07-06-2020 issued by M/S Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat, Islamabad-Pakistan as a proof of its purchase.

iv. Warrantor portion was sent to M/S Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat, Islamabad-Pakistan with directions to explain their position in this regard.

v. Copy of test report was sent to M/S Decent Pharma Plot # 30, Street # SS-3, National Industrial Zone, Rawat, Islamabad-Pakistan with directions to provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause issued to accused person(s) vide dated 14.03.2022

Reply of Show Cause Notice By Firm:

We hereby acknowledge the receipt of Show Cause Notice No. PQCB/R-635,636,637/2022

dated 14th March 2022 with following observations:

a) Product is Misbranded

b) Product is Substandard due to less volume.

1. It is stated respectfully that our firm was granted Registration Certificate of the above-mentioned veterinary drug in multi dose vial of 100 ml with the composition as under: 100 mg

Each ml contains: Gentamycin as Sulphate B.P

(Copy of Registration Certificate attached).

Now the spelling mistake has been rectified by DRAP (Copy attached)

2. DTL Report TRA No. 01-77001687/DTL dated 08-08-2020 (Batch No. 1-048) comply the sterility test and assay. The extractable volume deviates the stated limit.

3. DTL Report TRA No. 01-77001688/DTL dated 08-08-2020 (Batch No. 1-050) comply the sterility test and assay. The extractable volume deviates the stated limit.

4. DTL Report TRA No. 01-77001639/DTL dated 08-08-2020 (Batch No. I-051) comply the sterility test and assay. The exactable volume deviates the stated limit.

5. It is stated that our Quality Control and Quality Assurance Department have rechecked and found the filled volume of all batches within the stated limit of 100 ml

6. Keeping in view the abovementioned facts it is requested that:

a) Volume of the product may please be rechecked.

b) **As the product is supplied in multi dose packing, i.e.**

For cats and dogs: 0.5 ml to 1ml(approx.)

For Sheep and goats: 1-2ml (approx.)

For calves: 1-2 ml (approx.)

For Camel, Cows and Buffalo: 10-15 ml(approx.)

We are ready for supply of extra vials of the same drug if demanded by the Livestock department to compensate the less volume (if any).

Submitted for your kind consideration and favorable action please,

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

Summary:

Manufacturing Date:05.2020

Expiry Date: 05.2022

Sampling Date (Form 4): 08.06.2020

Sent to DTL (Form 6): 09.06.2020

Date of receipt in DTL: 09.06.2020

DTL Report Date (Form 7): 08.08.2020

Time Extension: N/A

1ST DI Communication with firm on dated: 18.09.2020

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated:10.11.2020

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 3

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 **Owners (New Management) 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 Owner (New Management) 2. Syed Talib Hashmi Owner (New Management)

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 Mand Bahauddin and took samples of ten different types of drugs on Form No.04 for the purpose o test/analysis.

ii. One out of ten drug samples, after test/analysis, was declared **Substandard** by Government Analy 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

Previous Proceedings & Decision by The Board:

258th meeting held on 05-04-2023

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Ms. Uzma Mazhar, Secretary DQCB, District Mandi Bahauddin attended the meeting via zoom meeting, whereas Mr. Muhammad Afzal, Drug Inspector Tehsil & District Mandi Bahauddin 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 appeared before the Board. Firm's quality control manager requested the Board to adjourn the case as their directors are out of country till 25th Ramadhan for performing Umrah. Hence, he requested the Board for hearing opportunity after Eid-ul-Fitr so that presence of both directors to represent the case can be ensured.

6. The Board, after due deliberation, unanimously decided to **adjourn the case** of **M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad** and to provide another yet final opportunity of personal hearing in the best interest of justice.

7. Personal hearing notice(s) issued to accused person(s) along with co-owners dated 20-04-2023

8. 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. 4

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 **Owners (New Management) 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 Owner (New Management) 2. Syed Talib Hashmi Owner (New Management)

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.

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 **258th meeting** held on **05-04-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Ms. Uzma Mazhar, Secretary DQCB, District Mandi Bahauddin attended the meeting via zoom meeting, whereas Mr. Muhammad Afzal, Drug Inspector Tehsil & District Mandi Bahauddin was present along with the original case record. Firm's quality control manager requested the Board to adjourn the case as their directors are out of country till 25th Ramadhan for performing Umrah. Hence, he requested the Board for hearing opportunity after Eid-ul-Fitr so that presence of both directors to represent the case can be ensured.

6. The Board, after due deliberation, unanimously decided to **adjourn the case** of **M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad** and to provide another yet final opportunity of personal hearing in the best interest of justice.

7. Personal hearing notice(s) issued to accused person(s) along with Co-Owners dated 20-04-2023.

8. 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. 5

PQCB R-472/2019

Tehsil Sambrial, District Sialkot

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.** 6. Faisal Muzammil Co-owner 7. Syed Talib Hashmi Co-owner 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.

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.

PQCB 258th meeting dated 05-04-2023:

13. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Amaad Ashraf, Drug Inspector Tehsil Sambrial District Sialkot was present along-with original case record. Mr. Hafiz M. Faisal, Secretary DQCB, Sialkot joined the meeting through zoom link. No-one among the nominated accused persons appeared before the Board, however, representative from the firm Ghulam Ghaus (Quality Control Manager) appeared before the Board on behalf of M/s Neomedix Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad and submitted written request for adjournment stating that the directors of the firm are on leave to perform Umrah. 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/last chance of personal hearing to the accused.

Personal Hearing Notice issued dated 20-04-2023

Case is placed before the Board for decision

PROCEEDINGS AND DECISION BY THE BOARD:

Case No. 6

PQCB R-599/2019

Tehsil Sambrial, District Sialkot

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.** 5. Faisal Muzammil Co-owner 6. Syed Talib Hashmi Co-owner 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.

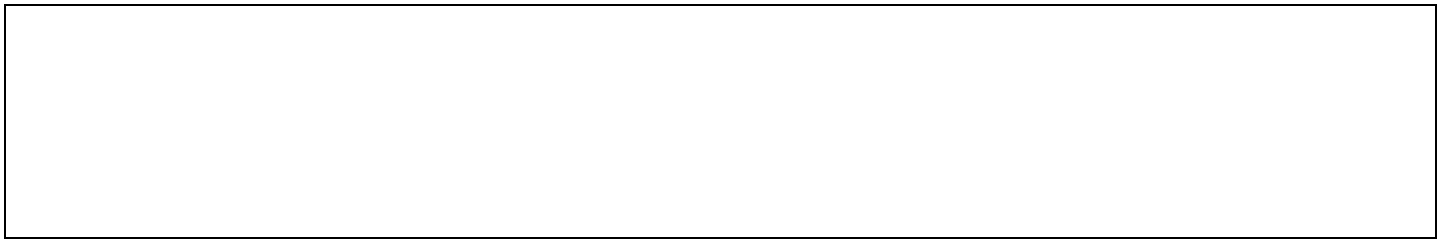
PQCB 258th meeting dated 05-04-2023:

10. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Amaad Ashraf, Drug Inspector Tehsil Sambrial District Sialkot was present along-with original case record. Mr. Hafiz M. Faisal, Secretary DQCB, Sialkot joined the meeting through zoom link. No-one among the nominated accused persons appeared before the Board, however, representative from the firm Ghulam Ghaus (Quality Control Manager) appeared before the Board on behalf of M/s Neomedix Plot No 5, N/5, National Industrial Zone, Rawat, Islamabad and submitted written request for adjournment stating that the directors of the firm are on leave to perform Umrah. 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/last chance of personal hearing to the accused.

Personal Hearing Notice issued to the accused dated 20-04-2023

Case is placed before the Board for decision

PROCEEDINGS AND DECISION BY THE BOARD:



Case No. 7

Case No.

PQCB R-292/2020

Benazir Bhutto Hospital, Rawalpindi

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/S Neomedix, Plot No. 5, N/5, national Industrial Zone, Rawat, Islamabad, Pakistan** through its Chief Executive Officer, Dr. Usman Qureshi. 2. Dr. Usman Qureshi — Chief executive Officer 3. Nadeem Aftab — Production Manager 4. Ghulam Ghaus — Quality Control Manager/Warrantor Of M/S Neomedix, Plot No. 5, N/5, national Industrial zone, Islamabad, Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Benazir Bhutto Hospital, Rawalpindi reported that: -

i. He, on 03-06-2020 inspected the Main Medicine Store of the Benazir Bhutto Hospital, Rawalpindi, and took sample of the subject drug on Form No. 4 for the purpose of test and analysis.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Suspension TEMPNIL 60ml [PARACETAMOL…120 mg/5ml]	600	M/S Neomedix, Plot No. N/5, National Industrial Zone, Rawat, Islamabad, Pakistan	01-72001117/DTL dated: 30Jul 2020	**Result of test/ analysis with specifications applied** BP 2020 **PHYSICAL DESCRIPTION** Pink colored suspension, filled in amber colored glass bottle with affixed label, sealed with silver aluminum screw cap imprinted with company names, further packed in labelled outer unit carton. **Orange color crystals, which remain undissolved on vigorous shaking, were observed in suspension. (DOES NOT COMPLY)** **IDENTIFICATION** Paracetamol identified. **ASSAY:** Stated: 120mg/5ml Determined: 99.282 mg/5ml Percentage: **82.73%** **(DOES NOT COMPLY)** Limit: 95-105% **RESULT:** **The sample is declared Sub-Standard on the basis of Assay test performed and Physical characteristics observed.**

iii. The Store keeper, Benazir Bhutto Hospital, Rawalpindi provided invoice/ warranty bearing No. 245-A dated 02-06-2020 issued by M/S Neomedix, Plot No. N/5, National Industrial Zone, Rawat, Islamabad, Pakistan.

iv. Warrantor Portion was sent to M/S Neomedix, Plot No. N/5, National Industrial Zone, Rawat, Islamabad, Pakistan.

v. A copy of Test/ Analysis report was also sent to M/S Neomedix, Plot No. N/5, National Industrial Zone, Rawat, Islamabad, Pakistan and they were directed to provide requisite information in this regard.

2. The 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 and Rules framed there under by the way of: -

a. **Manufacturing for Sale / Selling of Sub-standard Drug.**
b. **Issuance of false warranty.**

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

"Firm requested for retesting in response to the show cause."

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of The Drugs Act, 1976 in its **230th meeting held on 20-02-2021**. Mr. Zafar Iqbal, Secretary DQCB, District Rawalpindi, was present along with original record of the case. No one among the nominated accused persons of M/S Neomedix, Plot No. N/5, National Industrial Zone, Rawat, Islamabad, Pakistan was present. However, Malik Shahid Fareed (General Manager) appeared before the Board on behalf of M/S Neomedix, Plot No. N/5, National Industrial Zone, Rawat, Islamabad, Pakistan along-with the authority letter issued by the firm and requested for adjournment.

6. The Board after due deliberation and discussion unanimously decided to **adjourn the case** in the best interest of justice on request of the firm. The Board further decided to provide another chance of personal hearing to the accused.

7. Personal hearing notice(s) were issued to accused person(s).

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **232nd meeting held on 24-06-2021**. Mr. Kaiwan Hyder Drug Inspector Tehsil Murree District Rawalpindi appeared on the behalf of Secretary DQCB District Rawalpindi and Shafiq Khan Provincial Inspector of Drugs, Benazir Bhutto Hospital Rawalpindi were present along with original case record. Drug inspector briefed the Board about facts of the case and requested for the permission for prosecution. No one among the nominated accused persons were present. However, Representative of the firm, Ghulam Ghaus appeared before the Board and presented authority letter issued by the firm in favour of Mr. Malik Shahid Fareed (Manager of M/s Neomedix, Plot No. N/5, National Industrial Zone, Rawat, Islamabad, Pakistan) instead of him. In answer to this query, Ghulam Ghaus presented his appointment letter as Quality Control Manager of the firm with effect from 01-11-2019.

9. He submitted that the drug in question is substandard on the basis of assay with a narrow margin which is found out to be 82.73% while the limit is 95-105%, he requested the Board for the retesting of the drug sample. The Board on careful scrutiny of the case record observed that firm vide its letter no.QCM/N0120/2020 dated 19-11-2020 provided the names of prima facie to the Drug Inspector and mentioned the name of QCM as Roohi Asif while the representative present before the Board has provided its appointment letter according to which Ghulam Ghaus is the QCM w.e.f 01-11-2019.The Board further observed that the drug in question is manufactured in 05-2020, at the time of manufacturing of the subject drug sample the QCM of the firm was Ghulam Ghaus instead of Roohi Asif. This clearly reflects that the firm has provided misleading information by furnishing the wrong name of the Quality Control Manager. The Board showed its serious concern and displeasure against

the firm for submitting misguiding information to the Drug Inspector regarding the name of QCM of the firm and issued strict warning to **M/s Neomedix, Plot No. N/5, National Industrial Zone, Rawat, Islamabad, Pakistan with directions to be careful in future.** The Board further decided to **pend the case** with the directions to the Drug Inspector to **Re-investigate the case** in the light of documents submitted by the representative during proceeding of the meeting.

10. Revised Show cause notice was issued on 01-09-2022.

FIRM'S REPLY TO SHOW CAUSE NOTICE:

Referring to your letter No. PQCB/R-292/2020,dated 01-09-2022, which we received on 6th September 2022, regarding our product, Tempnil suspension, Batch 600 (Paracetamol 120mg/5ml), it is hereby stated that in our previous letters dated 01-02-2021, 18-02-2021 and 23-06-2021 we have replied for the subject. I'd request your kind office to close the case.

11. Personal Hearing Notice(s) issued to the accused along with the new management of M/S Neomedix (Pvt.) Ltd on 20-04-2023.

Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 05-2020

Expiry Date: 05-2022

Sampling Date: 03-06-2020

Sent to DTL (Form 6): 03-06-2020

Date of receipt in DTL: 05-06-2020

DTL Report Date: 30-07-2020

Time Extension: N/A

1ST DI Communication with firm on dated: 31-08-2020

Firm requested for retesting in response to the show cause.

Investigation Report Dated: 03-12-2020

Show cause notice issued: 25-01-2021

Revised cause notice issued: 01-09-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 8

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, District Lodhran 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:

244th meeting dated 31-05-2022:

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) dated 29-09-2023.

258th meeting dated 05-04-2023:

9. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Dr. Misbah-ud-Din, Secretary DQCB, District Lodhran attended the meeting online via zoom link & Mr. Faisal Farooq, Drug Inspector, Tehsil Dunyapur, District Lodhran was present along with the original case record. Among the nominated accused persons, Ghulam Ghaus, Quality Control

Manager/warrantor of **M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Pakistan** appeared before the board and submitted a written request for adjournment vide letter no. nil dated 05-04-2023, stating that both of their directors (Syed Talib Hussain & Faisal Muazamal) are on leave to perform Umrah and assured the presence of both directors in front of the Board to represent this case. Among the nominated accused persons, Shahid Raza, Proprietor of **M/s Marwa Trading 30-Khushal Colony, Near Molvi Ameer Shah Hospital, G.T Road, Peshawar** was present. No one among the nominated accused persons of **M/s Ali Medical Store, Kahror Pacca Road, Dunyapur, District Lodhran** was present. No one among the nominated accused persons of **M/s New Ikram Medicine, Whole Sale Medicine Market, Town Hall, Multan** was present.

10. 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.

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

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. 9

PQCB/R-98/2021

Bahawalpur Saddar

Misbranded & Sub-Standard (Assay Test

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan** through **M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan** through its Managing Director Muhammad Javeed. 2. Muhammad Javeed Managing Director 3. Saboor Ahmad Production Incharge 4. Buzarg Jamhir Quality Control Incharge/Warrantor of **M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan.**

Provincial Inspector of Drugs, Bahawalpur Saddar, District Bahawalpur reported that: -

i. He, on 03-03-2021, inspected the business premises of M/S Ikhlaq Brothers Medical Store Situated at Chak No. 7-BC, Bahawalpur and took samples of three different types of drug samples on Form No.04 for the purpose of test/analysis.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Solution. Dynate [Dimenhydrinate 12.5mg/4ml, 60ml oral solution.]	L489	M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan	01-77003414/DTL Dated. 06-05- 2021	**Analysis with specifications applied: MS** **Composition:** Each 4ml contains: Dimenhydrinate B.P……12.5 **Description:** **Clear Colorless liquid in sealed amber plasti Volume:60ml).** **Product Specifications on label claims that p Specifications.** **"Dimenhydrinate Oral Solution" monograph i BP". (The product is misbranded).** **PH:** **Limit: 5-7 Determined: 6** **Identification:** Dimenhydrinate is identified. **Ass** Stated 12.5mg/4ml **Determined 2.103mg/4ml** **Percentage 16.83%** Limit 90.0-110.0% **Dimenhydrinate:** Limit 5-7 Determined 6 **Result:** The sample is declared **Substandard** on the bas **Misbranded,** as defined under clause (vi) of sub- of section 3 of Drugs Act 1976.

iii. M/S Ikhlaq Brothers Medical Store Situated at Chak No. 7-BC, Bahawalpur provided Invoice/warranty No 46397 dated 24-02-2021 issued by M/S Zam Zam Pharma Bahawalpur who in turn provided invoice/warranty No. 1202, dated 18-01-2020 issued by M/s Convell Laboratories, Saidu Sharif, Sawat, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Zam Zam Pharma Bahawalpur and they were asked to explain their position in this regard.

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

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

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

b. **Issuance of false warranty**

3. Showcause was issued to accused person(s) vide dated 02.08.2021

4. Personnel Hearing notice(s) issued to accused person 12.09.2022

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its **250th** meeting held on **22-09-2022** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department, Punjab. Mr. Atiq-ur-Rehman Secretary DQCB District Bahawalpur and Mr. Muhammad Farrukh Saleem Drug Inspector Tehsil Bahawalpur Saddar were present along with original

record of the case. Drug Inspector Tehsil Bahawalpur Saddar briefed the Board about facts of the case and asked for permission for prosecution against the accused persons. No one among the nominated accused appeared before the Board on the behalf of **M/s Convell Laboratories, Saidu Sharif, Sawat, KPK, Pakistan.**

6. The Board after discussion decided to **adjourn** the case due to non-appearance of accused persons in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

Summary:

Manufacturing Date: 12.2019

Expiry Date: 12.2022

Sampling Date (Form 4): 03.03.2021

Sent to DTL (Form 6): 04.03.2021

Date of receipt in DTL: 04.03.2021

DTL Report Date (Form 7): 06.05.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 23.06.2021

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated: 26.07.2021

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

Case is placed before the Board for Decision**.**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 10

DISTRICT DERA GHAZI KHAN

PQCB/R-111/2022

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

ATTENDANCE:

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

BRIEF FACTS OF THE CASE

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

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

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

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

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

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

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

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

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

b. **Issuance of false warranty**

3. Show cause Notice (s) issued to the accused person(s) Dated 26-10-2022.

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

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

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

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

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

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

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

5. Case is placed before the Board for Decision

Summary:

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

PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 11

PQCB/R-521/2021

Tehsil Khiarpur Tamewali & District Bahawalpur

Misbranded & Sub-Standard (pH Test

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar-Pakistan** through its Chief Executive Officer Fawad Altaf. 2. Fawad Altaf — Chief Executive Officer 3. Shakeel Ahmad — Production Incharge 4. Muhammad Sadiq — Quality Control Incharge/Warrantor **of M/S Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar-Pakistan.**

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

i. He, on 30-10-2021, inspected the business premises of M/S Hasnain Medical Store, Railway Road Gulglan Wala Peer Tehsil Khairpur Tamewali, District Bahawalpur and took different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000110058, dated. 01-11-2021.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report
TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Suspension. Fedcid [Famotidine 10mg/5ml,60ml]
Mfg Date:
Nov-2020
Exp Date:
Oct-2022
Registration No.
059498</td><td>422</td><td>M/S Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar-Pakistan</td><td>01-86000276/DTL
Dated. 28-12-2021</td><td>
<u>Analysis with specifications applied:</u> MS.

Composition:

Each 5ml contains:

Famotidine U.S.P……10mg

<u>Description:</u>

White color suspension in a sealed amber glass bottle having white color aluminum cap with “FEDRO” logo on it. (Stated Volume: 60ml Approx).

Both primary and secondary labels claim USP specifications while the Famotidine Suspension is not present in USP. The USP monograph is of “Famotidine for Oral Suspension” which states that Famotidine for oral suspension contains the equivalent of NLT 90.0% and NMT 110.0% of the labelled amount of famotidine When constituted as directed. (The Product is misbranded).

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

<table>
<tr><td>Limit</td><td>6.5-7.5</td></tr>
<tr><td>Determined</td><td>6.083</td></tr>
</table>

Does not comply with the specifications.

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

Famotidine is identified.

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

<u>Famotidine:</u>

<table>
<tr><td>Stated</td><td>10mg/5ml</td></tr>
<tr><td>Determined</td><td>10.169mg/5ml</td></tr>
<tr><td>Percentage</td><td>101.69%</td></tr>
<tr><td>Limit</td><td>90-110%</td></tr>
</table>

<u>Result:</u>

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

iii. M/S Hasnain Medical Store, Railway Road Gulglan Wala Peer Tehsil Khairpur Tamewali, District Bahawalpur provided Invoice/warranty No 840, dated 25-10-2021 issued by M/S G.R Traders, House No. 108, Street No. 3 Muhajir Colony M.T.B Bahawalpur who in turn provided invoice/warranty No. 7484, Dated 04-03-2021 issued by M/S Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar-Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S G.R Traders, House No. 108, Street No. 3 Muhajir Colony M.T.B Bahawalpur and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar-Pakistan and they were asked to provide the requisite information in this regard.

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

   a. **Manufacturing for sale / sele of Substandard & Misbranded drug**

   b. **Issuance of false warranty**

3. Showcause was issued to accused person(s) vide dated 24.08.2022

Reply of Show Cause Notice:

That we have already recalled all the batches of famotidine suspension from the market and also stopped the manufacturing on the basis of suspension letter No. F-3-6/2021-Reg-1 (M-313) (Misc) dated 29th DEC 2021 from DRAP.

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

Case is placed before the Board for Decision

Summary:

Manufacturing Date: 11-2020

Expiry Date: 10-2022

Sampling Date (Form 4): 30.10.2021

Sent to DTL (Form 6): 01.11.2021

Date of receipt in DTL: 01.11.2021

DTL Report Date (Form 7): 28.12.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 21.02.2022

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated: 09.06.2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 12

No. PQCB/R-69/2019

Tehsil Liaqatpur District Rahim Yar Khan

ATTENDENCE

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Fedro Pharmaceutical Laboratories Pvt Ltd, 149 Industrial Estate Hayatabad Peshawar** through its Managing Director Fawad Altaf 2. Fawad Altaf Managing Director 3. Shakeel Ahmed Production Incharge 4. Muhammad Sadiq Quality Control Incharge/Warrantor of M/s Fedro Pharmaceutical Laboratories Pvt Ltd, 149 Industrial Estate Hayatabad Peshawar

BRIEF FACTS OF THE CASE

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

i. He, on 12-01-2019, inspected the business premises of M/s Shalimar Medical Store Abbasia Road, Tehsil Liaqatpur and took following drug sample on Form No. 04 for the purpose of test and analysis. Which after test/analysis was declared as **Substandard** and **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 Fedragyl DF (Metronidazole Benzoate equivalent to metronidazole 200mg, Diloxanide furoate 250mg)/10ml, 60ml approx	116	M/s Fedro Pharmaceutical Laboratories Pvt Ltd, 149 Industrial Estate Hayatabad Peshawar	TRA No.01-65000282/DTL dated:13-03-2019	**Analysis with specifications applied:** Manufacturer specifications **Description:** Erythrosine red colored viscous suspension in amber glass sealed bottle. ***A clot of greenish brown mass seen stick to interior lateral wall close to bottom of primary container.*** **(Does not comply with spes)** ***The label of the product does not bear the name of Pharmacopoeia or document according to which product is manufactured.*** **Identification:** Metronidazole Benzoate as metronidazole and Diloxanide furoate identified. **Assay:** Metronidazole 103.47% Complies Diloxanide Furoate 92.67% Complies **pH:** **Determined 4.76** Limit: 5.0-6.5 **(Does not comply)** **Deliverable volume:** Complies **Result:** The sample is **substandard** on the basis of physical description and pH test. The sample is **Misbranded** as defined under clause (vi) of sub-section (s) of section 3 of the drugs act, 1976.

ii. M/s Shalimar Medical Store Abbasia Road, Tehsil Liaqatpur provided Invoice/ warranty No. 309/ 1, dated 03-01-2019 issued by M/s New Ittehad Medicine Company, 8-Stadium Road, New Officer colony Rahim yar Khan as proof of its purchase.

iii. Warrantor portion of drug sample was sent to M/s New Ittehad Medicine Company, 8-Stadium Road, New Officer colony Rahim yar Khan and they were asked to explain their position in this regard.

iv. M/s New Ittehad Medicine Company, 8-Stadium Road, New Officer colony Rahim yar Khan provided invoice/warranty No. 485 dated 13-11-2018 issued by M/s Fedro Pharmaceutical Laboratories Pvt Ltd, 149-Hayat Abad Industrial Estate, Peshawar-Pakistan.

v. A copy of Test Report of drug sample was sent to M/s Fedro Pharmaceutical Laboratories Pvt Ltd, 149-Hayat Abad Industrial Estate, Peshawar-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 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/selling of Substandard & Misbranded drug.**

b. **Issuance of false warranty.**

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

Reply of the Firm to Drug Inspector:

The firm submitted written reply to the drug inspector stated that:

We have also sent a letter with tor the change of label claim of the subject product to Secretary Registration Board DRAP Islamabad). Furthermore, we are waiting for the DRAP reply, after that we will change our Label Claim & also include Product specifications.
We have also tested the stability of Fedragyl DF Suspension, Batch No. 116, the suspension batch no. 116, the suspension is clear of orange color having no clot of brown mass to interior internal wall of the bottle, and the pH is 5.8 which is within limit

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 **206th meeting held on 23-05-2018**. Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons. Secretary PQCB apprised the Board that the show cause/personal hearing notice was duly served to the accused persons through registered post.

5. Counsel person Sheikh Irfan Saeed advocate was appeared before the Board on the behalf of M/s Fedro Pharmaceutical Laboratories and stated that as per report of Govt Analyst, that the product is misbranded as specifications was not mentioned on label. The firm rectified the label of said drug and start mentioning B.P specification on label. The sample was also declared substandard as clot of greenish brown mass seen stick to interior lateral wall close to bottom of primary container. Counsel person stated that the Govt Analyst did not mention nature of clot nor he mentioned clot was appeared before or after constitution of suspension.

6. The Board, after detailed scrutiny of the case record and statement of the accused person observed that in order to dig out the root cause of this defect the Production and Quality Control & Assurance for subject drug need to be evaluated. Therefore, the Board decided to constitute a committee comprising of the followings to conduct Product Specific Inspection (PSI) of **M/s Fedro Pharmaceutical Laboratories Pvt Ltd, 149 Industrial Estate Hayatabad Peshawar** and submit report for consideration by the Board:

1.	**Prof Dr. Mehmood Ahmad** Member PQCB	Convenor
2.	**Munawar Hayyat** Chief Drugs Controller Punjab /Member	Member

7. Committee submitted PSI report of M/s Fedro Pharmaceuticals

PRODUCT SPECIFIC INSPECTION REPORT OF M/S FEDRO PHARMACEUTICAL (PVT) LTD, 149- INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR.

Panel Members:

Prof. Dr. Mahmood Ahmad (Member)

Dr. Muhammad Munawar Hayat, CDC Punjab.

Date of Inspection: 03-08-2019

Inspection was conducted with reference to order DATED 04-06-2019 in case no. PQCB/R-69/2019.

Premises:

Unit started in 1980, Total area (2 ACARS), covered area 40% of total),

Ware Houses, General Tablets, General Capsule, General Liquid, Penicillin section, Cephalosporin section (Dry suspension & capsule) and Quality Control Department are on ground floor.

Sample retention room, water treatment plant and account offices are on first floor.

Drug

Suspension Fedrogyl DF 60ml, Batch No. 116,

Date of Mfg. 10.2018

Expiry Date. 09.2020

Declare Substandard from DTL Bahawalpur, vide test report No. 01-65000282/DTL, dated 13.03.2019.

Staff

Designation	Person Name
Chief Executive officer	Fawad Altaf
Production Manager	Rizwan Ullah
QC Manager	Muhammad Sadiq
Warrantor	Muhammad Sadiq

OBSERVATIONS:

1. Sample was taken by Drug Inspector, Tehsil Liaqatpur District Rahim Yar Khan from M/S Shalimar Medical Store abbasia road, liaqatpur on 12-01-2019.
2. Drug Testing Laboratory Bahawalpur declared the sample Substandard on physical appearance and pH 4.76 (Limit: 5-6.5%).
3. Product Specification of suspension Fedrogyl DF 60ml mentioned in registration are Fedro specs and not mention on label of product, declared Misbranded Drug.

Batch Processing Record of Specific Product

1. Batch Number: 116
2. BMR Record: available.
3. QC retain sample: Available. Expire on 09/2020.
4. Testing method: In house method on UV/Vis spectrometer (Not fulfilled the legal requirement for validation of method).
5. Batch size: 1200Litres, or 20,000 Bottles

Findings

1. Upon reviewing the BMR of product it was revealed that production was started on 11.10.2018.
2. The mixing was done on 11-10-2018.
3. The firm was using deionized water and performing its all specification tests like pH, conductivity, total dissolved solids, chlorides, sulphates, etc.
4. The theoretical yield of batch is 1200litre.
5. The practical yield is 1197.6 litre, and loss is 0.2%.
6. The pH (during bulk) was 5.74 (Limit: 5-6.6).
7. The firm had performed analysis on UV/ Vis spectrophotometer (checked and found functional at time of inspection) and method was not validated.
8. The two stability chambers were found available and functional in QC lab.
9. The source of raw material was china.
10. The firm was using new glass bottle purchased from Ghani glass.

Conclusion

After careful evaluation of record, the panel is of opinion that the cause of substandard and Misbranded drug was

- The firm was advised to check the quality of citric acid and sodium benzoate and evaluate the cause of pH variation. on pH basis the variation is 0.24 at lower side, making suspension more acidic.
- The firm provided the calibration certificate of pH meter and pH meter was calibrated and in functional state.
- The firm improved the BMR documents in this case and established QA independent division current.
- The firm has written specification of formulation on label and provided the correct label at spot.

The case is presented to the honorable Board for final decision.

8. PSI report sent to the firm M/s Fedro Pharmaceutical Laboratories Pvt Ltd, 149-Hayat Abad Industrial Estate, Peshawar-Pakistan on dated 06-01-2023.

CORRECTIVE & PREVENTIVE ACTIONS (CAPA)

Firm submitted Corrective & Preventive Actions (CAPA) vide letter Ref no. FDL/PQCB-P/3063 dated 17-01-2023.

With reference to your letter no: PQCB/R-69/2019 dated 06/01/2023 regarding subject sited above, following Corrective and Preventive Actions has been taken.

1. Washed the test tubes and other glass apparatus thoroughly with distilled water, before use. All solutions should be freshly prepared. Keep the pH electrodes away from chemical fumes. Either use a fresh fine dropper or glass rod for each different sample or wash the dropper or rod well with water every time.
2. Wear gloves, goggles, and lab coats while handling solutions. Buffers should always be read at accurate pH. Do not immerse electrodes in the buffer solutions before rinsing the electrodes thoroughly with deionized water. Do not mix buffers with other solutions or contaminate with samples.
3. Following trend analysis and brain storming of root causes analysis and training conducting accordingly
4. Tested the excipient Sodium Benzoate using for the preservation of suspension. All the tests are within the limits.
5. Tested the excipient, citric acid using for the pH of suspension. All the are within the limits.
6. Deionizer are also washed and all the filters i.e. sand filter, carbon filter, soft cleaner filter as to improve the quality of deionized water.
7. Performed daily verification/Calibration of the PH meter with buffers solutions pH 4.0, pH 7.0 and pH 10 on regular basis.
8. SOP for CAPA amended accordingly after training of analysts.
9. SOP for CAPA is submitted.
10. Prior cleaning and washing of all Sampling areas and sampling tools and general are upgraded accordingly WHO guidelines
11. Training of QA, QC staff / officers will be conducted for implementation.
12. Updated an instrument and calibration certificates will be obtained by the third party in future.
13. Maintain and keeping daily cleaning and maintenance record of pH meter.
14. The samples are repeatedly analyzed and check by technical manager.
15. The pH meter's performance checked in parallel testing with controlled and previously passed samples.

Now the quality of the pointed products is of standard quality and stable.

9. Personal hearing notice(s) issued to accused dated 20-04-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 13

PQCB/R-3/2023

Government General Hospital, Ghulam Muhammad Abad, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Martin Dow Marker, Quetta, 7-Jail Road, Quetta-Pakistan** through its Managing Director, Sheikh Muhammad Inam 2. Sheikh Muhammad Inam — Managing Director 3. Rozina Farah — Production Incharge 4. Abid Fida — Quality Control Incharge 5. Muhammad Bilal — Warrantor of M/s Martin Dow Marker, Quetta, 7-Jail Road, Quetta-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Government General Hospital, Ghulam Muhammad Abad, District Faisalabad reported that: -

i. He, on 19-11-2022, inspected the premises of Main Medicine Store of Government General Hospital, Ghulam Muhammad Abad, District Faisalabad, took below mentioned 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. 148728 dated 19-11-2022.

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. Laxoberon [Each 5ml contains: Sodium Picosulphate monohydrate BP …. 5mg] **Mfg Date:** Oct 2022 **Expiry Date:** Oct 2025 **Regn No.** 019799	26837	M/s Martin Dow Marker, Quetta, 7-Jail Road, Quetta-Pakistan.	01-68020639/DTL dated: 06-01-2023	**Analysis with specifications applied:** MS **DESCRIPTION:** A clear golden orange liquid having fruity odor, contained in amber colored glass bottle with sealed metallic screw cap. **NOTE:** Product specifications mentioned on Label are **"BP"**, BP monograph of Sodium Picosulphate oral solution defines that **"it contains 95.0% to 105.0% of the stated amount of Sodium Picosulphate $C_{18}H_{13}NNa_2O_8S_2$"**. However, manufacturer specify contents on Label as **"Each 5ml contains Sodium picosulphate monohydrate BP … 5mg"** which is contradictory to BP and so Manufacturer's claim is false/misleading and in violation to Drugs Act 1976. **(Does not Comply)** **IDENTIFICATION:** Sodium picosulphate monohydrate is identified. **ASSAY:** Stated: 5.0 mg Sodium Picosulphate monohydrate/ 5ml Determined: 5.279 mg/ 5ml Percentage 105.60 % (Complies) Limit: 90-110% (Manufacturer's Specifications) **pH:** Stated: 5.0 – 7.0 (Manufacturer's Specifications) Determined: 6.33 (Complies) **RESULT:** Given sample is **Misbranded** with regards to Labelling **(as per Section 3 (s) (iv) of The Drugs Act 1976).**

iii. Store keeper Main Medicine Store of Government General Hospital, Ghulam Muhammad Abad, District Faisalabad provided invoice/warranty bearing No. 7881 dated 11-11-2022

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 invoice/warranty bearing No. 9000056587 dated 10-11-2022 issued by M/s Martin Dow Marker, Quetta, 75-M, Quaid-e-Azam Industrial Estate, Township, Kot Lakhpat, Lahore as a proof of its purchase of the subject drug sample.

v. A copy of test/analysis report was sent to M/s Martin Dow Marker, Quetta, 7-Jail Road, Quetta-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 19-04-2023

Firm replied to the Drug Inspector vide letter no. SMI/mm/RA/028/2023 dated 31-01-2023

Please note that the ***Product is manufactured in compliance with BP specs****. and the same is mentioned on label claim which is already approved as per registration letter. However, as the Company being a complaint organization, w****e will now process to implement revised label claim*** *as per your instructions regarding labelling in compliance to The Drugs Act 1976.*

NOTE: Firm submitted rectified label of the subject drug sample.

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

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 30-10-2022

Expiry Date: 29-10-2025

Sampling Date (Form 4): 19-11-2022

Sent to DTL (Form 6): 19-11-2022

Date of receipt in DTL: 23-11-2022

DTL Report Date (Form 7): 06-01-2023

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 24-01-2023

Retesting Request of Firm: NA

Investigation Report Dated: 15-02-2023

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 14

PQCB/R-2/2023

Allied Hospital, District Faisalabad

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Martin Dow Marker, Quetta, 7-Jail Road, Quetta-Pakistan** through its Managing Director, Sheikh Muhammad Inam 2. Sheikh Muhammad Inam — Managing Director 3. Rozina Farah — Production Incharge 4. Abid Fida — Quality Control Incharge 5. Muhammad Bilal — Warrantor of M/s Martin Dow Marker, Quetta, 7-Jail Road, Quetta-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Allied Hospital, District Faisalabad reported that: -

i. She, on 15-11-2022, inspected the premises of Central Pharmacy of Allied Hospital, District Faisalabad, took six different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Faisalabad vide memorandum no. 148225 dated 15-11-2022.

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. Laxoberon [Each 5ml contains: Sodium Picosulphate monohydrate BP …. 5mg] **Mfg Date:** Oct 2022 **Expiry Date:** Oct 2025 **Regn No.** 019799	26837	M/s Martin Dow Marker, Quetta, 7-Jail Road, Quetta-Pakistan.	01-68020307/DTL dated: 06-01-2023	**Analysis with specifications applied:** MS **DESCRIPTION:** A clear golden orange liquid having fruity odor, contained in amber colored glass bottle with sealed metallic screw cap. **NOTE:** Product specifications mentioned on Label are **"BP"**, BP monograph of Sodium Picosulphate oral solution defines that **"it contains 95.0% to 105.0% of the stated amount of Sodium Picosulphate $C_{18}H_{13}NNa_2O_8S_2$"**. However, manufacturer specify contents on Label as **"Each 5ml contains Sodium picosulphate monohydrate BP … 5mg"** which is contradictory to BP and so Manufacturer's claim is false/misleading and in violation to Drugs Act 1976. **(Does not Comply)** **IDENTIFICATION:** Sodium picosulphate monohydrate is identified. **ASSAY:** Stated: 5.0 mg Sodium Picosulphate monohydrate/ 5ml Determined: 5.359 mg/ 5ml Percentage 107.18 % (Complies) Limit: 90-110% (Manufacturer's Specifications) **pH:** Stated: 5.0 – 7.0 (Manufacturer's Specifications) Determined: 6.61 (Complies) **RESULT:** Given sample is **Misbranded** with regards to Labelling **(as per Section 3 (s) (iv) of The Drugs Act 1976).**

iii. Chief Pharmacy Technician of Central Pharmacy of Allied Hospital, District Faisalabad provided warranty bearing No. 7577 dated 11-11-2022 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 invoice/warranty bearing No. 9000056585 dated 10-11-2022 issued by M/s Martin Dow Marker, Quetta, 75-M, Quaid-e-Azam Industrial Estate, Township, Kot Lakhpat, Lahore as a proof of its purchase of the subject drug sample.

v. A copy of test/analysis report was sent to M/s Martin Dow Marker, Quetta, 7-Jail Road, Quetta-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 19-04-2023

Firm replied to the Drug Inspector vide letter no. SMI/mm/RA/027/2023 dated 27-01-2023

Please note that the ***Product is manufactured in compliance with BP specs****. and the same is mentioned on label claim which is already approved as per registration letter. However, as the Company being a complaint organization, w****e will now process to implement revised label claim*** *as per your instructions regarding labelling in compliance to The Drugs Act 1976.*

NOTE: Firm submitted rectified label of the subject drug sample.

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

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 30-10-2022

Expiry Date: 29-10-2025

Sampling Date (Form 4): 15-11-2022

Sent to DTL (Form 6): 15-11-2022

Date of receipt in DTL: 16-11-2022

DTL Report Date (Form 7): 06-01-2023

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 21-01-2023

Retesting Request of Firm: NA

Investigation Report Dated: 13-02-2023

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 15

PQCB/R-279/2022

Tehsil Phalia & District Mandi Bahauddin

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Akson Pharmaceuticals (Pvt.) Ltd., Plot No. 9-B/1&2, Old Industrial Estate Mirpur, Azad Kashmir** through its Managing Director, Siraj ud Din 2. Siraj ud Din Managing Director 3. Rashid Ahmad Production Incharge 4. Muhammad Azeem Quality Control Incharge/ Warrantor of M/s Akson Pharmaceuticals (Pvt.) Ltd., Plot No. 9-B/1&2, Old Industrial Estate Mirpur, Azad Kashmir

BRIEF FACTS OF THE CASE

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

i. He, on 19-04-2022 inspected the business premises of M/s Mian Healthcare Pharmacy, Phalia Bherowal Road, Adda Nawan Loak, Tehsil Phalia District Mandi Bahauddin, took two different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 124420 dated 21-04-2022.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report No. & Date</th><th>DTL Test Report Result</th></tr>
<tr>
<td>Suspension. Gepep 60ml [Each 5ml contains: Famotidine U.S.P …. 10mg]

Mfg Date:
Oct 2021

Expiry Date:
Sep 2023

Regn No.
035275</td>
<td>117</td>
<td>M/s Akson Pharmaceuticals (Pvt.) Ltd., Plot No. 9-B/1&2, Old Industrial Estate Mirpur, Azad Kashmir.</td>
<td>01-68015430/ DTL
Dated
23-07-2022</td>
<td><u>Analysis with specifications applied:</u> MS

<u>DESCRIPTION:</u> Yellowish colored liquid contained in amber color glass container sealed with metallic cap, packed in outer hard carton.

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

<u>ASSAY:</u>
<table>
<tr><td>Stated</td><td>10mg / 5ml</td></tr>
<tr><td>Determined</td><td>6.3338 mg / 5ml</td></tr>
<tr><td>Percentage</td><td>63.338 % (Does not Comply)</td></tr>
<tr><td>Limit</td><td>90.0–110.0%
(Manufacturer’s Specifications)</td></tr>
</table>
<u>LABELLING REQUIREMENTS:</u>

<u>STATED:</u> As per Section 3 (s) (iv) of The Drugs Act 1976, “Misbranded” means:

“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>OBSERVED:</u> In case of given sample, “USP Specifications” are printed on the label but in United States Pharmacopoeia no such monograph of Famotidine Oral Suspension is available, so manufacturer’s claim regarding product specifications is false/misleading and in violation to Drugs Act 1976. (Does not comply)

<u>RESULT: Given sample is Sub-Standard with regards to Assay and Misbranded with regards to Labelling as per Section 3 (s) (iv) of The Drugs Act 1976.</u></td>
</tr>
</table>

iii. Proprietor of M/s Mian Healthcare Pharmacy, Phalia Bherowal Road, Adda Nawan Loak, Tehsil Phalia District Mandi Bahauddin provided Invoice/Warranty bearing No. 4603 dated 17-02-2022 issued by M/s Ali Medicine Distributors, Wapda Colony Road Mandi Bahauddin as a proof of its purchase.

iv. Warrantor portion of drug sample and a copy of test/analysis report was sent M/s Ali Medicine Distributors, Wapda Colony Road Mandi Bahauddin who provided Invoice/Warranty bearing No. 9214 dated 22-01-2022 issued by M/s Akson Pharmaceuticals (Pvt.) Ltd., Plot No. 9-B/1&2, Old Industrial Estate Mirpur, Azad Kashmir as a proof of its purchase.

v. A copy of test/analysis report was sent to M/S Akson Pharmaceuticals (Pvt.) Ltd., Plot No. 9-B/1&2, Old Industrial Estate Mirpur, Azad Kashmir with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to firm’s request, the Provincial Quality Control Board in its 252nd meeting held on 01-11-2022, after due deliberation and discussion unanimously decide to turn down the firm’s request for retesting of the subject sample.

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

252th meeting held on 01-11-2022

2. The subject request for retesting of the drug sample was placed before the Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **252nd meeting** held on **01-11-2022** under the chairmanship of Secretary, Primary & Secondary Healthcare Department, Punjab. Muhammad Azeem Quality Control Manager of M/S AKSON Pharmaceuticals Pvt Ltd., appeared before the Provincial Quality Control Board to plead the said case.

3. The Secretary PQCB apprised that Drug Testing Laboratory report conveyed by the Provincial inspector of Drugs to manufacturer vide letter no. 161/DDC/PHL Dated **18-08-2022**. Manufacturer requested for retesting vide letter No AK/DTL/011/22 dated **25-08-2022.** The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter no. PQCB/P-573-07/2022 dated 21-09-2022 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above - mentioned batch and procurement proof of Primary Standard/Secondary Standard). and firm provided evidence.

4. The Board thoroughly evaluated the DTL test report and observed that the subject product fails to comply on the basis of Assay test of the active pharmaceutical ingredient which is remarkably less (**63.338 %**) than the lower admissible limit of Manufacturer's Specifications (90-110%). The Board further scrutinized the all relevant data submitted by the Government Analyst regarding the test /analysis and observed that Government Analyst has fulfilled all requirements of the test protocol as described in the Manufacturer's Specifications. **The test was performed on UV Spectrophotometer with Audit trail**. Moreover, after revamping, the Drug Testing Laboratories of the Punjab are testing the drug samples according to the International Standard of the test / analysis and all these laboratories are ISO Certified and are in process of WHO accreditation.

5. **Contrarily, the data submitted by the firm in controversion to the Government Analyst report in PQCB regarding the Assay test of subject drug was not according to the protocol of the Assay test as given in the Manufacturer's Specification provided to the Government analyst**. **The Board observed that firm has performed assay test on HPLC followed by USP specification whereas in USP no such monograph is available for suspension Famotidine but only monograph of Famotidine for oral suspension is available**. **Hence, the subject drug is declared Misbranded by the DTL, Faisalabad.**

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

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

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

b. **Issuance of false warranty**

8. Show-cause notice(s) issued to accused person(s) dated 20-01-2023

Firm replied to the show cause notice vide letter no. AK/PQCB/002/2023 dated 30-01-2023

*We have **requested the Provincial Quality Control Board for retesting** of said sample of Gepep Suspension Batch No. 117. **Our routine testing method of Gepep Suspension was UV Spectrophotometer**, which were in our use for at least 18 years. Actually in this method Excipients placebo is used in standard preparation, if there is some minute difference in preparation of placebo, then there is so much chances of result variations. Respected sir, **we have also developed alternative HPLC method for testing of above said product**, which was provided when we requested for retesting of said sample which was not considered. new developed HPLC method, the results were within the specified limit.*

*Respected Sir, before taking any action, **we again and again request to you for retesting of said sample of Gepep Suspension Batch No. 117 from Appellate Laboratory, National Institute of Health, Islamabad**. We are available for any justification/ enquiry.*

9. Personal hearing notice(s) issued to accused person(s) dated 20-04-2023

10. Case is placed before the Board for decision.

Summary:

Manufacturing Date: Oct-2021

Expiry Date: Sep-2023

Sampling Date (Form 4): 19-04-2022

Sent to DTL (Form 6): 21-04-2022

Date of receipt in DTL: 27-04-2022

DTL Report Date (Form 7): 23-07-2022

Time Extension: Granted in 246th meeting dated 05-07-2022

1ST DI Communication with firm on dated: 18-08-2022

Retesting Request of Firm: Yes (25-08-2022)

Fate of Retesting Request: Turned Down in 252nd meeting dated 01-11-2022

(Firm reiterated their retesting request in response to the Show Cause Notice on 30-01-2023)

Investigation Report Dated: 16-12-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 16

PQCB/R-79/2022

DHQ Teaching Hospital Sahiwal

Misbranded & Sub-Standard (Assay Test

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat, Pakistan** through its Managing Director/Warrantor Javaid Iqbal Satti. 2. Javaid Iqbal Satti — Managing Director/Warrantor 3. Kamran John — Production Incharge 4. Rahat Ali Khan — Quality Control Incharge **of M/S Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat, Pakistan.**

Provincial Inspector of Drugs, Sahiwal Teaching Hospital, District Sahiwal reported that: -

i. He, on 04-02-2022, inspected the premises of Main Medicine Store, Sahiwal Teaching Hospital, District Sahiwal and took a drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 163, dated 04-02-2022.

ii. Following Drug sample after test/analysis was declared as **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
Capsule. TAMSUBEN 0.4mg Capsule [Sustained release pellets of Tamsulosin HCl equivalent to Tamsulosin 0.4mg] **Mfg Date: Exp Date: Registration No.** Jan-2022 Jan-2024 088463	4575	M/S Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat, Pakistan	01-85001348/DTL Dated. 10-03-2022

DTL Teat Report Result

Analysis with specifications applied: **USP 2021.**

Composition:

Each Capsule contains:

Tamsulosin hydrochloride sustained relese pellets equivalent to Tamsulosin (USP)……..0.4mg

Description:

White colored, spherical pellets in hard gelatin capsule having transparent body and navy-blue cap in blister pack of seven capsules. Packed in outer carton.

The label on the blister as well as on the outer carton contains USP Finished Drug Product Specifications. Now USP States that "Tamsulosin Hydrochloride Capsule contains NLT 90.0% and NMT 110.0% of the labelled amount of Tamsulosin hydrochloride (C20H28N2O2S.HCl)" whereas the label claim on product is "Tamsulosin Hydrochloride sustained relese pellets equivalent to Tamsulosin (USP) 0.4mg" which is contradictory to the USP Specifications and is false/misleading information.

The Product is Misbranded.

Identification:

Tamsulosin HCl is identified.

Assay:

Tamsulosin HCl:

Stated	0.4mg/Cap
Determined	**0.496mg/Cap**
Percentage	**124.09%**
Limit	90.0-110.0%

Does not comply with the specifications.

Dissolution test:

Tolerance Limit:

Acid Stage:

Each unit drug release must be 13-34% in 02 hours.

Buffer Stage:

Each unit drugs release must be 47-68% at 3rd hour and NLT 80% at 8th hour.

Stage	Ebastine	Acceptance Criteria	Average	Remarks
		Acid Stage: Each unit drug release must be 13-34% in 02 hours. **Buffer Stage: Each unit drugs release must be 47-68% at 3rd hour and NLT 80% at 8th hour.**		**comply with specifications.**
Acid (02 Hr)	**06**			
Buffer (03 hr)	**Tamsulosin HCl**		**29.81%**	
Buffer (08 Hr)			**65.60%**	
			99.75%	

Unit No 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6
33.30%	**28.17%**	**26.31%**	**31.90%**	**29.58%**	**29.59%**
62.70%	**65.88%**	**64.96%**	**66.64%**	**67.43%**	**66.00%**
98.10%	**91.89%**	**101.57%**	**105.81%**	**98.30%**	**102.81%**

Result:

The sample is declared Substandard on the basis of Assay Test Moreover the sample is declared **Misbranded** as defined under clause (iv) of subsection (s) of section 3.

iii. Store Keeper of Main Medicine Store, Sahiwal Teaching Hospital, District Sahiwal provided Invoice/warranty No 1566, dated 11-1-2022 issued by M/S Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat, Pakistan and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat, Pakistan and they were asked to provide the requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Showcause was issued to accused person(s) vide dated 29.08.2022

Reply of Show Cause Notice:

Response to declaration of drug being declared MISBRANDED.

Although we agree that that our label claim is not in accordance with USP it is important to highlight here that the label claim is in 100% in accordance with the registration letter issued to us by DRAP for the product in question. We therefore manufactured the subject drug in accordance with section 23(a)vii which forbids the manufacturer to sell drugs **NOT IN ACCORDANCE WITH THE CONDITIONS OF REGISTRATION.** It is however negligent on our part that this contradiction between registration letter and USP was not brought into notice of DRAP.

Response to declaration of drug being declared SUBSTANDARD.

It is very important to highlight our intention in this case. The drug was declared substandard on basis of exceeding higher limit of assay i.e. 110%. The active pharmaceutical ingredient was found to be in excess of limit and not less than it. Therefore, we did not intend to gain any unfair financial advantage by manufacturing and selling the subject batch.

As per specification mentioned in the product registration letter and consequently on our label claim, we analyzed the final product while excluding hydrochloride from the equation. As a result, overage of 20.32mg Tamsulosin HCL pallets was added per capsule to achieve specified assay result. According to that, our assay result was within range i.e. 97.90%. However, USP requires the analysis to be done with HCl as part of the equation. When that analysis was done according USP, the overage of Tamsulosin HCl pallets was taken together with HCL leading to assay result way above higher limit of 110%.

This problem has occurred as a result of contradiction between product registration letter and USP. As soon as the problem came to our knowledge, we updated our label claim accordingly as well as supplied replacement against the misbranded and substandard stock to Sahiwal Teaching Hospital. Details of replacement stock have been attached in ANNEXURE A.

We therefore offer our sincere apologies and demand that we may not be prosecuted in the Drug Court and our registration letter not be recommended for suspension / cancellation.

VERIFICATION OF RE-CALLED STOCK:

No recall of subject batch was made as the relevant batch was supplied to the following institutions only:

1. DHQ SARGHODA (Stock declared of standard quality)

2. SAHIWAL TEACHING HOSPITAL (Replacement supplied)

4. Personnel Hearing notice(s) issued to accused person 09.01.2023

Case was 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 256th meeting held on 19-01-2023 under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Ahmad Awais, Secretary DQCB Sahiwal was present along with the original case record. Among the nominated accused persons Kamran John (Production Incharge) and Rahat Ali Khan (Quality Control Manager) of M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat, Pakistan did not appear before the Board at the time of case hearing. While, they submitted written request of adjournment vide letter nil dated 19.01.2023.

6. The Board after due deliberation and discussion unanimously decided to adjourn the case in the best interest of justice and provide another opportunity of hearing to the accused.

Summary:

Manufacturing Date: 01.2022

Expiry Date: 01.2024

Sampling Date (Form 4): 04.02.2022

Sent to DTL (Form 6): 04.02.2022

Date of receipt in DTL: 04.02.2022

DTL Report Date (Form 7): 10.03.2022

Time Extension: N/A

1ST DI Communication with firm on dated: 21.03.2022

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated: 14.07.2022

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

Case iss placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 17

PQCB R-343/2021

Shah Rukn-e-Alam Town, Multan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Bio Labs Pvt Ltd plot No. 145, Industrial Triangle Kahuta Road, Islamabad** through its Managing Director Usman Shoukat. 2. Usman Shoukat Managing Director 3. Naveed Anjum Production Manager 4. Muhammad Shaukat Quality Control incharge /Warrantor of M/s Bio Labs Pvt Ltd plot No. 145, Industrial Triangle Kahuta Road, Islamabad

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Shah Rukn-e-Alam Town, Multan reported that: -

i. His predecessor, on 09-12-2020, inspected the business premises of M/s Siddiqi & Sons, 50/D, Shamsabad colony, Multan and took four different types of Drug samples on Form No. 04 for the purpose of test and analysis and sent it to Drugs Testing Laboratory Multan.

ii. The following drug sample, after test/ analysis was declared **Substandard & 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>Injection Bmark-D Injection (Cholecalciferol Vitamin D3, 5mg/ml)

Mfg. Date: Sep-2019

Exp. date: Sep-2021

Reg# 095777</td><td>A-700</td><td>M/s Bio Labs Pvt Ltd plot No. 145, Industrial Triangle Kahuta Road, Islamabad</td><td>TRA No.01-89001347/DTL

dated:09-02-2021</td><td>Analysis with specifications applied: MS

<u>Description</u>:

Clear, colorless to slightly yellow oily liquid in amber glass ampoule of 1ml volume with printed label packed in a PVC tray of 1 ampoule in a labeled outer hard carton.

Product states “B.P specifications” as Finished Drug Product Specification on the label of immediate container as well as on outer unit carton. But B.P, Monograph of cholecalciferol injection clearly states that “Cholecalciferol injection is a sterile solution containing 0.75% w/v of Cholecalciferol” which is equivalent to 7.5mg/ml of Cholecalciferol. Whereas, Label claim of the product states “Each 1ml ampoule contains Cholecalciferol (Vitamin D3) 5mg” Which is false/ misleading & is in violation to Drug Act 1976, and is declared misbranded.

(Misbranded-Does not comply)

<u>Identification:</u>

Cholecalciferol identified.

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

<table><tr><td>Stated</td><td>5mg/ml</td></tr><tr><td>Determined</td><td>2.84mg/ml</td></tr><tr><td>Percentage</td><td>56.71%</td></tr><tr><td>Limit</td><td>89.33-110.66%</td></tr></table>
(Does not comply)

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

<u>Average Volume:</u>

<table><tr><td>Limit</td><td>NLT Stated</td></tr><tr><td>Determined</td><td>1.0ml</td></tr></table>
(Complies)

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

iii. M/s Siddiqi & Sons, 50/D, Shamsabad colony, Multan provided invoice/ Warranty No. 21984 dated 21-08-2020 issued by M/s Prime Care, 12-A, 11 Education Town, Wahdat Road, Lahore who in turn provided invoice/warranty No. 244A Dated 16-10-2019 issued by M/s Bio Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate, Lahore who in turn provided invoice/warranty No. Nil Dated 14-10-2019 issued by M/s Bio Labs Pvt Ltd plot No. 145, Industrial Triangle Kahuta Road, Islamabad as a proof of its purchase.

iv. Warrantor portion was sent to M/s Prime Care, 12-A, 11 Education Town, Wahdat Road, Lahore and they were asked to explain its position in this regard.

v. A copy of test report was sent to M/s Bio Labs Pvt Ltd plot No. 145, Industrial Triangle Kahuta Road, Islamabad with directions to provide relevant information in this regard. and they were asked to provide the requisite information in this regard. 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. **Retesting request** was considered in **16 Committee-Meeting** of PQCB held on **16-06-2021** in which committee decided to **turn down** the request as the committee was of considerate view that the firm has not provided vital information/data to justify the test/analysis of its product. Contrarily the data submitted by the Government Analyst clearly indicated that the drug was tested according to the protocol as described the monograph of British Pharmacopoeia. Besides, the report itself when embodies the protocol of test applied by the Analyst would become conclusive evidence of the results therein.

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

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

b. **Issuance of false warranty**

3. Show Cause notice(s) issued to the accused on 07-03-2021

Reply of Firm to Show Cause Notice

1. This is in reference to your letter bearing No. PQCB/R-343/2021 dated 07-03-2022 received at our premises regarding the captioned matter.
2. Your good office vide the aforementioned letter has sought a clarification with regards to retesting request wherein M/s Bio-Labs (Pvt.) Ltd had requested for the retesting of Injection Bmark-D Batch No. A-700 (the "**Product**") which was allegedly declared as misbranded and sub-standard by the Government Analyst Drug Testing Laboratory Multan vide TRA 01-89001347/DTL dated 09-02-2021 (the "**DTL Report**")
3. In response to the letter under reply, we would like to submit as under:

i. That M/s Bio-Labs (Pvt.) Ltd (the "Company") is a highly respected and trusted

pharmaceutical Company in Pakistan having a state-of-the-art cGMP compliant manufacturing facility and is engaged in the manufacturing and selling of essential lifesaving drugs, solid and oral dosage forms, topical products and injections. The Company has further strengthened its image by displaying firm commitment to quality and strict adherence to drug laws.

ii. That as per the DTL Report, the Product has been declared as

"the above sample is Misbranded & Substandard"

iii. It is submitted that with regards to the non-compliance of assay is concerned, the retention sample of the Product has been re-examined by the technical staff of the company and the sample of the Product is well compliant with all the required specification.

iv. That at time of registration, the product was registered as per "BP specifications" (Reg. No. 095777) by the Drug Regulatory Authority of Pakistan, with same strength and same mentioned on registration letter No. f.8-2/2019-Reg-II (M-287) dated 31st May, 2019. (Copy of the registration letter is attached herewith as Annexure A)

v. That the specifications mentioned in the registration letter is to be changed to "as per innovator's specification" and same has been intimated to the DRAP for rectification in the registration letter. (Copy of the letter to DRAP is attached as Annexure B)

vi. That it is pertinent to note that the artwork of the Product has been rectified and detailed instructions have been provided. (Copy of the New Art Work is attached herewith as Annexure C)

vii. That it may be stated the Company has never contravened the provisions of drug laws and the rules made thereunder. The Company is also duly complying with the cGMP guidelines.

viii. That the Company received the Drug Inspector's letter No.174/DDC/SRA dated 12-03-2021 wherein the Company was informed that the Product had been allegedly declared as misbranded and substandard vide the DTL Report dated 09-02-2021 and was further directed to furnish an explanation regarding the same.

ix. That subsequently, the Company acting in due diligence immediately requested for the retesting of the Product vide letter bearing No. B-Mark-D/700/01 dated 18-03-2021. It is most imperative to note that the request was duly made within the ten (10) day prescribed time period as envisaged under Section 22(4) of the Drugs Act, 1976. The copy of the same letter has also been sent to the Chairman Provincial Quality Control Board, Punjab.

4. Personnel Hearing notice is issued to accused person(s) on 12-08-2022.

PREVIOUS PROCEEDINGS OF THE CASE:

PQCB's 249th meeting held on 23-08-2022:

5. 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. Ms. Iram Kaukab Secretary DQCB District Multan and Mr. Abdulrauf Drug Inspector Shahrukn-e-Alam Town, Multan was present along with original case record. No-one from the nominated accused Persons appeared before the Board on behalf of M/s Bio Labs Pvt Ltd plot No. 145, Industrial Triangle Kahuta Road, Islamabad, however, representative from the firm Tariq Khalil (Head of Regulatory Affairs) was present along-with counsel person of the firm M. Shoaib Safdar. Secretary PQCB apprised the Board that the Court Directions from Honorable Lahore High Court has been received in which the Court has directed the secretary to entertain the review petition and decide in accordance with law. The Board after careful perusal of the case, with deliberation and discussion unanimously decided to Pend the case with directions to address court directions regarding review petition of retesting request of the firm.

6. Personal hearing Notice dated 18-08-2022 issued in compliance to Court Directions issued by Honorable Lahore High Court.

PQCB's 249th meeting held on 23-08-2022

7. In compliance to Order Lahore High Court, Lahore dated 12-08-2022 in W.P No.48251/2022 of M/S Bio Labs Vs Province of Punjab etc Orders, the subject review petition was placed before the Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **249th** meeting held on **23-08-2022** under the chairmanship of vice chairperson (PQCB). M. Shoib Safdar Advocate, Counsel of M/S Bio-Labs appeared before the Board to plead the case.

8. The Board after careful perusal of the case record and the directions of Honorable Lahore High Court, Lahore observed that the review petition of the firm against the orders of retesting request was returned vide PQCB letter dated 17-03-2022 and firm filed the writ petition against the letter of Provincial Quality Control Board dated 11-08-2022, whereas the subject drug sample was expired on 05-2022 and the firm has misleaded the Honorable Court by hiding the facts of the case regarding expiry of the sample which shows malafide intentions of the firm.

9. The Board further observed that the retesting request of the firm was heard at length by the Board in its 16th Committee meeting dated 16-06-2021 and the Board unanimously decided to turn down the request of the firm on merit as the subject drug sample contained visible particles. The Board further observed that fair opportunity of personal hearing was given to accused person for request of retesting of sample and Board decided to Turn down the subject request for retesting. Once again, the Firm is provided with fair opportunity of personal hearing in its 249th meeting dated 23-08-2022 in the light of review filed by the firm and subsequently by the order of Lahore High Court Lahore orders in writ petition no **28252/2022**.

10. In view of above, the Board after due deliberation unanimously decided to **turn down** the subject review petition and **upheld** its previous decision taken in 16th Committee meeting. The Board further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

Personal hearing notice(s) issued to accused person(s) on 20-04-2023.

Case is placed before the Board for Decision.

Summary of the case:

- **Mfg. date: 09-2019**
- **Exp. Date: : 09-2021**
- **Sampling date (Form 4): 09-12-2020**
- **Sent to DTL (Form 6): 10-12-2020**
- **Date of receipt in DTL: 11-12-2020**
- **DTL Report Date (Form 7): 09-02-2021**
- **DI 1st intimation to firm: 17-02-2021**
- **Retesting request if any: Yes, turned down in 16th committee meeting dated: 16-06-2021**
- **Investigation report Dated: 04-02-2022**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 18

PQCB/R-598/2021

Tehsil Sarai Alamgir, District Gujrat

Sub-Standard (Identification) & Misbrande

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S B.J Pharmaceuticals 18-km, Mandiali Stop, Sheikhupura Road, Lahore** through its Chief Executive Officer Muhammad Bilal 2. Muhammad Bilal — Chief Executive Officer 3. Shazadah Mamoon Ashraf — Production In-charge 4. Saleem Shahid — Quality Control In-Charge of **M/S B.J Pharmaceuticals 18-km, Mandiali Stop, Sheikhupura Road, Lahore.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Sarai Alamgir, Gujrat reported that :-

i. He, on 25-03-2021, inspected the business premises of M/s Javaid Medical Store near Haji Hotel, Railway crossing, Sarai Alamgir, Gujrat and took sample of three different types of drugs on Form No.04 for the purpose of test/analysis and sent the sample of below-mentioned drug to Drug Testing Laboratory, Faisalabad vide memo number 000087882 dated 26-03-2021.

ii. One out of three drug samples, after test/analysis, was declared **Substandard & 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>Results of DTL Report</th></tr>
<tr><td>Capsule Leecam [Each capsule contains: Piroxicam as beta cyclodextrin… 20mg]
Mfg. Date 01-2021
Expiry Date: 01-2023
Reg No. 074358</td><td>012</td><td>M/S B.J Pharmaceuticals 18-km, Mandiali Stop, Sheikhupura Road, Lahore.</td><td>TRA No. 01-68008005/DTL
Dated: 14-07-2021</td><td>
Specifications of Test Applied: MS/ USP 2021
Description:
Off-white colored powder encapsulated in red colored hard gelatin capsule, contained in PVC-ALU blister pack of 10 units, packed in outer hard carton.
Identification:
Piroxicam is identified (MS) whereas Beta Cyclodextrin as per specified on label along with API in given sample was not identified when tested by applying the identification tests B and D of Betadex as per USP 2021 (Does Not Comply)
Assay:
Stated: 20 mg/ Capsule
Determined: 20.694 mg// Capsule
Percentage: 103.47 % (Complies)
Limit: 90-110% (Manufacturer’s Specifications)
Dissolution Test: Complies the dissolution test as per Manufacturer’s Specifications as detailed below:
<table>
<tr><th>Level</th><th>No. tested</th><th colspan="6">Acceptance criteria</th><th>Remarks</th></tr>
<tr><td rowspan="2">S1</td><td rowspan="2">6</td><td colspan="6">Each unit is less than Q + 5 percent</td><td rowspan="2">Complies</td></tr>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit 5</td><td>Unit 6</td></tr>
<tr><td></td><td></td><td>96.7%</td><td>96.1%</td><td>95.7%</td><td>94.9%</td><td>96.7%</td><td>95.8%</td><td></td></tr>
</table>
Labelling Requirements:
Stated:
As per Section 3 (s) (iv) of The Drugs Act 1976, “Misbranded means:
“it’s label or container anything accompanying which, bears any statements, design or device which makes any false claim for a drug or which is false or misleading in any particular.”
Observed:
Label claim of given sample is “Each capsule contains: Piroxicam as beta cyclodextrin… 20mg”, whereas on the basis of tests performed only Piroxicam is identified in given sample so the label claim is false/ misleading and is in violation to Drugs Act, 1976. (Does not comply)
Result:
Given sample is Sub-standard and Misbranded with regards to tests performed.
</td></tr>
</table>

iii. M/s Javaid Medical Store near Haji Hotel, Railway crossing, Sarai Alamgir, Gujrat, provided invoice/ warranty number SI-01346 dated 09-02-2021 issued by M/S B.J Pharmaceuticals 18-km, Mandiali Stop, Sheikhupura Road, Lahore as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/S B.J Pharmaceuticals 18-km, Mandiali Stop, Sheikhupura Road, Lahore.

v. A copy of test report of the drug sample was sent to M/S B.J Pharmaceuticals 18-km, Mandiali Stop, Sheikhupura Road, Lahore with directions to provide the requisite information and to explain their position in this regard. In response, the firm requested for re-test/ analysis of the drug sample. The retesting request of the firm was turned down by the Board in its 242nd meeting dated 14-04-2022.

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

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

ii. **Issuance of false warranty.**

3. Show cause notice(s) issued to the accused persons dated 31-10-2022

Personal hearing notice(s) issued to the accused persons dated 20-04-2023

Summary:

Manufacturing Date: 01-2021

Expiry Date: 01-2023

Sampling Date (Form 4): 25-03-2021

Sent to DTL (Form 6): 26-03-2021

Date of receipt in DTL: 02-04-2021

DTL Report Date: 14-07-2021

Time Extension: 232nd meeting dated 24-06-2021

1ST DI Communication with firm on dated: 27-07-2021

Date of Retesting Request of Firm: 06-08-2021

Fate of retesting Request: Turn Down (242nd meeting dated 14-04-2022)

Investigation Report Dated: 20-08-2022

Case is placed before the Board

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 19

PQCB/R-707/2020

Tehsil Chichawatni & District Sahiwal

Misbranded & Sub-Standard (Assay and Dissolution

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Crest Pharmaceuticals, 43 Industrial Triangle, Kahuta Road, Islamabad** through its CEO/Director Tariq Mahmood Malik Muhammad. 2. Tariq Mahmood Malik Muhammad CEO/Director/Production Manager/Warrantor 3. Dr Amar ul Ala Butt Director 4. Syed Musarrat Ali Quality Control Incharge **of M/s Crest Pharmaceuticals, 43 Industrial Triangle, Kahuta Road, Islamabad.** 5. Muhammad Ishtiaq Proprietor/Warrantor **of M/S Zahid Enterprises Medical Store, Masood Town Arifwala Road, District Sahiwal.**

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 30-12-2019, inspected the business premises of M/S Al-Usman Medical Store, Chishti Chowk Kamalia Road Chichawatni, District Sahiwal and took different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo. No.0000055019, dated. 31-12-2019.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report
TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Dispersible Tablet Recobal [Mecobalamin 500mcg]
Mfg Date:
Jan-2019
Exp Date:
Jan-2021
Registration No.
068672</td><td>190106</td><td>M/S Crest Pharmaceuticals, 43 Industrial Triangle, Kahuta Road, Islamabad</td><td>01-25004991/DTL
Dated. 06-04-2020</td><td>
<u>Analysis with specifications applied:</u> MS.

Composition: Each Dispersible Tablet contains: Mecobalamin……. 500mcg

<u>Description (MS):</u> Pink Color (Coated) round biconvex tablet with both sides plain packed in Alu-Alu Blister packing.

Batch no. is not mentioned on primary packaging moreover contradictory statement on label i.e., “Dispersible Tablet” claimed on secondary packaging whereas only “Tablet” claimed on primary packaging and upon physical inspection the tablet was found to be coated. Furthermore, to add the method provided by the manufacturer does not contain any physical description of the tablet. <u>Therefore, the sample is declared Misbranded.</u>

<u>Identification (MS):</u> Mecobalamin is identified.

<u>Assay (MS): Mecobalamin</u>
<table>
<tr><td>Stated</td><td>500mcg/tablet</td></tr>
<tr><td>Determined</td><td>387.01mcg/tablet</td></tr>
<tr><td>Percentage</td><td>77.402% Does not comply with specifications</td></tr>
<tr><td>Limit</td><td>90-110%</td></tr>
</table>
<u>Dissolution Test (MS):</u> Does not comply with manufacturer’s specifications as detailed below: <u>Tolerance Limit:</u> Average of 12 units should not be less than 80% of the label claim.
<table>
<tr><th>Stage</th><th>Number Tested</th><th>Acceptance Criteria</th><th>Average</th><th>Remarks</th></tr>
<tr><td></td><td>12</td><td>Avg of 12 units should not be less than 80%</td><td></td><td></td></tr>
<tr><td>Determined</td><td>Mecobalamin</td><td>
<table>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit 5</td><td>Unit 6</td></tr>
<tr><td>13.38%</td><td>13.37%</td><td>8.77%</td><td>7.69%</td><td>9.19%</td><td>13.82%</td></tr>
<tr><td>14.14%</td><td>14.07%</td><td>9.49%</td><td>9.63%</td><td>9.99%</td><td>14.37%</td></tr>
</table>
</td><td>11.49%</td><td>Does not comply with specifications</td></tr>
</table>
<u>Result:</u> The sample is declared Substandard on the basis of Assay and Dissolution Test. Moreover, the sample is Misbranded as defined under subsection (s) of section 3 of the Drugs Act 1976.
</td></tr>
</table>

ii. M/S Al-Usman Medical Store, Chishti Chowk Kamalia Road Chichawatni, District Sahiwal provided Invoice/warranty No 4967, dated 25-12-2019 issued by M/S Zahid Enterprises Medical Store, Masood Town Arifwala Road, District Sahiwal who in turn provided invoice/warranty no. C 28636, dated. 03-12-2019 issued by M/S Zam Zam Pharma House No. 26/A/S Street No. 10 Model Town-A Bahawalpur who in turn provided invoice/warranty no. 75, dated. 02-12-2019 issued by M/S Medisell Pharma, Near Javed Electronic, Hafizabad Road, Gujranwala who in turn provided invoice/warranty no. 594, dated. 07-03-2019 issued by M/S Crest Pharmaceuticals, 43 Industrial Triangle, Kahuta Road, Islamabad as a proof of its purchase.

iii. Warrantor portion of drug sample was sent to M/S Zahid Enterprises Medical Store, Masood Town Arifwala Road, District Sahiwal and they were asked to explain their position in this regard.

iv. A copy of test/analysis report was sent to M/S Crest Pharmaceuticals, 43 Industrial Triangle, Kahuta Road, Islamabad and they were asked to provide the requisite information in this regard. In response the firm challenged the Drug Testing Laboratory report and the office of Provincial Quality Control Board place the said retesting request in the 247th Meeting of Retesting dated 21-07-2022 and Board after unanimous decision decided to turn down the said retesting request.

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

Accused	Offences
1. **M/s Crest Pharmaceuticals, 43 Industrial Triangle, Kahuta Road, Islamabad** through its CEO/Director Tariq Mahmood Malik Muhammad. 2. Tariq Mahmood Malik Muhammad CEO/Director/Production Manager/Warrantor 3. Dr Amar ul Ala Butt Director 4. Syed Musarrat Ali Quality Control Incharge **of M/s Crest Pharmaceuticals, 43 Industrial Triangle, Kahuta Road, Islamabad.**	1. Manufacture for Sale /Sale of Substandard & Misbranded Drug Drug 2. Issuance of false warranty
1. Muhammad Ishtiaq (Proprietor/Warrantor) **of M/S Zahid Enterprises Medical Store, Masood Town Arifwala Road, District Sahiwal.**	1. Stocking for sale/ sale of Substandard & Misbranded Drug 2. Issuance of false warranty

3. Show-cause was issued to accused person(s) vide dated 15-11-2022.

Reply of Show Cause Notice:

Brief Facts of the Case

¿ Sample Drawn on Form - 4 on 30-12-2019: 30-12-2019

¿ Sample Received in DTL on: 02-01-2020

¿ Report Signed by Govt. Analyst on: 06-04-2020

¿ Extension granted by PQCB on: 27-02-2020 (218th Meeting)

¿ Fourth Portion (Manufacturer's Portion): Not Provided

¿ Drug Insp. Claimed to send letter 56 & 81 on: 19-06-2021 & 16-07-2021 (Not RCVD)

¿ Received First Letter From Drug Inspector on: 28-08-2021 (No. 129 DI CCW) Copy of Form-4, Form-7, Fourth Portion and Invoice of Crest request.

¿ Form 7 & Warranty Received on: 16-09-2021 vide letter No. 141/DI CCW, dated 13-09-2021

¿ Re-Testing Requested on: 16-09-2021

¿ Re-Testing Request turned down by PQCB on: 21-07-2022 (247th Meeting) After ten months of request.

In the last letter (No. 215/DDC/CCW) received from Respected Deputy Drug Controller/Drug Inspector, we came to know that we applied for Re-testing after the expiry of drug.

Extract from Drugs Act 1976

Section 22(4) of the Drugs Act 1976 reads as:

> Notwithstanding anything contained in any other law for the time being in force, any document purporting to be a report signed by a Government Analyst shall be admissible as evidence of the facts stated therein without formal proof and such evidence shall be conclusive unless the person from whom the sample was taken or the said warrantor has, within thirty days of the receipt of the copy of report notified in writing to the inspector or the Drug Court or as the case may be, the Central Licensing Board or the Registration Board before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

We applied for Re-Test of product on the same day (within the legitimate limits) after receiving the copy Test Report No. TRA 01-25004991/DTL dated 06-04-2020 and invoice warranty No. 594 dated 07-03-2019 of Crest Pharmaceuticals vide letter No. 141/DI/CCW dated 13-09-2021, received on 16-09-2021. Whereas Section 22(4) of the Drugs Act 1976 allows to challenge the report of Government Analyst within Thirty days of the receipt of the copy of report.

Drug Inspector of Drugs Tehsil Chichawatni District Sahiwal writes in his letter No. 129/DI/CCW dated 28-08-2021 that he wrote letter **No. 56/DI/CCW on 19-06-2021**. It means the very first letter written by Inspector of Drugs was after the expiry of said product i.e, **January 2021 (almost five months after the expiry date).**

Hence, it is not the fault at the ends of crest pharmaceuticals that the sample met its expiry date before challenging for Re-Test.

In this particular case, we are deprived of our two basic rights which Drugs Act 1976 provides us, i.e,

1. Fourth (Manufacturer's) Portion (Under Section 19(3)(iv), and

2. Appellate Testing (Under Section 22(4) of Drugs Act 1976

It is humbly requested to please withdraw Show Cause Notice No. PQCB/R-707/2020,

dated 12-02-2023, received on 23-02-2023 and drop the proceedings against us to meet

the ends of justice.

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

Summary:

Manufacturing Date:01-2019

Expiry Date:01-2021

Sampling Date (Form 4): 30.12.2019

Sent to DTL (Form 6): 31.12.2019

Date of receipt in DTL: 31.12.2019

DTL Report Date (Form 7): 06.04.2020

Time Extension: N/A

1ST DI Communication with firm on dated: 16.06.2021

Date of Retesting Request of Firm: 16.09.2021

Fate of Retesting Request: Turn Down (Time Barred) in 247 meeting dated 21.07.2022

Investigation Report Dated:23.10.2022

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 20

PQCB/R-486/2021

Iqbal Town, District Faisalabad

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Danas Pharmaceuticals (Pvt.) Ltd., 312-Industrial Triangle, Kahuta Road, Islamabad-Pakistan** through its Managing Director, Muhammad Mustafa 2. Muhammad Mustafa Managing Director 3. Muhammad Latif Production Incharge/ Warrantor 4. Muhammad Naeem Quality Control Incharge of M/s Danas Pharmaceuticals (Pvt.) Ltd., , 312-Industrial Triangle, Kahuta Road, Islamabad-Pakistan. 1. Hamza Sharaf Warrantor of **M/s Harmain Traders Office No. 14 Al Hayat Market Namak Mandi Peshawar**.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 20-02-2021, inspected the business premises of M/s New Classic Distributors, situated at Office, P-114, Street No. 01, Block-A, Al-Fiaz Colony, Satiana Road District Faisalabad, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide memorandum no. 85715 dated 21-02-2021.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Capsule. Omenza [Each capsule contains: Omeprazole USP (as EC Pellets) …… 20mg]

Mfg Date:
Nov 2020

Expiry Date:
Nov 2022

Regn. No.
038690</td><td>C400</td><td>M/S Danas Pharmaceuticals (Pvt.) Ltd., , 312-Industrial Triangle, Kahuta Road, Islamabad-Pakistan.</td><td>01-68007386/DTL

dated

09-04-2021</td><td>
Analysis with specifications applied: USP 2020

<u>DESCRIPTION:</u> Off white pellets, <u>encapsulated in yellow color transparent body and yellow color opaque cap of hard gelatin capsules</u>, contained in Alu-PVC packing of 10’s.

NOTE: Manufacturer Specify “Red/Red colored hard gelatin capsule shells size # 2, filled with white to off white spherical enteric coated pellets” but given sample contains “off white colored spherical pellets encapsulated in yellow color transparent body and yellow color opaque cap” which does not comply with Manufacturer’s description of hard gelatin capsule. (Does Not Comply)

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

<u>ASSAY:</u>

Stated: 20mg/ Capsule

Determined: 19.435 mg/ Capsule

Percentage: 97.17% (Complies)

Limit: 90 – 110 % (USP 2020)

<u>DISSOLUTION TEST:</u> Complies the dissolution test 2 of USP 2020 as detailed below:

<u>Acid Stage</u>:

Tolerance Limit: Not more than 10% of labelled amount of Omeprazole in 2 Hours in 900ml of 0.1N HCl, in Apparatus I at 100 rpm

<table>
<tr><th>Level</th><th>Number Tested</th><th colspan="6">Acceptance Criteria</th><th>Remarks</th></tr>
<tr><td rowspan="2"></td><td rowspan="2">6</td><td colspan="6">No individual value exceeds 10% dissolved</td><td rowspan="2">Complies</td></tr>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit5</td><td>Unit 6</td></tr>
<tr><td>L1</td><td>After 2 Hours</td><td>0%</td><td>0%</td><td>9.5%</td><td>0%</td><td>0%</td><td>0%</td><td></td></tr>
</table>
<u>Buffer Stage:</u>

Tolerance Limit: Not less than 75% (Q) of the labelled amount of Omeprazole in 45 minutes, in 900 ml of 0.05M pH 6.8 phosphate buffer in Apparatus 1 at 100 rpm

<table>
<tr><th>Level</th><th>Number Tested</th><th colspan="6">Acceptance Criteria</th><th>Remarks</th></tr>
<tr><td rowspan="2"></td><td rowspan="2">6</td><td colspan="6">Each unit is not less than Q + 5%</td><td rowspan="2">Complies</td></tr>
<tr><td>Unit 1</td><td>Unit 2</td><td>Unit 3</td><td>Unit 4</td><td>Unit5</td><td>Unit 6</td></tr>
<tr><td>S1</td><td>After 45 Minutes</td><td>104.0%</td><td>110.3%</td><td>108.7%</td><td>99.5%</td><td>108.2%</td><td>108.2%</td><td></td></tr>
</table>
<u>RESULT:</u> Given sample is Sub-Standard with regards to description (Physical characteristics) of Hard gelatin Capsules.
</td></tr>
</table>

iii. Proprietor of M/s New Classic Distributors, situated at Office, P-114, Street No. 01, Block-A, Al-Fiaz Colony, Satiana Road District Faisalabad provided invoice/warranty bearing No. 35895 dated 15-12-2020 issued by M/s Harmain Traders situated at First Floor Al Hayat Market Namak Mandi Peshawar as a proof of its purchase.

iv. M/s Harmain Traders situated at First Floor Al Hayat Market Namak Mandi Peshawar in-turn provided invoice/warranty bearing No. WAR-HT-01-12/20 dated 09-12-2020 issued by M/S Danas Pharmaceuticals (Pvt.) Ltd., 312-Industrial Triangle, Kahuta Road, Islamabad-Pakistan as a proof of its purchase.

v. Warrantor portion of drug sample was sent to M/s Harmain Traders Office No. 14 Al Hayat Market Namak Mandi Peshawar.

vi. A copy of test/analysis report was sent to M/S Danas Pharmaceuticals (Pvt.) Ltd., , 312-Industrial Triangle, Kahuta Road, 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:

M/s Danas Pharmaceuticals (Pvt.) Ltd., 312-Industrial Triangle, Kahuta Road, Islamabad-Pakistan	a. **Manufacture for sale /Sale of Substandard drug** b. **Issuance of false warranty**
M/s Harmain Traders Office No. 14 Al Hayat Market Namak Mandi Peshawar	a. **Sale of Substandard drug** b. **Issuance of false warranty** **(Issuance of Illegal Authority Letter to M/s New Classic Distributors)**

3. Show-cause notice(s) issued to accused person(s) dated 25-08-2022

Firm submitted written reply to the show cause notice vide letter dated 05-09-2022

The said Batch No. C400 of our product Omenza 20mg Capsule is of standard quality in terms of Identification, Assay. Dissolution Test & Acid Stage. Honorable DTL, Faisalabad has declared the said batch as sub-standard on the basis of description i.e. color of hard gelatin capsule shells 3 ***On 04/06/2021, an addendum letter was sent to honorable DTL, Faisalabad explaining our position in terms of hard gelatin capsules' color.*** *On the basis of above mentioned points,* ***we do hereby request your good self to please withdraw show cause notice that we already have shared information with honorable DTL, Faisalabad*** *through addendum letter explained and hereby feel ourselves rightful to plea that we should be given a chance to defend ourselves in person in front of honorable board to Clarity our position regard.*

4. Personal hearing notice(s) issued to accused person(s) dated 18-11-2022

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 **253rd meeting** held on **29-11-2022** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Ms. Rubina Akhtar, Secretary DQCB, District Faisalabad and Mr. Shahbaz Farooq, Drug Inspector, Iqbal Town, District Faisalabad was present along with the original case record. No one among the nominated accused persons of M/s Danas Pharmaceuticals (Pvt.) Ltd., 312-Industrial Triangle, Kahuta Road, Islamabad-Pakistan was present.

6. Secretary Provincial Quality Control Board apprised the Board that firm has submitted written request for adjournment vide letter dated 24-11-2022 stating that stating that the firm's counsel is busy in Supreme Court of Pakistan, Islamabad on 29-11-2022. The Board, after due deliberation and detailed discussion, unanimously decided to **adjourn the case** of **M/s Danas Pharmaceuticals (Pvt.) Ltd., 312-Industrial Triangle, Kahuta Road, Islamabad-Pakistan** and to provide another opportunity of personal hearing in the best interest of justice.

7. Personal hearing notice(s) issued to accused person(s) dated 19-12-2022

Previous Proceedings & Decision by The Board:

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **255th meeting** held on **29-12-2022** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Ms. Rubina Akhtar, Secretary DQCB, District Faisalabad was present along with the original case record. No one among the nominated accused persons of M/s Danas Pharmaceuticals (Pvt.) Ltd., 312-Industrial Triangle, Kahuta Road, Islamabad-Pakistan and M/s Harmain Traders Office No. 14 Al Hayat Market Namak Mandi Peshawar was present.

9. Secretary Provincial Quality Control Board apprised the Board that firm has submitted written request for adjournment vide letter dated 27-12-2022 stating that the firm's counsel is not available being busy in Supreme Court of Pakistan, Islamabad on 29-12 -2022. The Board, after due deliberation and detailed discussion, unanimously decided to **adjourn the case** of **M/s Danas Pharmaceuticals (Pvt.) Ltd., 312-Industrial Triangle, Kahuta Road, Islamabad-Pakistan** and to provide another yet final opportunity of personal hearing in the best interest of justice.

10. Personal hearing notice(s) issued to accused person(s) dated 20-04-2023

11. Case is placed before the Board for decision

Summary:

Manufacturing Date: 11-2020

Expiry Date: 11-2022

Sampling Date (Form 4): 20-02-2021

Sent to DTL (Form 6): 21-02-2021

Date of receipt in DTL: 24-02-2021

DTL Report Date (Form 7): 09-04-2021

Time Extension: Not Time Barred

1ST DI Communication with firm on dated: 02-05-2021

Retesting Request of Firm: Yes (07-05-2021)

Fate of Retesting Request: Firm withdrew its retesting request vide letter dated 06-08-2021

Investigation Report Dated: 31-05-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 21

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: -

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.

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.

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.

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 258th meeting held on 05-04-2023

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th Meeting** held on **05-04-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Adil Jameel Awan, Secretary DQCB, District Rajanpur joined the meeting through zoom link. No one among the nominated accused of **M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan** was present.

6. The case was left-over due to time constraint.

7. Personal Hearing notice(s) issued to accused person(s) on 20-04-2023.

PQCB's 259th meeting held on 18-04-2023

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **259th Meeting** held on **18-04-2023** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice Chairperson, PQCB). Mr. Adil Jameel Awan, Secretary DQCB, District Rajanpur joined the meeting through zoom link. No one among the nominated accused of **M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan** was present.

9. Keeping in view the facts of the case and absence 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/ final opportunity of personal hearing to the accused person

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 22

PQCB/R-600/2021

Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat

Sub-Standard (Description & Weight per unit area

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Faisal Pharmaceutical Industries 602-B S.I.E Sargodha Road Faisalabad** through its Chief Executive Officer Faisal Khalid 2. Faisal Khalid Chief Executive Officer/ Warrantor 3. Afnan Production In-charge 4. Aleena Jamil Quality Control In-Charge of **M/S Faisal Pharmaceutical Industries 602-B S.I.E Sargodha Road Faisalabad.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat reported that :-

i. He, on 16-08-2021, inspected the premises of Main Medicine Store of Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat and took sample of four 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 104139 dated 16-08-2021.

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	Results of DTL Report
Steriband Gauze +Gauze Swabs B. P.C. 10CM x 10 CM (8 ply) **Mfg. Date 07-2021** **Expiry Date: 07-2024** **Reg. No. 019784**	1678	M/S Faisal Pharmaceutical Industries 602-B S.I.E Sargodha Road Faisalabad.	TRA No. 01-68011539/DTL Dated: 18-10-2021	**Specifications of Test Applied:** BPC 1973 **Description:** Cotton cloth having weaving defects and not clean, containing dark brown to brown color threads in a sealed pack. **(Does not comply)** **Weight/ Area:** Stated: 14-16 g/ m² (BPC 1973) Determined: **24.81 g/ m² (Does not comply)** **Warps:** Stated: 69-77/ 10cm (BPC 1973) Determined: 70.37/ 10 cm (Complies) **Wefts:** Stated: 53-61/ 10 cm (BPC 1973) Determined: 54.13/ 10cm (Complies**)** **Absorbency (Sinking Time)** Stated: NMT 10 Seconds (BPC 1973) Determined: 5.67 seconds (Average of 3 tests) (Complies) **Sterility Test:** Stated: Should be sterile (BPC 1973) Determined: Sterile (Complies**)** **Result:** Given sample is **Sub-standard** with regards to description (Physical Characteristics) and weight per unit area.

iii. Store keeper of Main Medicine Store of Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat, provided invoice/ warranty/ delivery Challan number FP-20211508 dated 14-08-2021 issued by M/S Faisal Pharmaceutical Industries 602-B S.I.E Sargodha Road Faisalabad.as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/S Faisal Pharmaceutical Industries 602-B S.I.E Sargodha Road Faisalabad.

v. A copy of test report of the drug sample was sent to M/S Faisal Pharmaceutical Industries 602-B S.I.E Sargodha Road Faisalabad. 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. Retesting request of the firm was turned down by the Provincial Quality Control Board in its 241st meeting dated 31-03-2022

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

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

ii. **Issuance of false warranty.**

3. Show cause notice(s) issued to the accused persons dated 31-10-2022

Firm submitted written reply to show cause notice vide letter no Nil dated Nil received on 25-11-2022 sating that:

In the meeting of PQCB dated 31-03-2022, our request of retesting the sample of Gauze swab B#1678 was turned down by the Board. As concluded by DTL report, our concerned product complies with the stated specifications provided by the B.P.C in terms of Warp and weft.

As the ground of retesting is based on weight of gauze which is dependent on the warp and weft. The warp and weft was found to match the required specs of B.P.C, the determined weight beyond acceptable range for the same sample is not possible. Also, the yarn used in the weaving can not produce the weight as reported by DTL. Any 1-2 g/m^2 doesn't make sense with the analysis, if in case, the DTL emphasizes on their results to be true, I would like to mention here that the decrease in the weight of final product still isn't harmful to patients in any way or other.

With the given justification, I request the Board members to drop the case and oblige.

PREVIOUS PROCEEDINGS BY THE BOARD:

PQCB 256th meeting dated 19-01-2023:

4. 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. No-one among the nominated accused persons was present on behalf of M/S Faisal Pharmaceutical Industries 602-B S.I.E Sargodha Road Faisalabad. Secretary PQCB apprised the Board that the firm has submitted written request for adjournment. 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 the accused persons.

Summary:

Manufacturing Date: 07-2021

Expiry Date: 07-2024

Sampling Date (Form 4): 16-08-2021

Sent to DTL (Form 6): 16-08-2021

Date of receipt in DTL: 20-08-2021

DTL Report Date: 18-10-2021

Time Extension: N/A

1ST DI Communication with firm on dated: 01-12-2021

Date of Retesting Request of Firm: 27-12-2021

Fate of retesting Request: Turn Down (241st meeting dated 31-03-2022)

Investigation Report Dated: 18-08-2022

Case is placed before the Board

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 23

PQCB/R-267/2022

DHQ Hospital, District Gujranwala

Misbrande

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Genetics Pharmaceuticals (Pvt.) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road, Lahore** through its Managing Director Aamir Qayyum 2. Aamir Qayum Managing Director 3. Anjum Pervaiz Production Incharge 4. Shahbaz Hussain Quality Control Incharge 5. Samia Zaheer Quality Assurance Incharge 6. Mubashra Irfan Warrantor of **M/S Genetics Pharmaceuticals (Pvt.) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road, Lahore.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs DHQ Teaching Hospital, Gujranwala reported that:-

i. He, on 27-05-2022, inspected the premises of Medicine Store DHQ Teaching Hospital, Gujranwala and took sample of four different types of drugs on Form No.04 for the purpose of test/analysis and sent the sample of below mentioned drug to Drug Testing Laboratory, Faisalabad vide memo number 0000127856 dated 27-05-2022.

ii. The 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 Report TRA No. & Date	DTL Test Report Results
Capsule, Candizol [Each capsule contains: Fluconazole (JP)…150mg] **Mfg. Date:** 03-2022 **Exp. Date:** 02-2024 **Reg. No.** 085114	22CN001	M/S Genetics Pharmaceuticals (Pvt.) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road, Lahore.	TRA No. 01-68016107/DTL Dated: 28-07-2022.	**Analysis with specifications applied:** Manufacturer's Specifications **Description:** White powder encapsulated in hard gelatin capsule, having off-white body and blue cap, contained in Alu-Alu blister packed in outer hard carton. **Identification:** Fluconazole is identified. **Assay:** Stated: 150 mg/ capsule Determined: 150.618 mg/ capsule Percentage: 100.412% (Complies) Limit: 93.0-107.0% (BP 2022) **Dissolution Test:** Complies Labelling Requirements: 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 ,"JP Specs" are printed on the label but in JP 2021, monograph of fluconazole capsule (50 mg and 100 mg) is given but no such monograph of Fluconazole 150mg Capsule is available, so manufacturer's claim regarding finished product specifications is false/ 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. Store Keeper of Medicine Store DHQ Teaching Hospital, Gujranwala, provided invoice/ warranty/ no. MNF-21973 dated 12-05-2022 issued by M/S Genetics Pharmaceuticals (Pvt.) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road, Lahore as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/S Genetics Pharmaceuticals (Pvt.) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road, Lahore.

i. A copy of test report of the drug sample was sent M/S Genetics Pharmaceuticals (Pvt.) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road, Lahore 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 Misbranded Drug**

ii. **Issuance of false warranty.**

3. Show cause notice(s) issued to the accused persons dated 11-04-2023

Personal hearing notice(s) issued to the accused persons dated 20-04-2023

Case is placed before the Board

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 24

PQCB/R-325/2022

Allied Hospital, District Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Hilton Pharma (Pvt.) Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi-Pakistan** through its Director, Shahzad Akhtar 2. Shahzad Akhtar Director 3. Adnan Ahmed Production Incharge 4. Waqas Ahmed Khan Khilji Quality Control Incharge 5. Nadeem Arif Warrantor of M/s Hilton Pharma (Pvt.) Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Allied Hospital, District Faisalabad reported that: -

i. She, on 15-10-2022, inspected the premises of Central Pharmacy of Allied Hospital, District Faisalabad, took ten 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. 144525 dated 15-10-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Injection. Artem [Each 1ml ampoule contains: Artemether …. 80mg] **Mfg Date:** Sep 2022 **Expiry Date:** Aug 2026 **Regn No.** 015529	145145	M/s Hilton Pharma (Pvt.) Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi-Pakistan.	01-68019501/DTL dated: 14 Dec 2022	**Analysis with specifications applied:** IP 2020 **DESCRIPTION:** Clear colorless oily solution filled in transparent glass ampoule with red color printing placed in plastic tray 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 "**The product complies with Hilton Pharma Specs.**" and it is manufactured after the expiration of timeline to apply such specifications despite the availability of Artemether Injection monograph in International Pharmacopoeia, 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:** Artemether is identified. **ASSAY:** Stated: 80 mg/ ml Determined: 77.932 mg/ ml Percentage 97.415 % (Complies) Limit: 90-110% (Ph. Int. 2020) **EXTRACTABLE VOLUME:** Stated: NLT Nominal Volume (1ml) (Ph. Int. 2020) Determined: 1.12 ml (Complies) **STERILITY TEST:** Stated: Must be Sterile (Ph. Int. 2020) Determined: Sterile (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. 7777 dated 13-10-2022 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 invoice/warranty bearing No. 90271424 dated 10-10-2022 issued by M/s Hilton Pharma (Pvt.) Ltd., Plot No. 13-14, Sector 15, Korangi 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 Hilton Pharma (Pvt.) Ltd., Plot No. 13-14, 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:

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. KA-014/2023 dated 23-02-2023

Artem Injection 80mg meets Hilton Pharma specification as well as International Pharmacopeia as per DTL Report. There is no question about product quality, efficacy and safety. However, printed packaging components were not implemented due to consumption of existing large inventory of printed packaging components.

We have already applied for the change of specification from Hilton Pharma to International Pharmacopeia & waiting for approval from DRAP for immediate implementation of International Pharma specification.

We request to please close the matter as we will be complying with International Pharmacopoeia specification after getting approval of change in specification from DRAP.

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

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 09-2022

Expiry Date: 08-2026

Sampling Date (Form 4): 15-10-2022

Sent to DTL (Form 6): 15-10-2022

Date of receipt in DTL: 19-10-2022

DTL Report Date (Form 7): 14-12-2022

Time Extension: Not Time Barred

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

Retesting Request of Firm: NA

Investigation Report Dated: 09-01-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 25

No. PQCB/R-326/2022

Tehsil Burewala, District Vehari

ATTENDENCE

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Hisun Pharmaceutical industries, 37-A, R-2 Industrial Estate Gadoon-Pakistan** through its Managing Director Rana Muhammad Nawaz. 2. Rana Muhammad Nawaz Managing Director 3. Muhammad Shahid Inayat Quality Control Manager 4. Muhammad Abdullah Abubakar Production Incharge 5. Muhammad Nawaz Warrantor of M/s Hisun Pharmaceutical industries, 37-A, R-2 Industrial Estate Gadoon-Pakistan.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 22-03-2022 inspected business premises of M/s Pak Madina Corporation, Muhammad Nagar, Marzi pura, street no. 6 Tehsil Burewala, and took following drug sample on Form No. 4 for the purpose of test/analysis and sent to DTL Multan vide memorandum no. 121949 dated 23-03-2022.

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

Name of drug	Batch no.	Name of manufacturer	TRA No & Date	DTL Test Report Results
Suspension Famonil 60ml [Famotidine 10mg/5ml, 60ml] **Mfg Date**: 12-2021 **Exp. Date:** 12-2023 **Regn. No**: 047829	S-648	M/s Hisun Pharmaceutical industries, 37-A, R-2 Industrial Estate Gadoon-Pakistan.	No. 01-94002968 dated 26-05-2022	**Results of test/analysis with specifications applied:** MS **DESCRIPTION:** Light green color suspension in labeled amber plastic bottle sealed with white plastic screw cap packed in a labeled outer hard carton. The product does not contain Finished Drug product specifications on label as well as on outer carton. (M**isbranded Does not comply)** **IDENTIFICATION:** Famotidine identified **ASSAY:** UV- spectrophotometer

Assay	Stated	Found	Limit	Percentage
Famotidine	10mg/5ml	10.66mg/5ml	90-110%	106.68% comply

pH:

Stated: 6.5-7.5

Determined: 5.21 Does not comply

RESULT: The sample is **Substandard** on the basis **of pH Test & Misbranded** as defined under section 3 (s) (vi) of the Drugs act 1976

iii. M/s Pak Madina Corporation, Muhammad Nagar, Marzi pura, street no. 6 Tehsil Burewala provided Invoice/warranty No. 428 dated 14-02-2022 issued by M/s Marva Trading 30 Khushal Colony near Molvi Ameer Shah Memorial Hospital GT Road Peshawar.

iv. Warrantor Portion was sent to M/s Marva Trading 30 Khushal Colony near Molvi Ameer Shah Memorial Hospital GT Road Peshawar, who in turn provided invoice/warranty no. 32 dated 08-01-2022 issued by M/s Hisun Pharmaceutical industries, 37-A, R-2 Industrial Estate Gadoon-Pakistan as a proof of its purchase.

v. A copy of Test/ Analysis report was sent to M/s Hisun Pharmaceutical industries, 37-A, R-2 Industrial Estate Gadoon-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 and Rules framed there under by the way of:-

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

b. **Issuance of false warranty**

Summary:

Manufacturing Date: 12-2021

Expiry Date: 12-2023

Sampling Date: 22-03-2022

Sent to DTL (Form 6): 23-03-2022

Date of receipt in DTL: 28-03-2022

DTL Report Date: 26-05-2022

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

Date of Retesting Request of Firm: No

Investigation Report Dated: 21-01-2023

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

***Reply of the Firm in response to show cause notice vide letter dated 24-02-2023*:**

It is submitted that our product Famonil 60ml Suspension (Batch No. S-648) has been

declared as Misbranded on the basis of absence of finish product specification on label and unit carton and Substandard on the basis of low pH by Drug Testing Laboratory (DTL) Multan. In this regard following is submitted: -

a. **Misbrand**. Above said product /batch was manufactured in December 2021. DRAP

allowed timeline for change of pharmacopoeia specification till 26th July 2022 vide letter No F.3-5/2020-1 &VII (M-297) dated 27 July 2021 & F.3-(M-297)/Human Import dated 07th Feb 2022. Therefore, grace period we changed all the pharmacopoeia specifications of all the products including this product, hence amended Unit Carton and Label.

b. **Substandard due to low pH**. It is hereby clarified that our product is Liquid Suspension (range of pH 5.0 - 7.50) whereas the stated pH taken by DTL Multan is

of Dry Suspension (Range of pH 6.5 - 7.5. Therefore, the pH is within 5.0 - 7.5. in this connection, please refer your letter No. PQCB/R-81/2022 dated 30 August 2022 wherein pH limit of our same product (Famonil Suspension) was mentioned as 5.0 - 7.5.

Moreover, the above said Batch was manufactured in December 2021. At that time, pH and other parameters were according to specifications. The probability of dropping of pH may be due to exposure of product to elevated temperature. Although temperature is controlled inside the factory premises, but the product might have been exposed to high temperature during transportation, or during storage at distributor warehouse or medical store.

You know that weather in area of lower Punjab become highly hot during summer. The product has faced one summer season. So, we think that this might be the cause of lowering in pH. The assay of active ingredient (Famotidine) remained in the specified range, mentioned in U.S.P. So, this little drop in pH didn't affect the active ingredient's stability. Thankfully, the patient will have received full medicine for his illness.

2. Further, many researches are available, which tell that increase in temperature inversely

affect the pH. We are attaching a reference of a website telling this relationship of Temperature and pH.

3. Aforementioned in view it is requested that company will take extra care to ensure quality

in future, hence lenient view may be considered against Hisun Pharma as a special case.

Your sympathetic and favorable consideration in this case will highly be appreciated

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

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 26

PQCB/R-345/2022

Punjab Institute of Cardiology, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Hoover Pharmaceuticals Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan** through its Chief Executive Officer, Mir Anjum Ishaque 2. Mir Anjum Ishaque Chief Executive Officer 3. Azhar Mahmood Production Manager 4. Muhammad Yaqoob Quality Control Manager/ Warrantor of M/s Hoover Pharmaceuticals Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan.

BRIEF FACTS OF THE CASE

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

i. She, on 28-09-2022, inspected the premises of Main Medicine Store of Punjab Institute of Cardiology, Lahore, took four different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide memorandum no. 141979 dated 28-09-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Gel. AROCAINE GEL [LIGNOCAINE HCL 2% W/W] **Mfg Date:** Oct 2021 **Expiry Date:** Oct 2023 **Regn No.** 036110	H54	M/S Hoover Pharmaceuticals Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan.	01-183001513/DTL dated 05-12-2022	**Analysis with specifications applied: BP 2022** **PHYSICAL DESCRIPTION:** Colorless transparent preparation claimed to be gel in a sealed metal collapsible tube with a screw cap, claimed weight= 15.0g **ASSAY OF LIGNOCAINE HCl:** Stated: 20mg / 100mL Determined: 19.2 mg/ gram Percentage: 96% Limit: 95.0 – 105.0% of the stated amount **LABELLING:** ***As per BP "Lidocaine gel" is a sterile solution of Lidocaine Hydrochloride monohydrate in a suitable water-miscible basis, as well as, The gel complies with the requirements stated under Topical semisolid preparations and the general chapter of "Topical semisolid preparations" states in LABELLING "The label states: where applicable, that the preparation is sterile".*** **(MISBRANDED)** **RESULT:** The above sample is **MISBRANDED,** as per THE DRUGS ACT 1976 [3 {s (i) (ii)}].

iii. The Store Officer of Main Medicine Store of Punjab Institute of Cardiology, Lahore provided warranty bearing No. 09-00104 dated 26-09-2022 issued by M/s Hoover Pharmaceuticals

Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Hoover Pharmaceuticals Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan.

v. A copy of test/analysis report was sent to M/s Hoover Pharmaceuticals Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 20-02-2023

Firm replied to the Show Cause Notice vide letter no. HO-PQCB 02/23-001 dated 28-02-2023

In this regard it is submitted that the Government Analyst has declared allegedly the report as misbranded which is not according to the legal provisions of Drugs Act 1976 and the rules framed thereunder on the following grounds:

1. The Government Analyst declares the misbranded as per Drugs Act 1976[3 (s (i) (ii)}1. The

perusal of these sections / sub-sections clearly reveals that these provisions are linked with mainly two words.

i. Prescribed manner. under section 3(s)(1)

ii. Information required by the rules to appear on the label... under section 3(s) (ii)

2. Both these words or terms has been clearly defined under section 3 of Drugs Act 1976 reproduced as

i. Section 3(t) "Prescribed" mean prescribed by rules.

ii. Section 3(x) "rules" means rules made under this act. On the subject of labeling the rules has been framed as Drugs (Labeling and Packing) rules, 1986.

So the inference of above sections clearly indicates the above said rules shall be considered.

***The perusal of these rules does not show any lacking in the label of Arocaine Gel**.*

*All the provisions required by the rules has been followed. It is important to mention that under the said rules (15) **the requirement of the word "Sterile" is only mentioned in the labeling for medical devices and not for other dosage forms** particularly the semi-solid in collapsible tubes. Therefore, **the report is not justified in the legal sense**.*

*You may appreciate the **assay of the product in question is quite within the limits**. However, in good faith for the ongoing batches, **we have started to print the word "Sterile" for the entire satisfaction of your side**.*

In the light of above, it is requested that the proceedings in the case may kindly be dropped and the case may be filed.

Furthermore, firm verified the names of the accused persons nominated in the instant case.

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

5. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 09-2022

Expiry Date: 09-2024

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

Sent to DTL (Form 6): 28-09-2022

Date of receipt in DTL: 28-09-2022

DTL Report Date (Form 7): 05-12-2022

Time Extension: Granted in 254th Meeting dated 13-12-2022

1ST DI Communication with firm on dated: 17-01-2023

Retesting Request of Firm: NA

Investigation Report Dated: 23-01-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 27

PQCB/R-139/2020

Tehsil Liaqatpur, District Rahim Yar Khan

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Iceberg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risalpur, KPK- Pakistan** through its Chief executive Officer Muhammad Fayaz 2. Muhammad Fayaz — Chief Executive Officer 3. Kamran Khan — Production Incharge 4. Adil Hussain — Management 5. Haseeb-ul-Haq — Quality Control Incharge 6. Najeeb Ullah — Management/Warrantor Of M/s Iceberg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risal pur, KPK- Pakistan. 1. Najeeb Ullah — Proprietor/Warrantor Of **M/s Najeeb Traders House # 52, street # A6, Al-Khidmat Hospital Road, Nishtar Abad, Peshawar.** 2. Faisal Masood — Proprietor/Warrantor Of **M/s Al-Qasim Medicine Company 4A, Model Town, Rahim yar Khan.**

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 06-12-2019 inspected M/s Karim Medical Store Main Bazar Shedani Sharif, Tehsil Liaqat Pur, and took sample of drug on Form No. 4 for the purpose of test and analysis.

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

Name of drug	Batch no.	Name of manufacturer	DTL Test Report No. & Date	DTL Test Report Results
Suspension Vefec [Cephradine 250mg/5ml, 60ml after Reconstitution	D-141	M/s Iceberg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshehra Industrial Estate, Risalpur, KPK-Pakistan .	01-65002882/DTL dated: 10 Feb 2020	**Result of Test/Analysis with Specifications applied:** USP 2018 **COMPOSITION** 5ml of suspension contains: Cephradine USP …….250mg **DESCRIPTION (MS):** Off white colored powder in sealed amber glass bottle. Upon reconstitution, light yellow colored suspension is formed, (Stated Volume: 60 ml after reconstitution. The label of the product does not bear the name of Pharmacopoeia or document according to which product is manufactured. **(The product is Misbranded)** **IDENTIFICATION (USP)** Cephradine is identified. **ASSAY (USP)** **Ce**phradine **Stated:** 250mg/5ml **Determined:113.9875mg/5ml** **Percentage: 45.595%** **LIMIT: 90-125%** **RESULT:** The sample is declared **Substandard** on the basis of Assay test **and Misbranded** under clause (vi) of subsection (s) of section 3 of the Drug Act 1976.

iii. M/s Karim Medical Store Main Bazar Shedani Sharif, Tehsil Liaquat Pur provided Bill/ warranty bearing Invoice no. 38648 dated 30-10-2019 issued by M/s Al-Qasim Medicine Company 4A, Model Town, Rahim yar Khan.

iv. Warrantor Portion was sent to M/s Al-Qasim Medicine Company 4A, Model Town, Rahim yar Khan.

v. M/s Al-Qasim Medicine Company 4A, Model Town, Rahim yar Khan in turn provided Bill/Warranty bearing Invoice no. 13851 dated 20-08-2019 issued by M/s Najeeb Traders House # 52, street # A6, Al-Khidmat Hospital Road, Nishtar Abad, Peshawar who in turn provided Bill/Warranty bearing Invoice no. ICB 466 dated 13-03-2019 issued by M/s Iceberg Pharmaceuticals Plot No. 144, Nowshera Industrial Estate Risal Pur, KPK-Pakistan.

vi. A copy of Test/ Analysis report was sent to M/s Iceberg Pharmaceuticals Plot No. 144, Nowshera Industrial Estate Risal Pur, KPK-Pakistan and they were directed to provide requisite information in this regard. In response, the firm requested for re-test/ analysis of the drug sample from National Institute of Health, Islamabad.

vii. Pursuant to request of firm, the PQCB Portion of drug sample was sent to NIH, Islamabad by the office of PQCB for re-test/ analysis 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
Suspension Vefec 60ml	D-141	M/s Iceberg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshehra Industrial Estate, Risalpur, KPK- Pakistan	No. 069-P/2021 dated 09-03-2021	**Description:** Off White granular powder which on reconstitution wit distilled water produces off white suspension contained in ambe colored labelled glass bottle further packed in an outer carton. **Identification:** Cephradine identified **pH**: Determined: 5.2 Limit: 3.5-6.0 **complies with USP-39.** **Volume:** Determined: 60ml Limit: 60ml Complies with volume stated on the label **Assay: Cephradine** **Stated:** 250mg/5ml **Found:** 163.95mg/5ml **Limit:** 90-125% **Percentage: 65.58%** **Does not comply with USP-39.** **Result:** The sample is **of sub-standard** quality on the basis of test performed.

viii. A copy of NIH test Report was sent to M/s Iceberg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshehra Industrial Estate, Risalpur, KPK- 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:

M/s Iceberg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risalpur, KPK- Pakistan	i. Manufacturing/selling/stocking for Sale of Substandard Drug. ii. Issuance of false warranty.
M/s Najeeb Traders House # 52, street # A6, Al-Khidmat Hospital Road, Nishtar Abad, Peshawar	i. Distribution/selling/stocking for sale of Substandard Drug. ii. Issuance of false warranty
M/s Al-Qasim Medicine Company 4A, Model Town, Rahim yar Khan.	i. Selling/stocking/Distributing for sale of Substandard Drug. ii. Issuance of false warranty.

Summary

Manufacturing Date: 03-2019

Expiry Date: 03-2021

Sampling Date: 06-12-2019

Sent to DTL (Form 6): 07-12-2019

Date of receipt in DTL: 12-12-2019

DTL Report Date: 10-02-2020

1ST DI Communication with firm on dated: 23-06-2020

Date of Retesting Request of Firm: 30-06-2020

Fate of Retesting Request: substandard from NIH (on basis of Assay 65.58%)

Investigation Report Dated: 28-06-2021

1. Show-cause notice(s) issued to the accused

Firm submitted reply of Show cause vide letter Ref no. Re/PQCB/141/01 dated 09-08-2021

Reference to your letter No. PQCB/R -139/2020 regarding the declaration of the product Vefec Dry Suspension 250mg/5ml Batch No: D-141 (as Substandard &Misbranded) The said product was declared Misbranded via No. TRA. 01-65002882/DTL whereas the label and unit carton of the product clearly bear the specification according to which product was manufactured in direction for preparation i.e.,

For Oral Suspension

When prepared as directed each 5 ml of suspension contains:

Cephradine U.S.P ….. 250 mg

Moreover, we tested and analyze the above noted batches retention samples which were found in compliance with their specification.

In response to your letter No DI - LQP/298 Dated: 23-06-2020 we recalled the stock from our distributor the recalled stock detail is attached herewith for your ready reference.

Towards commitment for a quality products manufacturing for verification of the root cause analysis of the said substandard products following corrective and preventive actions were conducted by the firm after intimation of report of said product.

1. The API source was changed and now using more authentic source of API of said drug.

2. The Dry powder filling Machine which was semiautomatic was replaced by fully Automatic machine

3. Worked on product development data i.e.

a. Authentic sourcing of API

b. Pilot Batch Manufacturing

4. IPC (In Process Control) strategy was revised/reviewed.

5. Worked on ICH stability study and revised/reviewed all the procedures related to the determination of the product quality.

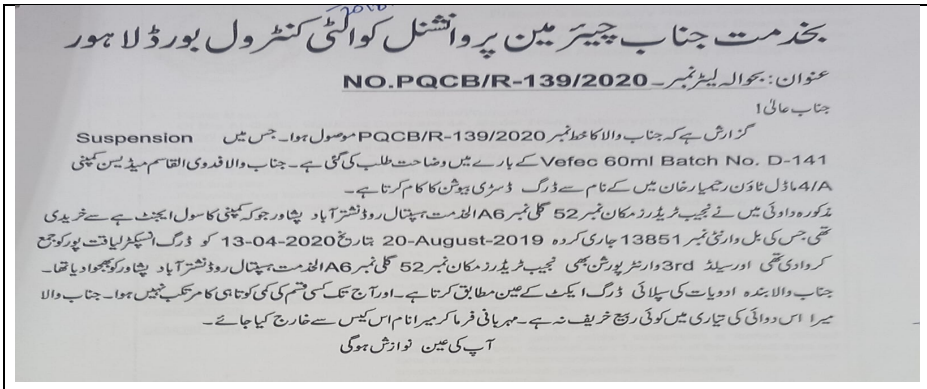
6. Reviewed all quality control system and were in placed and now operating effectively.

Needless to mention that our worthy organization and our quality control department never compromise on the quality and efficacy of the product and appreciate your guidelines and your check and balance and on behalf of your feedback of our product we strictly observe our quality and will improve it further inshallah.

We also appreciate your suggestions which make us sounder regarding the quality manufacturing.

The requested documents are attached here with for your ready reference. If you have any further directions or instructions we will appreciate and follow all matters.

Al-Qasim Medicine company Reply of show cause notice vide letter nil received in office of PQCB dated 20-08-2021



بخدمت جناب چیئرمین پروانشل کوالٹی کنٹرول بورڈ لاہور

عنوان: بحوالہ لیٹر نمبر۔ NO.PQCB/R-139/2020

جناب عالی!

گزارش ہے کہ جناب والا کا خط نمبر PQCB/R-139/2020 موصول ہوا۔ جس میں Suspension Vefec 60ml Batch No. D-141 کے بارے میں وضاحت طلب کی گئی ہے۔ جناب والا فدوی القاسم میڈیسن کمپنی 4/A ماڈل ٹاؤن رحیم یار خان میں کے نام سے ڈرگ ڈسٹری بیوشن کا کام کرتا ہے۔

مذکورہ دوائی میں نے نجیب ٹریڈرز مکان نمبر 52 گلی نمبر A6 الخدمت ہسپتال روڈ نشتر آباد پشاور جو کہ کمپنی کا سول ایجنٹ ہے سے خریدی تھی جس کی بل وارنٹی نمبر 13851 جاری کردہ 20-August-2019 بتاریخ 13-04-2020 کو ڈرگ انسپکٹر لیاقت پور کو جمع کروادی تھی اور سیلڈ 3rd وارنٹر پورشن بھی نجیب ٹریڈرز مکان نمبر 52 گلی نمبر A6 الخدمت ہسپتال روڈ نشتر آباد پشاور کو بھجوادیا تھا۔ جناب والا بندہ ادویات کی سپلائی ڈرگ ایکٹ کے مین مطابق کرتا ہے۔ اور آج تک کسی قسم کی کوتاہی کا مرتکب نہیں ہوا۔ جناب والا میرا اس دوائی کی تیاری میں کوئی ریچ خریف نہ ہے۔ مہربانی فرما کر میرا نام اس کیس سے خارج کیا جائے۔

آپ کی مین نوازش ہوگی

4. Personal Hearing notice(s) issued to accused person(s) dated 09-01-2023

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 **256th meeting** held on **19-01-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Amjad Farooq, Secretary DQCB Rahim Yar Khan was present along with the original case record. No one among the nominated accused persons of M/s Iceberg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risal pur, KPK, Pakistan appeared before the Board. No one among the nominated accused person of M/s Najeeb Traders House # 52, street # A6, Al-Khidmat Hospital Road, Nishtar Abad, Peshawar appeared before the Board. Among the nominated accused person Faisal Masood (Proprietor/Warrantor) Of M/s Al-Qasim Medicine Company 4A, Model Town, Rahim yar Khan appeared before the Board. He submitted that he provided invoice/warranty issued by Najeeb traders, which was verified, to the concerned Drug inspector within time.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case in the best interest of justice due to absence of the firm. The Board further decided to provide another chance of hearing to M/s Iceberg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risalpur, KPK, Pakistan.

In response to personal hearing notice dated 09-01-2023 JSK Medica Pvt Ltd submitted letter vide ref # A-07/23 dated 16-03-2023 received in office of PQCB dated 21-03-2023

Pursuant to the instructions from and on behalf of my cleint Mr. Kamran Anjum Director of JSK Medica (Pvt) Ltd having its head office at Nishtarabad, Peshawar, I do hereby serve you the reply of your show cause Notice vide Letter # PQCB/R-139/2020, dated 09-01-2023.

That you have issued the above-mentioned personal hearing notice to the M/S lceberg Pharmaceuticals (Pvt) Ltd, situated at Risalpur Industrial Zone Nowshera through its responsible namely:

1. Muhammad Fayaz — Chief Executive Officer
2. Kamran Khan — Production Incharge
3. Adil Hussain — Management
4. Haseeb-ul-Haq — Quality Control Incharge/warrantor
5. Najeeb Ul Haq — Management/Warrantor

Now, It is for your kind information that some time ago the above-stated responsible and other co-owners and co-sharers of above-mentioned Pharmaceutical Company has sold their respective shares in the factory along with leasing rights of plot # 144, situated at Nowshehra Industrial Risalpur KPK Pakistan to Mr. Kamran Anjum (Director of JSK Medica (Pvt) Ltd along with others and at the instant the said factory is going through its renovation and upgradation phase of its manufacturing facilities and it has stopped the production since last six months.

Therefore, you the authority is requested to issue the notices of pursuance to M/s lceberg Pharmaceuticals (Pvt) Ltd, its Chief Executive Officer and its other responsible on their personal addresses for further proceedings and correspondence.

As JSK Medica (Pvt) Ltd has no concern with the name, title, products and management of lceberg

Pharmaceuticals (Pvt.) Ltd.

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

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD

Case No. 28

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.

PREVIOUS PROCEEDINGS BY THE BOARD:

PQCB 258th meeting dated 05-04-2023:

4. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Shahzad Chaudhary, Drug Inspector Tehsil Ferozewala District Sheikhupura was present. Ms. Asma Rasheed, Secretary DQCB, Sheikhupura joined the meeting through zoom link. No-one among the nominated accused was present on behalf of M/s Intervac Pvt. Ltd. Situated at 18-km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura. The case was leftover due to time constraints.

PQCB 259th meeting dated 18-04-2023:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **259th meeting** held on **18-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Ms. Asma Rasheed, Secretary DQCB, Sheikhupura and Mr. Shahzad Chaudhary, Drug Inspector Tehsil Ferozewala District Sheikhupura were present. No-one among the nominated accused was present, however, representative from the firm, Vivian Joy (Q.A. Inspector) appeared before the Board on behalf of M/s Intervac Pvt. Ltd. Situated at 18-km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura and submitted written request for adjournment. The Board after due deliberation and discussion unanimously decided to adjourn the case in best interest of justice. The Board further decided to give another opportunity of personal hearing to the accused.

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

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 29

PQCB/R-725/2020

Tehsil Khiarpur Tamewali & District Bahawalpur

Misbranded & Sub-Standard (Physical Test

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Lawrence Pharma (Pvt.) Ltd., 10.5 Km, Sheikhupura Road, Lahore-Pakistan** through its Chief Executive Officer, Muhammad Farrukh Arif 2. Muhammad Farrukh Arif Chief Executive Officer 3. Rehana Iqbal Production Incharge/ Warrantor 4. Akhtar Ali Quality Control Incharge **of M/s Lawrence Pharma (Pvt.) Ltd., 10.5 Km, Sheikhupura Road, Lahore-Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He, on 17-09-2020, inspected the business premises of M/s Sajjad Medical Store, Main Road Khairpur Tamewali, District Bahawalpur, took four different types of drug samples on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Bahawalpur vide memorandum no. 74662 dated 18-09-2020.

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

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Injection. Cyanocobalamine [Cyanocobalamin: 500mcg] **Mfg Date:** July 2020 **Expiry Date:** May 2022 **Regn No.** 049047	B12H-0278	M/s Lawrence Pharma (Pvt.) Ltd., 10.5 Km, Sheikhupura Road, Lahore-Pakis tan.	01-77002328/DTL dated: 17-11- 2020	**Analysis with specifications applied:** USP 2020 **COMPOSITION:** Each 2ml Contains: Cyanocobalamin B.P……. 500mcg **DESCRIPTION:** Pink color liquid filled in amber glass sealed ampoule. (Stated volume: 02ml). 12 out of 20 ampoules have visible particulate matter seen with the naked eye. **(Does not comply with the parenteral specifications)**. Product specifications on label claims that product is of BP specifications. However, "cyanocobalamin Injection" monograph is not present in BP. Furthermore, generic on the primary packaging label claims "Cyanocobalamine", however, both the pharmacopoeia i.e. BP and USP spells it as "Cyanocobalamin" **(The product is misbranded).** **VOLUME (USP)** **Limit:** ----------NLT nominal vol **Determined:** ------- 2.3ml **pH (USP):** **Limit:** ---------- 4.5 – 7.0 **Determined:** -------- 4.713 **STERILITY (USP):** The product is sterile. **IDENTIFICATION (USP):** Cyanocobalamin is identified. **ASSAY (USP):**

Generic	Stated	Determined	Percentage	Limit
Cyanocobalamin	500mcg/ 2ml	537mcg/ 2ml	107.40%	95.0-115.0%

RESULT: The sample is declared **SUB-STANDARD** on the basis of PHYSIACL TEST and **MISBRANDED** as defined under clause (vi) of sub-section (s) of section 3 of the Drug Act 1976.

iii. Proprietor of M/s Sajjad Medical Store, Main Road Khairpur Tamewali, District Bahawalpur provided invoice/ warranty No. 34254 dated 01-09-2020 issued by M/s Muneeb Waqar Medicine Company, Office # 67 Block-C Chishtian, District Bahawalnagar as a proof of its purchase of the subject drug.

iv. Warrantor portion of drug sample was sent to M/s Muneeb Waqar Medicine Company, Office # 67 Block-C Chishtian, District Bahawalnagar who provided invoice/ warranty bearing No. 8797 dated 10-08-2020 issued by M/s Lawrence Pharma (Pvt.) Ltd., 10.5 Km, Sheikhupura Road, Lahore-Pakistan.

v. A copy of test/analysis report was sent to M/s Lawrence Pharma (Pvt.) Ltd., 10.5 Km, Sheikhupura Road, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

6. Showcause was issued to accused person(s) vide dated 23.01.2023

Reply of Show Cause Notice:

1. The DTL. Bahawalpur had reported that the sample is substandard on the basis of description and misbranded on the basis of Product specification that is an extra 'e' in the word "Cyanocobalamine" instead of "Cyanocobalamin".

It is stated that:

Description: Substandard

2. The DTL. Bahawalpur had not given the protocol of test/analysis being carried out for the determination of visual test in amber glass ampoules. The conclusion that out of 20 ampoules the particulate matter seen in 12 ampoules visibly. It is not revealed; was the injection solution poured solution in a transparent measuring cylinder or made some device for this purpose. The report also did not exhibit that it was analyzed at some specialized visual conditions.

3. Sample of 75 ampoules (3x25) were received by the Govt. Analyst, DTL, Bahawalpur, whereas, only 20 ampoules were considered for the visible particulate matter testing.

4. The DTL, Bahawalpur has not exposed that the said sample is injurious in nature and dangerous to health.

5. The investigating officer/Inspector of Drugs may be knowing the legal position of visible particulate matter, which is cited as under:

i. That the drug cannot be construed as substandard on physical appearance Authority **1984 PCr.L.J 1580** and **1985 PCr. L.J 2064** (Annex-1).

ii. In other case the honourable court ordered that simple remarks that the sample contained visible particulate matter/suspended particles which are visible to naked eye would not be sufficient to declare drug as substandard

and adulterated Authority **PLJ 2003 Lah.2003 YLR 350 (Lah.)** (Annex-2).

The H'able court further opined that CDL at Karachi doesn't indicate any filthy, putrid or decomposed substances or which contains any foreign matter, vermin, worm, rodent or insect or drug has been manufactured, packed, or held under un-sanitary conditions whereby it may have been contaminated with dirt, filth, or any other foreign matter or whereby it may have been rendered injurious to health.

iii. The Apex Court interpreted that substandard drug is that which is not confirming to identity, purity and stated strength (Annex-2).

Further to submit:

6. The Govt. Analyst, DTL, Bahawalpur has declared the sample as of sterile quality.

7. The keeping sample of the aforementioned product was immediately retested by our Quality Control Section. The incharge QC, QA and the analyst are of the view that the sample is of standard quality in all respect. This is also confirmed by the Govt. Analyst, DTL, Bahawalpur.

Product specifications: Misbranded

8. The inadvertent minor error of putting 'extra 'e' in the word "Cyanocobalamine" instead of "Cyanocobalamin" by the printer was immediately rectified. The observation of Govt. Analyst, DTL, Bahawalpur is commendable.

9. The 'extra 'e' in the name did not affect the products quality and even not noticed by the health providers.

10. It is further to submit that with reference to the PQCB letter No. PQCB/Misc-01 dated 16/06/2021 regarding subject misbranding of drugs (Annex-3) we have been constantly upgrading all the packing and labelling material for compliance as per law.

11. The distributors were immediately informed on phone and also circulated a letter for the withdrawal of the injection Cyanocobalamin 2ml Batch No. B12H-0278 (Annex-4).

On receiving the test and analysis report, our company had withdrawn the product, the minor typographic error was rectified immediately, the conclusion of substandard report on the basis of visual test in amber glass ampoules on the basis of capricious particular matter is not clear.

In view of the above submissions it is requested to kindly withdraw the show cause notice, keeping in view the technical grounds mentioned above. Please save the poor bread earners from the agony they are facing by minor allegation declared in the DTL, report. We are prepared to appear before the PQCB for explanting our position in personal hearing, please.

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

Case is placed before the Board for Decision

Summary:

Manufacturing Date: 07-2020

Expiry Date: 05-2022

Sampling Date (Form 4): 17.09.2020

Sent to DTL (Form 6): 09.07.2020

Date of receipt in DTL: 18.09.2022

DTL Report Date (Form 7): 17.11.2020

Time Extension: N/A

1ST DI Communication with firm on dated: 18.12.2020

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated: 02.12.2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 30

Case No.

PQCB R-578/2021

Tehsil Pind Dadan Khan, District Jhelum

ATTENDENCE

Secretary DQCB **Drug Inspector**	1. **M/s Medera Pharmaceuticals Pvt. Ltd. Plot no. 249/A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan,** through its Chief Executive Officer Hamayun Kabir. 2. Hamayun Kabir Chief Executive Officer. 3. Muhammad Siraj Production Incharge. 4. Abdul Wajid Quality Control Incharge/Warrantor. Of M/s Medera Pharmaceuticals Pvt. Ltd. Plot no. 249/A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Tehsil Pind Dadan Khan & District Jhelum reported that:

i. His predecessor, on 22-06-2021 inspected a business premises M/s Bilal Medical Store, Village Pinanwal, Pind Dadan Khan, took sample of subject drug on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide memo number 000009882,dated 22nd June,2021.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report</th><th>DTL Test Report Result</th></tr>
<tr><td>Capsule AMAZOLE

(Omeprazole 20mg)

Mfg Date: 03-2021

Exp Date: 05-23

Reg number: 024750</td><td>174</td><td>M/s Medera Pharmaceuticals Pvt. Ltd. Plot no. 249/A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan</td><td>01-74002272/ DTL dated: 26 Oct 2021</td><td>
Result of test/ analysis with specifications applied: USP 2021

<u>DESCRIPTION:</u>

White to off white coloured pellets filled in hard gelatin capsule shells comprised of transparent pink coloured cap and transparent colourless body, packed in Alu-PVC (White coloured) blister of 1x7, further packed in labelled outer carton containing 2 blisters (14 capsules)

<u>DISSOLUTION TEST (USP Test 2)</u>:

Acid Resistance Stage:
<table>
<tr><th>L 1</th><th>Unit 1</th><th>Unit 2</th><th>Unit 3</th><th>Unit 4</th><th>Unit 5</th><th>Unit 6</th><th>Average</th></tr>
<tr><td></td><td>46.09</td><td>27.53</td><td>8.56</td><td>19.92</td><td>27.29</td><td>23.73</td><td>25.52</td></tr>
</table>
Limit: The average of the 6 units is NMT 10% of omeprazole dissolved.

(DOES NOT COMPLY)
<table>
<tr><th>L 2</th><th>Unit 7</th><th>Unit 8</th><th>Unit 9</th><th>Unit 10</th><th>Unit 11</th><th>Unit 12</th><th>Average (L1 + L2)</th></tr>
<tr><td></td><td>21.25</td><td>14.70</td><td>36.35</td><td>33.04</td><td>10.63</td><td>28.24</td><td>24.78</td></tr>
</table>
Limit: The average of the 12 units is NMT 10% of omeprazole dissolved. (DOES NOT COMPLY)
<table>
<tr><th>L 3</th><th>Unit 13</th><th>Unit 14</th><th>Unit 15</th><th>Unit 16</th><th>Unit 17</th><th>Unit 18</th><th>Average (L1 + L2 + L3)</th></tr>
<tr><td></td><td>3.50</td><td>26.03</td><td>13.48</td><td>16.09</td><td>26.06</td><td>24.23</td><td rowspan="3">19.04</td></tr>
<tr><td></td><td>Unit 19</td><td>Unit 20</td><td>Unit 21</td><td>Unit 22</td><td>Unit 23</td><td>Unit 24</td></tr>
<tr><td></td><td>32.08</td><td>4.51</td><td>4.31</td><td>6.62</td><td>2.79</td><td>0.00</td></tr>
</table>
Limit: The average of the 24 units is NMT 10% of omeprazole dissolved. (DOES NOT COMPLY)

Note: <u>Buffer stage was not performed as contents of omeprazole was released in acid resistance stage more than the specified limit.</u>

<u>IDENTIFICATION: Omeprazole Identified.</u>
<table>
<tr><th>Assay</th><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limits</th><th>Comments</th></tr>
<tr><td>Omeprazole</td><td>20mg/ Capsule</td><td>21.832 mg/ Capsule</td><td>109.16 %</td><td>90 % - 100%</td><td>Complies</td></tr>
</table>
<u>Result:</u> <u>The sample is substandard as it failed to comply with the Dissolution test.</u>
</td></tr>
</table>

ii. The Proprietor, M/s Bilal Medical Store, Village Pinanwal, Pind Dadan Khan provided warranty/invoice bearing No. 176658 dated 01-06-2021 issued by M/s Tariq Pharmacy, Muhammadia Chowk, Jhelum.

iii. Warrantor Portion was sent to M/s. Tariq Pharmacy, Muhammadia Chowk, Jhelum.

iv. M/s Tariq Pharmacy, Muhammadia Chowk, Jhelum provided warranty/invoice bearing No. 1512 dated 10-04-2021 issued by M/s Medera Pharmaceuticals Pvt. Ltd. Plot no. 249/A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.

v. A copy of Test/ Analysis reports was sent to M/s Medera Pharmaceuticals Pvt. Ltd. Plot no. 249/A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan and they were directed to explain their position. 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, which was considered by the Provincial Quality Control Board in its 246th meeting held on 05-07-2022 and the Board after due deliberation unanimously decided to turn down the request.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976/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. The firm filed Petition for withdrawal of PQCB order no. PQCB/P-1002-10/2021 dated 05-07-2022 to turn down re-testing request.

SUBJECT: PETITION FOR WITHDRAWAL UNLAWFUL PQCB/P-1002-10/2021 DATED 05-07-2022 TO TURN DOWN RETESTING REQUEST WHICH WAS NEVER SUBMITTED BY M/S MEDERA PHARMACEUTICALS (PVT) LTD KAHURA ROAD, ISLAMABAD RELATED TO CAPSULE AMAZOLE (OMEPRAZOLE 20MG).

Kindly refer to No. PQCB/P-1002-10/2021 dated 05-07-2022 with dispatch date 13-09-2022 received by the company on 05-10-2022

The following submissions are made

That correspondence of the company with Inspector and PQCB may please be taken as an integral component of this Petition. Because impugned order is without meaningful personal hearing and without annulated confrontation for the legal as well as factual controversies. The genuine adjournment request was rejected mechanically. The facts have been twisted in this Order and SC-Judgment has been misinterpreted +misconstrued either due to ignorance or innocence of the author of the impugned PQCB ORDER
2. That above non-Speaking Order/ Decision of the PLCB contained in para 10 of the Order is based upon the concealments and misrepresented facts presented before the PLCB member and reproduced below
10 in view of the above the Board deliberately, unanimously decided to Turn Down the request of the firm and further directed the Drug Inspector of the concerned area to expedite investigation of the subject Case and submit final report for consideration by the Board.
3. That the vital Fact that COMPANY NEVER SIBMITTED ANY REQLUEST FOR RETESTING of Capsule Amazole 20mg B# 174 Manufactured by M/S Medera Pharmaceuticals (Pvt) ltd. 249- A Industrial Triangle Kahuta Road Islamabad declared substandard vide an unlawful Test Analysis report No TRA 0174002272/DTL Dated 26.10.2020. The phrase stated in para "The company would use its right to submit request of Retest provided under section 22 (5) of the Drug act I976 as and when required at an appropriate time, in line with the principle laid down by honourable Supreme Court of Pakistan. "This single factum is enough for withdrawal of Unlawful Non-Speaking Impugned PQCB Order of Turn Down of Retesting Request issued vide NO. No. PQCB/P-1002-10/2021 dated 05-07-2022.
4. The Impugned Order is silent and deliberately about the PRELIMINARY OBJECTIONS which makes the report unlawful.
a. The Test Report is time barred which is violation of Section 22 (4) which has the mandatory requirement that test / report must be issued within sixty days. In this case, the sample of CAPSULE AMAZOLE 20mg B 174 had been received at DIL, Rawalpindi on 30.06.2021 The Government Analyst DTL. Rawalpindi Report No. TRA 0174002272/DTL DATED 26.10.2021 is TME BARRED - Unlawful as submitted by the Government Analyst. DTL Rawalpindi after 118 days from the start date to the end data, instead of statuary period of 60 days prescribed under section 22(2) of the Drugs Act 1976. Report received after prescribed period, not conclusive and the Government Analyst committed violation of mandatory Section 22 ( ) of the Drug ACT 1976 the law by submitting report without obtaining extension of time from the PQCB Punjab. Since mandatary provision of law i.e., Section 22 (2) of the Drugs Act 1976 has been violated and based on such delayed test report no conviction can be awarded anywhere in any court of law. Reliance 1984 P Cr. L J 1580, 1985 P.Cr.L.J. J 2064, PLJ 2012 Cr.C (Quetta) 546 (DB). the procedure prescribed for obtaining extension is reproduced below
22 Reports of Government Analysts: ()---
(2) The Government Analyst as far as may be, shall submit the report referred to in sub-section (1) within sixty days of the receipt by him of the sample of the drug and if he is not able to do so for reasons beyond his control, shall communicate the reasons to the Inspector in writing and shall endorse its copy to the Board concerned who shall have the sample tested from the same or any other Government Analyst or a Government Drug Testing Laboratory or any other Laboratory and shall ensure the receipt of results of such test and analysis within a further period as may be prescribed and shall make the test report available to the Inspector for further action. Please note that
I. It is astonishing that no rules have been made to prescribe "further period" while granting extension period for make the test report available to the inspector for further action.

II. The Courts have acquitted accused persons on this single ground in many similar cases - because ILEGALITY committed by violation of mandatory section 22(2).

b. That non-performing of TEST in Buffer Stage raises reasonable doubts. The performance of test in Acidic Media is also erroneous as raw data related to assay and Calculations of Omeprazole for the twenty-four units L1-L24 not given which makes the Report as Doubtful Non-conclusive and Unlawful.
5. That LAST PARA OF THE JUDGMENT DB Judgement of Honourable Lahore High Court has settled the issue of Unlawful Report and remedy of Retesting while dismissing Intra-Court Appeals Nos. I27 and 128 of 1989 filed by PQCB Provincial Quality Control Board and others--Appellants Versus IRZA Pharma and others---Respondents reported as 1992 ML D 48l reproduced below
"In this view of the matter, we are not impressed by the legality of the reports, and also the contention that another efficacious remedy is available to the respondent by reverting to the Federal Testing laboratory. When the basic test report does not conform to the provisions of law, it is wholly without jurisdiction and incapable to be acted upon. Hence asking the respondent to choose the aforesaid remedy is nothing but to perpetuate the tyranny. Hence we repel the contention, and we also disapprove the action taken otherwise than law which is nothing but amounts to tyranny of law, and the citizens are to be saved therefrom. Resultantly we hold that the view of the matter taken by the learned single Judge of this court is not open to any exception. Hence, we do not find any substance in this appeal which is dismissed accordingly".
Appeal dismissed
6. That as per requirement of Section 22 (4) of the Drug Act 1976 and based upon credible evidence the company had declared/notified its intention to adduce evidence in controversion to the above subject test /analysis report of Government Analyst DTL Rawalpindi within TEN DAYS. The section 22 (4) is reproduced below
Section 22 (4)of the Drug Act 976 (4) Notwithstanding anything contained in any other law for the time being in force any document purporting to be a report signed by a Government Analyst shall be admissible as evidence of the facts stated therein without formal proof and such evidence shall be Conclusive unless the person from whom the sample was taken or the said warrantor has within thirty days of the receipt of a copy of the report notified in writing to the Inspector or the provincial Quality Control Board or, as the case may be, the Central Licensing Board or the Registration Board or the Drug Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report
The report of the Government Analyst becomes non-Conclusive when intention to adduce evidence in controversion is declared under Sub-Section (4) of Section 22 of the Drugs Act 1976. Consequently, the Test /Analysis Report TRA 0174002272/DTL DATED 26.10.2021

becomes legally valueless, cannot be used against the company, then Provincial Quality Control Board either drop the proceedings, being the petitioner 's case covered within the category of a "Case of No Evidence" OR send the Sample of Drug kept by PQCB under Sub-Section (3) of Section 19 for Retest Either ON THE REQLUEST OF COMPANY OR ITS OWN DISCRETION under Sub-Section (5) of Section 22 of the Act to get a final report. Section 22(5) of the Drug Act 197E is reproduced below

22(5)-Where a person has, under sub-section (4), notified his intention of adducing evidence in contravention of a Government Analyst 's report, the Provincial Quality Control Board or, as the case may be the Central Licensing Board or the Registration Board or the Drug Court may, of its own motion or in its discretion at the request either of the complainant or the accused cause the sample of the drug lying with the Board concerned under sub-section (3) of section 19 to be sent far test or analysis to the Federal Drug Laboratory or any other laboratory specified for the purpose by the Federal Government which shall make the test or analysis and report in writing signed by or under the authority or the person for the time being in-charge of the Federal Drug Laboratory, or, as the case may be, such other laboratory, the result thereof and such report shall he conclusive evidence of the facts stated therein.

Furthermore, it was submitted in an unambiguous manner that the company would use its Right to Submit Request of Retest provided under section 22 (5) of the Drug Act l976 as and when required at appropriate time, in line with the principle laid down by honourable Supreme Court of the Pakistan. Furthermore, it was submitted by the company in an unambiguous manner that the company would use its Right to Submit Request or Retest provided under section 22 (5) of the Drug Act 1976 as and when required at appropriate time, in line with the principle laid down by Honourable Supreme Court of Pakistan.

7. That the therapeutic ingredient Omeprazole has been determined as 109.16% against the limit 90-100%. However, sample has been erroneously declared as substandard based on Dissolution Test. The impugned Order is silent about the company defence /viewpoints contained in its letter No. Med-I18-DIPIK-D-2021 Date. 26.1.202I submitted as a reply to letter Na.44/DI/ PDK received on 22.11.2021 along- with an UNLAWFUL TIME BARED Test Analysis Report 0174002272/DTL DATED 26.10.2021 related to capsule Amazole 20mg B.l74 Manufactured by M/S Medera Pharmaceuticals (Pvt) Ltd. 249/A, Industrial Triangle, Kahuta Road Islamabad.

8. That Impugned PQCB Order is silent about the vital issue that whether, after purchasing drugs from manufacturer, the same were stored under the conditions laid down or stated on carton. Reasonable possibility of sample obtained by the Drug Inspector and subsequently sent to the Laboratory having been deteriorated due to its improper storage after purchase from the manufacturers not ruled out. Accused held, entitled to the benefit of doubt and the convictions and sentence were set aside. Reliance I985 P Lr. L J 28I. 1984 P Cr. LJ 1580. The section 32 (3) of the Drugs Act 1976 require that it must be ascertained that drug while in possession of purchaser, was safely stored and remained in the same state as when he had acquired it from manufacturer. No doubt improper storage conditions outside labelled instructions, may adversely affect the quality of the drug physically and chemically, Potency and the state of certain drugs was depended to some extent upon conditions in which they were required to be stored and had been stored prior to test by the concerned laboratory. Nobody know that whether storage conditions were complaint to Section 32 of the Drugs Act l976 during the process of sampling. Transport and Storage. The superior courts by giving the benefit of doubt had acquitted many accused.

4. That Impugned PQCB Order has not touched the Company viewpoint /Explanation contained in para "related to Dissolution Testing reproduced as-The Government Analyst has declared the disputed drug as non-complaint to USP-Dissolution Test. The ultimate OBJECTIVE DF DISSOLUTION TESTING Is to ensure adequate and reproducible bioavailability, the objective of the dissolution tests prescribed in the individual monographs of The International Pharmacopoeia is to attain information about the drug-release characteristics of a particular formulation or batch of a product under standardized test conditions. Compliance with the test provides an assurance that most of the active ingredient will he dissolved in an aqueous medium within a reasonable amount of time when the preparation is subject to a mild agitation. Compliance with the dissolution test does not by itself guarantee bioavailability or bioequivalence to other products. A dissolution experiment evaluates the rate and extent that a compound. That there is need to understand "THE DISSOLUTION Disintegration time is the time required for a dosage form to break up into granules of specified size (or smaller) under carefully specified conditions. Whereas dissolution is, a process by which solid substance enters in the solvent to yield a solution Dissolution testing is a requirement for all sold oral dosage forms and is used throughout the development life cycle for product release and stability testing. It is a pivotal analytical test used for detecting physical changes in an active pharmaceutical ingredient and formulated product FACTORS RELATED TO DISSOLUTION TEST PARAMETERS-Temperature Dissolution Medium, Viscosity, Humidity and Detection Errors must be well defined / validated for accurate results free of errors. The report is silent on these vital issues.

There are seven USP defined types of dissolution apparatus: baskets, paddles, reciprocating cylinders, flow through cells, paddle over disk types cylinders, and reciprocating holders. Although USP 2 paddles are most widely used, most dissolution apparatus incorporate any number of each type (often all of them) The report is silent on the point that which apparatus was used? AND whether Pre-requisite and DISSILUTION APPARATUS SUITABILITY TEST were considered /performed?

ESSENTAIL AND VITAL PREQUESITE DF DISSOLUTION TEST - UINITED STATES PHARMACDPELA (USP) DISSOLUTION APPARATUS SUITABILITY TEST Calibration of dissolution test apparatus is a Good Practice for Pharmaceutical Quality Control Laboratories as well as a regulatory requirement for Quality Control (QC) labs within regulatory authorities, pharmaceutical manufacturing plants and independent quality control labs. Dissolution test apparatus must demonstrate that they are fit for use before results generated from their use are deemed credible. QC professionals must skills to be able to conduct bath mechanical calibration [also known as Operation Qualification (OQ) and Performance Verification Testing [PVT also known as Performance Qualification (PQ)] of dissolution test apparatus. USP Prednisone Reference Standard tablets and substance. The Apparatus Suitability section in <711> describes the procedure and requirements tor qualification of dissolution apparatus. Analytical instrument qualification/calibration is also required by FDA current Good Manufacturing Practices (cGMPs) and IS0/IEC 17025 an international standard specifying general requirements for the competence of testing and calibration laboratories. The USP Performance Verification Test (PVT) is used to determine the trueness and precision of the results in comparison with results from a broadly based international study. The test can also be diagnostic of errors in technique.

That based upon the United States Pharmacopeia (USP) Dissolution Apparatus Suitability test results and the preliminary data obtained from an international collaborative study to assess the pharmaceutical quality of furosemide products in different countries. Based on the USP calibrator data submitted by the participants representing four lots of each of No-disintegrating (Salicylic Acid) and Disintegrating (Prednisone) tablets, overall variability can be high and failures to meet the specification in a dissolution run can be frequent. This elevated level of variability and failure are dependent on the combination of calibrator and apparatus type. Calibrator-apparatus combinations of Prednisone tablets/Basket Method and Salicylic Acid tablets/Paddle Method show some sort of interaction. Therefore, use of these combinations to test suitability of dissolution apparatus needs to be evaluated. However, Prednisone Tablets with the Paddle

Method and Salicylic Acid tablets with the Basket Method however, appear to provide sufficient information for dissolution apparatus calibration and their use should be continued.
That the absence of the full protocols of test in the above report is a clear violation of Drug laws. Reports of Analyst must be conclusive and must disclose the tests applied to formulate opinion of Government Analyst. There is always a chance of errors in tests / analysis report that would be of adverse consequence and affects substantial rights of a person. Therefore, the description of the experiment including method evaluating standards / results must be Crystal clear whenever report would be disputed. Reliance on PLD 2003 Lalh 115 (Please Note federal legislation prevails when there is a conflict with provincial legislation), The honourable Supreme Court has held in case reported as 2019 SCMR 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." 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
(I) The Tests Applied
(II) The Protocols Applied to Carry out These Tests and
III) The Result of the Test (S).
The Government Analyst DTL, Rawalpindi - Test /Analysis Report No. TRA/01-74001022/DTL Dated 29.06.2021 is illegal as no Protocols Applied to carry out this tests. It must be kept in mind that the reasonable possibility of an error being committed by the Government Analyst during analysis, calculations and testing sample cannot be eliminated. The company has a right to satisfy itself that the chance of a mistake has been eliminated. It can do so if sufficient factual data is given in the report. The factual data by itself will evaluate whether the test was done appropriately without any error and mistake. A mistake in sample preparation may adversely affect the result whereby giving less than 100 % result of the 100% added contents.
10. That the maxim. Acommuni Observantia Non-EST Recedendum (where a thing is provided to be done in a particular manner, it must be done in that manner: and if not so done, the same would not be lawful. Violations of mandatory provisions in the present case, are LLEGALITIES which always results in ACQUITTAL By the Courts in Complaints filed by Inspector on the direction of PQCB
In the light of above, it is requested that
1) The PQCB may please withdraw the impugned Order of Turn Down of Retesting Request which was never submitted by the company
2) The case based upon an illegal, faulty and non-conclusive Test / Analysis Report No. TRA 01-74001022/DTL Dated 29.06.2021 issued by Government Analyst, DTL Rawalpindi may please be dropped for the interest of Justice and Fair Play.

3. Show-cause was issued to accused person(s) vide dated 21-11-2022.

4. Personal Hearing notice(s) issued to accused person(s) vide dated 26-01-2023.

PREVIOUS PROCEEDINGS AND DECISION OF THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under Section 11 of the Drugs Act 1976 in its **257th meeting** held on **07-02-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Muhamad Khurram Shehzad, Secretary, DQCB Jhelum and Mr. Shahid ul Hassan Drug Inspector, Tehsil Pind Dadan Khan, District Jhelum were present along with the original case record. No one among the nominated accused persons was present. Counsel of the firm Advocate Khawaja Tahir Mehmood appeared before the board on the behalf of M/s Medera Pharmaceuticals Pvt. Ltd. Plot no. 249/A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan. The representative of the firm reiterated the statements already furnished in the written reply of show cause by the firm. He further emphasized that the firm's Petition. No. Med-03-DIPDK- 01- /2021 Date 06 -10-2022 submitted for withdrawal of PQCB Order No. PQCB/P-1002-10/ 202I Dated 05-07-2022 should be addressed first.

6. The Board after careful scrutiny of the DTL report and record submitted by the firm observed that subject drug sample was declared of substandard quality on the basis of Dissolution Test. The Board after due deliberation and discussion unanimously decided to pend the case to present in next meeting after verification from the record.

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

Case is placed before the Board for decision.

Summary:

Manufacturing Date: 03-2021

Expiry Date: 05-2023

Sampling Date: 22-06-2021

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

Date of receipt in DTL: 30-06-2021

DTL Report Date: 26-10-2021

Time Extension: granted

1ST DI Communication with firm on dated: 19-11-2021

Date of Retesting Request of Firm: -26-11-2021

Fate of Retesting Request: -Turned down

Investigation Report Dated: 04-10-2022

CURRENT PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 31

PQCB SM-19-8-2022

Nishtar Town, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Nawabsons Laboratories Pvt Ltd Jia Bagga Off Raiwind Road, Lahore** through its Managing Director/ Chief Executive Officer/ Production Incharge Arjumand Akhtar. 2. Arjumand Akhtar S/O Akhtar Hussain Bhutta Managing Director/ Chief Executive Officer/ Production Incharge R/O 7-A, Friends Colony Multan Road Lahore. 3. Nadeem Akhtar Bhutta Quality Control Incharge R/O 7-B, Friends Colony Multan Road, Lahore. Of **M/S Nawabsons Laboratories Pvt Ltd Jia Bagga Off Raiwind Road, Lahore**

BRIEF FACTS OF THE CASE

Drug Inspector Nishtar Town, Lahore reported that: -

i. He, on 18-02-2021, inspected the business premises of M/S Nawabsons Laboratories Pvt Ltd Jia Bagga Off Raiwind Road, Lahore along with Mr. Hafiz Alam Sher (Deputy Drug Controller O/o CDC Punjab) & Mr. Kamran Habib (Naib Qasid O/o CEO (DHA), Lahore and recovered & seized 3 Following Articles on Form No. 5 from the custody of accused Arjumand Akhtar S/O Akhtar Hussain Bhutta (Managing Director) from the said premises. The detail of articles are as follow:

Sr No.	Name of Drugs	Batch No.	Mfg. By	Quantity	Reason of Seizure & Sealing
1	A transparent plastic jar containing grayish black lumpy material with powder without any label.	Nil	Nil	200gms	i. Stocking of raw material for manufacturing of drugs without any label and purchase record. ii. Raw material containers placed on floor. iii. Dirty and dusty Conditions of Raw material store. iv. Improper storage conditions.
2	White powder contained in a polythene bag without any label.	Nil	Nil	100gms	
3	Plastic Scoops of various sizes.	Nil	Nil	03 No.	i. Plastic Scoops being used for dispensing of raw material in violation of GMPs.

ii. The Raw material store situated at Ground Floor was locked and sealed on 18-02-2021 which was desealed in compliance of the Honourable Drug Court, Lahore orders Dated 25-02-2021 in desealing Application No. 67/2021.

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

a. **Stocking of raw material for manufacturing of drugs without any label and purchase record.**

b. **Plastic Scoops being used for dispensing of raw material in violation of GMPs.**

c. **Raw material containers placed on floor.**

d. **Dirty and dusty Conditions of Raw material store.**

e. **Improper storage conditions.**

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

Reply to Show Cause:

Pl. refer to your Show Cause Notice No. PQCB/SM-19-08-2022 dated 26-09-2022, received on 05-10-2022, in this regard our humble submissions are as under.

1. That Provincial Drug Inspector inspected /visited our manufacturing unit on 18-02-2021 and seized few articles on Form No. 5 under section 18 (1) (f) of Drugs Act 1976.

2. That Drug Inspector also sealed Raw Material Store situated at Ground Floor, which was de-sealed on 25-02-2021 in compliance of directions of Chairman Drug Court.

3. That Honourable Drug Court truly observed that we have fundamental right to run lawful business and it was truly observed and certified by Drug Inspector on de-sealing memo wherein he admitted that no further contraventions recorded/identified upon inspection. Section 18 (1) (s) of Drugs Act 1976 attracts in the proceedings which is reproduced as follows for reference of the Board. Section 18. Powers of Inspectors (1)

(a)

(b)

(c)

(e)

(f) Seize such drug and all material used in the manufacture thereof and any other articles, including registers, Cash memos, invoices and bills, which he has reason of believe may furnish evidence of the commission of an offence punishable under this act or any rule.

Provided that where the contravention is such which can be remedied, the stock shall not be seized upon undertaking in writing of the person not to sell drug without remedying the defect, under intimation to the Board concerned.

We have complied the provisions of Law and same is verified by concerned Drug Inspector on De-

sealing Memo.

Drug Inspector also sample for test and analysis on Form No. 4, which are declared as of

STANDARD QUALITY by Government analyst Drugs Testing Laboratory Lahore. Evidence enclosed.

4. That allegation regarding seized transparent plastic jar containing grayish black lumpy material with powder without any label is misconceive. Its identification was written with marker on it. Slip was pasted with clear description at the time of Inspection and we still stand by it that it is chocolate brown color duly purchased from Ali Hassan Group of companies copy of invoice.

We have challenged the same before Drug Inspector in writing & hereby again challenge the allegation that seized drug is not a drug and notify our intention to send the sample of the seized chocolate brown color to Drug Testing Laboratory for it's Analysis/identification. Sample should be prepared in our presence as required under law.

5. We are enclosing herewith the requisite documents and information for your perusal & record.

i. Attested copy of our drug Manufacturing License.

ii. Name of Production Incharge/CEO/M.D with CNIC copy.

Arjumand Akhtar Bhutta.

iii. Name of Quality Control Incharge / Director with CNIC copy.

Nadeem Akhtar Bhutta.

iv. What's App identification.

0331-4609648 & 0321-4756355

v. E-mail:

nawabsonslabs786@gmail.com

Under the circumstances it is most respectfully prayed to withdraw the Show Cause Notice under reply as we have remedied the defects if any u/s 18 (i) (f) of Drugs Act 1976 and Drug Inspector has on record verified it. Sample taken for Analysis purpose are declared of standard quality hence no offence committed by us, so requested to drop the proceedings in the interest of justice and fair play.

4. Personal Hearing notice(s) issued to accused person(s) on 19-12-2022.

PREVIOUS PROCEEDINGS OF THE CASE:

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. Dr. Shoaib Gurmani, CEO (DHA) Lahore (Member DQCB), and Mr. Hassan Haider Shah, Drug Inspector, Nishtar Town, Lahore were present along with original case record. No one among the nominated accused persons was present on behalf of **M/S Nawabsons**

Laboratories Pvt Ltd Jia Bagga Off Raiwind Road, Lahore. The Secretary PQCB apprised the board that the firm has submitted a written request for adjournment of the case.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case in best interest of justice. The Board further decided to provide another/ final opportunity of personal hearing to the accused persons.

Personal hearing notice(s) issued to accused person(s) on 20-04-2023.

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 32

PQCB/ R-732/2019

PSSHMC Hospital, Muzaffargarh

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s P.D.H Pharmaceuticals Pvt Ltd, 19-Km, Ferozpur Road, Lahore-Pakistan** through its Chief Executive Officer Gohar Elahi 2. Gohar Elahi Chief Executive Officer 3. Nadeem Ahmad Production Manager 4. Dur-e-Anjum Quality Control Manager/ Warrantor of M/s P.D.H Pharmaceuticals Pvt Ltd, 19-Km, Ferozpur Road, Lahore-Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs PSSHMC Hospital Muzaffargarh reported that:-

i. He, on 25-07-2019, inspected the premises of M/s PSSHMC Hospital Muzaffargarh and took following Drug samples on Form No. 04 for the purpose of test and analysis and sent it to Drugs testing Laboratory Multan.

ii. The 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>Chewable Tablet Calcium-P (Elemental Calcium 400mg, Vitamin-D: 5mcg)</td><td>906807</td><td>M/s P.D.H Pharmaceuticals Pvt Ltd, 19-Km, Ferozpur Road, Lahore-Pakistan</td><td>TRA No.01-56009072/DTL

dated:26-11-2019</td><td>
Analysis with specifications applied: BP-2019
<u>Description:</u>
White to off white color oblong shaped tablet scored on one side and line of bisection on the other side, in sealed amber glass bottle with white cap, packed in an outer carton.
<u>Identification:</u>
Calcium and Vitamin D3 identified.
<u>Assay:</u> Calcium
<table>
<tr><td>Stated</td><td>400mg/Tab</td></tr>
<tr><td>Determined</td><td>387.64mg/Tab</td></tr>
<tr><td>Percentage</td><td>96.91% (Complies)</td></tr>
<tr><td>Limit</td><td>85-115%</td></tr>
</table>
<u>Vitamin D3</u>
<table>
<tr><td>Stated</td><td>5mcg/Tab</td></tr>
<tr><td>Determined</td><td>0.65mcg/Tab</td></tr>
<tr><td>Percentage</td><td>13.23%</td></tr>
<tr><td>Limit</td><td>90-120%</td></tr>
</table>
(Does not Comply)
Weight variation:
<table>
<tr><td>Limit</td><td>NMT 2 Tablets should deviate from ±5%</td></tr>
<tr><td>Average weight</td><td>1205.11mg</td></tr>
</table>
(Complies)
<u>Result</u>: The above sample is <u>Sub-standard</u> on the basis of Assay of Vitamin D3.
Note: Extension has been granted via order no: PQCB/DTL-M/211/2019 Dated 30-09-2019 by PQCB..
</td></tr>
</table>

iii. Store keeper M/s PSSHMC Hospital Muzaffargarh provided invoice/ Warranty No. 2019-07-00032 dated 17-7-2019 issued by M/s P.D.H Pharmaceuticals Pvt Ltd, 19-Km, Ferozepur Road, Lahore-Pakistan as a proof of its purchase.

iv. A copy of test report and Warrantor portion was sent to M/s P.D.H Pharmaceuticals Pvt Ltd, 19-Km, Ferozepur Road, Lahore-Pakistan with directions to provide relevant information in this regard. and they were asked to provide the requisite information in this regard. 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.

v. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>NIH Test Report No. & Date</th><th>NIH Test Report Results</th></tr>
<tr><td>Calcium-P Tablets</td><td>906807</td><td>M/s P.D.H Pharmaceuticals Pvt Ltd, 19-Km, Ferozpur Road, Lahore-Pakistan</td><td>0213-P/2020

dated: 18-02-2021</td><td>
Analysis with specifications applied: Manufacturer specifications

<u>Description:</u>

White oblong shaped, chewable tablets having inscription with monogram of “PDH” on one side whereas plain from other side packed in labeled amber colored glass bottle further contained in an outer carton.

<u>Identification:</u> Calcium and Vitamin-D identified.

<u>Assay:</u>
<table>
<tr><td>Calcium carbonate Equivalent to elemental calcium</td><td>Stated</td><td>Found</td><td>Limit</td><td>Percentage</td></tr>
<tr><td></td><td>400mg/tab</td><td>269.33mg/tab</td><td>85-120%</td><td>67.33%</td></tr>
<tr><td>Vitamin D</td><td>5mcg/Tab</td><td>4.58mcg/Tab</td><td>80-120%</td><td>91.6%</td></tr>
</table>
Does not comply with Manufacturer specification.

<u>Result:</u> The sample is of <u>Substandard</u> quality on the basis of tests performed.
</td></tr>
</table>

vi. Copy of NIH Report was sent to M/s P.D.H Pharmaceuticals Pvt Ltd, 19-Km, Ferozpur Road, Lahore-Pakistan.

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) vide 07-03 -2022

Reply of the Show Cause Notice

1. M/S P.D.H Pharmaceuticals (Pvt) Ltd (hereafter referred as The Company) is one of the leading and trusted national companies, best known for its high-quality products, which is fully compliant with Drugs Act 1976 and rules framed there under. Its firm commitment to quality and adherence to high standards/ cGMP guidelines is the hallmark of The Company to meet the high expectations of the patients as well as Health care providers.

2. As far as the allegation of substandard nature of chewable Tab. CALCIUM-P bearing batch no. 906807 is concerned, the Batch Manufacturing Record prepared at the time of manufacturing by the Production department headed & operated with full independence & sole responsibility by the Production Incharge of The Company depicts that they got issued the raw material of Calcium in the required standard quantity for using in manufacturing and used the same quantity in production of the said batch. Copy of Manufacturing/Production Order & dispensing card is attached here with as ready reference (Attached as Annexure A).

3. While the quality Control department, headed and operated with full independence &sole responsibility by the Quality Control Incharge of The Company, tested all the required quality parameters of the said product during manufacturing and at the time of batch release of chewable Tab. CALCIUM-P bearing batch no. 906807 and found them satisfactory. Relying on these satisfactory reports, this batch was released to be sold. Copy of In Process Quality Control test results and Finished Product test results along with Certificate of Analysis is attached herewith as ready reference (Attached as Annexure B)

4. It is pertinent to mention here that upon the receipt of government analyst report DTL Multan vide report TRA No. 01-56009072/DTL dated 26-11-2019, the Quality Control department had tested/analysed the retained sample of the same batch of the product and found satisfactory results complying with the Specifications of all the tests performed. Copy of Certificate of Analysis of retained sample is attached herewith as ready reference. (Attached as Annexure C)

5. As the impugned NIH report is conclusive one u/s 22(5) of the Drugs Act 1976, therefore, without prejudice to and in addition to The Company's reply dated 17-12-2019 in respect of DTL Multan report, only The Impugned NIH report will be discussed here. As far as the alleged abnormalities/ contraventions pointed out in The Impugned NIH Report are concerned, they are most likely based on deviations from mandatory testing protocol and non-observance to mandatory provisions of Drugs Acts 1976 and rules framed there under by the Federal Government Analyst as follows:

i. The Federal Government Analyst has applied wrong specifications i.e. Manufacturer specifications for testing of this product. While this product has B.P specifications to be complied with after its incorporation in British Pharmacopoeia in 2011. It is pertinent to mention here that The Ministry of Health Government of Pakistan vide its notification No. F. 6-21/2007-Reg-l (South) dated Islamabad the 3nd October, 2007 has already issued directions to the Appellate Laboratory N.I.H Islamabad regarding Drug Specifications as follows:

"4. all the finished drugs having pharmacopoeia specifications shall be tested according to the specifications enlisted in the official compendia, even if the manufacturer fail to print the same on the label. 5. As far as non-pharmacopoeia products are concerned; Ministry of Health relies on the specifications submitted by the manufacturer and Drugs Registration Board has not been approving these specifications. These products shall be tested according to the manufacturer specifications submitted by them, til their inclusion into the official compendia".

Copy of Ministry of Health notification No F 6-21/2007-Reg-I1 (South) dated Islamabad the 3rd October, 2007 is attached here with as ready reference. (Attached as Annexure D)

ii. The product i.e. chewable Tab. CALCIUM-P bearing batch no. 906807 was registered in 2009 with Manufacturer (P.D.H) Specifications as then the product was not included in any official pharmacopoeia listed in the Section 3 of Drugs Act, 1976. But after the inclusion of the said drug in British Pharmacopoeia i.e. B.P in 2011, The Company adopted B.P specifications, as mentioned in label claim of the product, in compliance of the notification of The Ministry of Health, Government of Pakistan bearing No. F. 3-2/2006- Reg-II-South (M-197) Government of Pakistan (Ministry of Health) dated Islamabad 05th June, 2006 wherein The Ministry of Health had issued directions to All The Manufacturers as follows:

"All the firms shall adopt the specifications mentioned in the official pharmacopoeias for all the formulations except those drugs not included in the official pharmacopoeias. For these drugs manufacturers may adopt their own specifications till the inclusion of that formulation in the official pharmacopoeias. After this decision firms will not be allowed to adopt their own specifications for the drugs which are included in any of the official pharmacopoeias, listed in the Section 3 of Drugs Act 1976"

Copy of Ministry of Health notification No. E 3-2/2006-Reg-ll-South (M-197) Government of Pakistan (Ministry of Health) dated Islamabad 05th June, 2006 is attached here with as ready reference (Attached as Annexure E)

So, the federal government analyst applied manufacturer specifications for the purpose of test and analysis of the questioned drug not only in sheer violation of notifications of Ministry of Health but also Drugs (Specifications) rules 1978 despite the fact that label claim of the product was B.P Specifications.

iii. Furthermore, it is mandatory for Government analyst, who caused the testing/analysis of the sample to be performed and prepared DTL/NIH report, to meet the statutory requirement of section 16 of the Drugs Act 1976. But in the case in hand, no proof of qualifying such statutory requirement by Government Analyst has been provided with the Impugned NIH/DTL report or your show cause. So the impugned DTL/NIH report is illegal and without lawful authority which has no essence in the eye of law.

iv. The both reports i.e. DTL Multan report & NIH reports are totally conflicting i.e. at variance to each other which create serious doubts even on the sanctity of the impugned NIH report. The comparison of the assay of chewable Tablet Calcium-P batch no. 906807 by the two government analysts is as follows:

Therapeutically active ingredient	**Government Analyst DTL Multan results**	**Chief-Appellate Laboratory NIH, Islamabad**
Elemental Calcium	96.91% Limit 85%-115%	67.33% Limit 85-120%
Vitamin D	13.33% Limit 90%-120%	91.60% Limit 80%-120%

It is imperative to mention here that the grievance of The Company in respect of the DTL Multan report was only to the extent of the determination of 13.33% (Limit 90%-120%) Vitamin D which has been determined as 91.6% (Limit 80%-120%) by the appellate laboratory proving the product as standard quality in respect of challenged aspect.

iii. Even otherwise the federal government analyst while performing the test deviated from Manufacturer specification. According to Manufacturer Specifications, 0.1 M Zinc Chloride VS was to be used as titrant but federal government analyst used 0.1 M Zinc Sulphate as titrant rendering this test faulty & invalid even on the basis of manufacturer specifications. Copy of old method of analysis based on Manufacturer Specifications is attached here with as ready reference. (Attached as Annexure F)

6. On the other hand, the Drug inspector also committed sheer violations of mandatory provisions of Drugs Acts 1976 as follows:

i. Warrantor portion (if any) of the sample of the product taken on form # 4 was not provided by the Drug Inspector to the manufacturer till today in sheer violation of mandatory provision of section 19(3) (III) of Drug Act 1976. thus, violating the principle of NATURAL JUSTICE i-e; "WHEN A LAW REQUIRED A THING TO BE DONE IN A PARTICULAR MANNER, THEN IT MUST BE DONE IN THAT MANNER".

Reliance is based on

2018 PLD 189 SUPREME COURT

2018 PLD 97 SUPREME COURT

ii. Non-observance to said procedure by Drug Inspector makes the whole transaction not only illegal but also highly doubtful. So the case deserves to be dropped on account of this illegality committed by the Drug Inspector. Recently, PQCB has unanimously dropped a Case No. PQCB R-577-09 / 2016 related to Infusion Dorcip, Batch No. De-075 declared as Adulterated and Sub-Standard by Government Analyst, Drug Testing Laboratory, Rawalpindi vide DTL Report TRA. No. 1077/DTL Dated: 22-09-2016. PQCB had observed that this case was fit for prosecution on the basis of report. But, this case was DROPPED because warrantor portion was not sent to the manufacturer within statutory period as prescribed under Section 19 (3) of the Drug Act 1976.

7. So, based on above discussed procedural violation by Provincial Inspector of Drugs, mandatory protocol/compulsions and their deviances by Federal Government Analyst, The Impugned NIH Test Report has no substance and no legs to stand upon and should be rejected and deemed a nullity in essence and spirit. Therefore, the entire proceedings/actions based on this faulty and invalid The Impugned NIH Report are

void ab initio and are unlawful and this case deserves to be dropped.

8. It is also pertinent to mention here that without prejudice to the quality of the said batch of the product, The Company has already replaced the said stock vide invoice # 2021-01-00880 dated 04-01-2021 and the same has been declared of standard quality after testing on B.P specifications. Copy of invoice no. 2021-01-00880 dated 04-01-2021 along with its DTL report/form-7bearingserial no. 000046207 is attached herewith as ready reference. (Attached as Annexure G)

9. That PARA 2 of SCN alleges that

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

i. Manufacturing for sale/sale of Substandard drug

ii. ii. Issuance of false warranty

Comments/Explanation:

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

II. As far as allegation of issuance of false warranty is concerned, it is groundless and based upon misreading of relevant law. The warranty was issued after release of standard quality report by Quality Control Department of The Company which was good and sufficient reason available at the time of sale of the product and issuance of warranty for believing the product of standard quality. So, the offence of issuance of

false warranty has been added just to manipulate the scenario. Section 27(2)(b) is reproduced below:

27 (2) whoever himself or by any other person on his behalf (a) or

(b) gives to the purchaser a false warranty in respect of any drug sold by him that the drug does not in any way contravene the provisions of section 23 and is not able to prove that, when he gave the warranty, he had good and sufficient reason to believe the same to be true.

5. **That PARA 3 of SCN alleges that**

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

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

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

iii. Other suitable legal action [s] should not be taken against you.

Comments/Explanation

I. It is respectfully repeated / reiterated that impugned NIH report being conclusive one which forms basis of this SCN is itself illegal and non-conformity to section 16 of Drugs Act 1976, Drugs (Specifications) Rules 1978 and notifications of Ministry of Health, Government of Pakistan as discussed in detail in supra paragraphs.

II. The prosecution would be unlawful because it would be based upon illegal and invalid report which cannot be used as evidence in any criminal trial.

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

6. That PARA 4 of SCN alleges that

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

Comments/Explanation

I. For the names of accused persons, please see below mentioned reply of the SCN by Gohar Elahi, The Chief Executive Officer.

REPLY + EXPLANATION BY Gohar Elahi (Chief Executive officer):

- The legal system all over the globe including Pakistan recognizes "company" as a "Juristic person" with its own rights, capable of owning property, creating contracts, and conducting litigations with responsibility towards wrongdoings and profiting. A company being juristic person having no physical existence is run and managed by human beings / its board and same is the case with M/S P.D.H Pharmaceuticals (Pvt)

Ltd (The Company).

- Any company manufacturing pharmaceutical drugs under valid drug manufacturing license is liable for all legal acts and omissions of all the prevailing laws including the Drugs Act 1976 as stated in section 11 & 34 of the Drugs Act 1976 and Rule 5 of the Punjab Drug Rules 2007 reproduced below:

I. **34. OFFENCES BY COMPANIES**, etc.- Where the person guilty of an offence under this Act, 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.

II. **11.(5).(e)** to ascertain the names of such directors, partners and employees of the company, corporation, firm or institution who are prima facie responsible for the commission of any offence under this Act or the rules and allow an Inspector to institute prosecution only against such persons;

III. **Punjab Drugs Rules, 2007. 5**-Procedure for the Board.5.(4) Before referring a case to a Drug Court, the Provincial or the District Board shall ascertain the name of the director, partner and employee of the company, corporation, firm or institution who is prima facie responsible for the commission of the offence under the Act or the rules and may allow an inspector to institute prosecution against such person.

• Regulatory Compliance is the central and integral component of M/S P.D.H Pharmaceuticals (Pvt) Ltd (The Company). The functionaries of The Company have been given, by the Board of Directors, full autonomy / power based upon sole responsibility to ensure that all the regulatory requirements (strict compliance to Drugs Act

1976/DRAP Act 2012 and rules framed there under) are strictly fulfilled. For this purpose, in The Company as required under Drug (Licensing, Registration & Advertisement) Rules 1976, the production department and quality control department headed and operated by production incharge and quality control incharge respectively are fully independent and bound by law to exercise all powers and perform all actions required to ensure the strict compliance to all regulatory requirements including compliance to Drugs Act 1976/DRAP Act 2012 and rules framed there under. The approval / consent of the Board of Directors, Chief Executive or other Directors is not required at all to exercise such powers and perform actions by the production incharge and quality control incharge for the strict compliance to all regulatory requirements. Meaning thereby that the production incharge and quality control incharge take independent decisions without prior consent and knowledge of the Chief Executive officer, Directors and the Board of Directors.

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

1. Mr. Nadeem Ahamd Production Incharge

2. Miss Dur-e-Anjum Quality Control Incharge

3. Miss Dur-e-Anjum Warrantor

of M/S P.D.H Pharmaceuticals (Pvt) Ltd, 19-KM Ferozpur road, Lahore

• Since in this case, the Chief Executive officer has no nexus with the issues (allegations) under consideration in the said show cause as all routine manufacturing and quality control/assurance operations are done without his prior knowledge and consent. So, in the light of above, it is requested that name of Gohar Elahi, Chief Executive officer may please be deleted from the Show Cause Notice or any other legal proceedings

under the Drug Act 1976 or Rules framed there under in the best interest of justice.

Reliance:

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). Judgement by Muhammad Akram, Actg. C.J and G. Safdar Shah, J "---------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. -----But if the prosecution would be disposed to foist liability also then the burden would lie on it to show that the said offence had been committed within their knowledge and consent".

Please also note that Mr. Nadeem Ahmad Production Manager and Miss Dur-e-Anjum Quality Control Manager have left their jobs from M/S P.D.H Pharmaceuticals (Pvt) Ltd many years ago. So their SHOW CAUSE NOTICES be kindly considered as UNSERVED and are being sent back to along with this reply.

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

11. Please also find the relevant person's contact no.; Miss. Fatima Bajwa Manager Regulatory Affairs #0333-6429299. So, in the light of all aforesaid arguments you are requested to drop this case on account of faulty, invalid and illegal impugned NIH report, deviation by Government Analyst and criminal negligence on the part of the drug inspector in the supreme interest of justice.

4. Personal hearing notice(s) issued to accused person(s) 0n 24-06-2022

PREVIOUS PROCEEDINGS OF THE CASE:

PQCB's 246th meeting held on 05-07-2022:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **246th meeting held on 05-07-2022** under the Chairmanship of vice chairperson of Provincial Quality Control Board, Punjab in the presence of Board members as mentioned above. No one among the nominated accused appeared before the Board on the behalf of M/s P.D.H Pharmaceuticals Pvt Ltd, 19-Km, Ferozepur Road, Lahore-Pakistan. Secretary PQCB apprised the Board that written request for adjournment has been received from the Manager Regulatory Affairs of firm stated that whole technical staff nominated in the said personal hearing notice had left their job long ago and CEO of the firm is also ill. Further the firm have to engage a counsel for proper pleading of this case before the learned Board which is not possible due to paucity of time. It is therefore humbly prayed that said case may kindly be adjourned for the next date of hearing.

6. The Board after discussion decided to **adjourn the case on the request** of the firm. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

7. Personal hearing notice(s) issued to accused person(s) on 09-01-2023.

PQCB's 256th meeting held on 19-01-2023:

8. The 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. Abdul Latif, Secretary DQCB, District Muzaffargarh and Mr. Wajid Nawaz, Drug Inspector, PSSHMC Hospital, Muzaffargarh, was present along with the original case record. No among the nominated accused of M/s P.D.H Pharmaceuticals Pvt Ltd, 19-Km, Ferozpur Road, Lahore-Pakistan was present, however, Counsel Person of the firm Advocate Dr. Imran. Mehmood Ch. and Dr. Samia Akram (Manager Regulatory Affairs) appeared before the board to represent the firm. The representatives of the firm pleaded that no personal hearing was received by the firm regarding this particular case and they are not prepared to defend themselves in this case as they have come for another case of M/s P.D.H Pharmaceuticals on agenda of this meeting. They requested the board to have a lenient view and adjourn the case for next meeting.

9. Keeping in view the facts of the case, 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 person.

Personal hearing notice(s) issued to accused person(s) on 20-04-2023.

Case is placed before the Board for Decision.

Summary of the case:

- **Mfg. date:06-2019**
- **Exp. Date: 05-2021**
- **Sampling date (Form 4): 25-07-2019**
- **Sent to DTL (Form 6): 25-07-2019**
- **Date of receipt in DTL: 29-07-2019**
- **DTL Report Date (Form 7): 26-11-2019**
- **DI 1st intimation to firm: 08-06-2021**
- **Retesting request if any: Yes, allowed in 14th Committee Meeting**
- **Fate of retesting: NIH Substandard**
- **Investigation report Dated: 22-12-2021**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 33

PQCB/R-64/2021

Bahawalpur Saddar

Misbranded & Sub-Standard (Assay Test

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Rakaposhi Pharmaceutical (Pvt) Ltd 97km Industrial Estate Hayatabad Peshawar** through its Chief Executive Officer Jahanzeb. 2. Jahanzeb — Chief Executive Officer 3. Abdul Aziz — Production Manager/ Warrantor 4. Gohar Shah — Quality Control Manager/Warrantor of **M/s Rakaposhi Pharmaceutical (Pvt) Ltd 97km Industrial Estate Hayatabad Peshawar.** 5. Abdul Rasheed S/O Nazar Muhammad — Proprietor 1 6. Muhammad Altaf S/O Nazar Muhammad — Proprietor 2 of **M/s Al-Shifa Medical Store Situated at Jhangi Wala Road Near Pulli Nawab Pura Bahawalpur Saddar.**

BRIEF FACTS OF THE CASE

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

i. He, on 03-03-2021, inspected the business premises of M/s Al-Shifa Medical Store Situated at Jhangi Wala Road Near Pulli Nawab Pura Bahawalpur and took samples of two different types of drug samples on Form No.04 for the purpose of test/analysis.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Powder for Reconstitution, Ricxime [Cefixime as Trihydrate:100mg/5ml]	AD-099	M/s Rakaposhi Pharmaceutical (Pvt) Ltd 97km Industrial Estate Hayatabad Peshawar	01-77003416/DTL Dated. 06-05-2021	**Analysis with specifications applied:** USP 2020. **Composition:** Each 5ml (1Teaspoonful) contains: Cefixime as trihydrate (USP)……100mg on reconstitution **Description: Light yellow to yellowish brown powde sealed amber colored plastic bottle. Upone reconstitut light yellow to yellowish brown suspension is formed. (st volume:30ml) the label of the product does not bear name of pharmacopoeia or document according to which product is manufactured. (The product is misbranded)** **PH:** **Limit: 2.5-4.5** **Determined: 3.885** **Identification (USP)** Cefixime is identified. **Assay:** **Cefixime:** **Stated: 100mg/5ml** **Determined: 23.44mg/5mll** **Percentage: 23.44%** **Limit: 90.0-120.0%** **Does not comply.** **Result:** The sample is **declared Substandard** on the basis of Assay and **Misbranded** as defined under clause (vi) of subsectio of section 3 of Drugs Act 1976.

iii. M/s Al-Shifa Medical Store Situated at Jhangi Wala Road Near Pulli Nawab Pura Bahawalpur provided Invoice/warranty No SDB-0040204 dated 17-12-2020 issued by M/S Millat Pharma Street No. 4, Fahad Colony, Bahawalpur who in turn provided invoice/warranty No. 23033, dated 20-08-2020 issued by M/s Rakaposhi Pharmaceutical (Pvt) Ltd 97km Industrial Estate Hayatabad Peshawar as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Millat Pharma Street No. 4, Fahad Colony, Bahawalpur and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/s Rakaposhi Pharmaceutical (Pvt) Ltd 97km Industrial Estate Hayatabad Peshawar 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: -

Accused	Offences
1. **M/s Rakaposhi Pharmaceutical (Pvt) Ltd 97km Industrial Estate Hayatabad Peshawar** through its Chief Executive Officer Jahanzeb. 2. Jahanzeb Chief Executive Officer 3. Abdul Aziz Production Manager/ Warrantor 4. Gohar Shah Quality Control Manager/Warrantor of **M/s Rakaposhi Pharmaceutical (Pvt) Ltd 97km Industrial Estate Hayatabad Peshawar.**	1. Manufacture for Sale /Stocking for sale/ Selling of Substandard & Misbranded Drug. 2. Issuance of false warranty
7. Abdul Rasheed S/O Nazar Muhammad Proprietor 1 8. Muhammad Altaf S/O Nazar Muhammad Proprietor 2 of **M/s Al-Shifa Medical Store Situated at Jhangi Wala Road Near Pulli Nawab Pura Bahawalpur Saddar.**	1. Selling & Stocking for Sale of Drugs without qualified person.

3. Show-cause issued to accused person(s) vide dated 01.07.2021

Reply of Show Cause Notice By Firm:

It is with reference to your letter No. PQCB/R-64/2021 dated 01/07/2021 received in this office on dated 08-07-2021 and wherein it has been mentioned that the product Suspension Ricxime 30 ml B. No. AD-099 has been declared sub-standard as well as misbranded vide Government Analyst report No.TRA01-77003416/DTL dated 06-05-2021 by DTL Bahawalpur. It is assumed that the government analyst error is calculating the assay results of the product because as per our records all tests result lies within the prescribed/claimed limits of specifications. The non-printing of Pharmacopoeial reference on the label and carton is not intentional but has inadvertently been remained unprinted, as corrective and preventive measures, the printing of which is now done on both, carton as well as on label.

We have been granted registration of the product Ricxime suspension by the authorities concerned on dated 4th October, 2017 and since then we are manufacturing this product. We are regularly conducting the stabilities studies of all our registered products including this one as per our prescribed schedule and our stability studies shows that the said product in question is stable. Similarly, we have tested the retention samples of Ricxime Dry Suspension B. No. AD-099 and found it of standard quality (Stability data is attached for your kind perusal). However, there is a possibility that the product might be exposed to somewhere uneven environmental conditions in the distribution ware house, where neither no check was made for temperature, RH%, nor any record held by inspector concerned.

On the directions of the worthy Drug inspector Bahawalpur vide letter No. 46/511-12/DDC,BWP (Sadaer) dated Bahawalpur 01/06/2021 ,we have recalled the product from the market. Moreover, since there was no stock of Ricxime Dry Suspension batch No. AD-099 available in the factory therefore stopping of its further sale was out of question. We have received 27 bottles from distributor in Faisalabad The Bright Pharma Faisalabad.

Reply of Show Cause Notice By Firm:

Para 02 of this letter stated as: 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:-

a) Selling & Stocking for sale of drugs without Qualified Person

Sir, with due respect, it is humbly informed you that I was unfortunately absent during the

routine visit of respective drug inspector. As you know there is panic of pandemic of COVID-19, I had already been suffering Fibro Carcinoma and have low immunity as well (Old Age), I was not feeling well and decided to stay at home.

It is modestly requested to you to consider my legal reason behind this contravention and I pledge not to repeat this offense in future and acquit me from this charge.

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

Summary:

Manufacturing Date:03.2020

Expiry Date: 03.2022

Sampling Date (Form 4): 03.03.2021

Sent to DTL (Form 6): 04.03.2021

Date of receipt in DTL: 04.03.2021

DTL Report Date (Form 7): 06.05.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 01.06.2021

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated:22.06.2021

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 34

PQCB/R-309/2021

Bahawalpur Saddar

Misbranded & Sub-Standard (Physical Test

ATTENDENCE

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

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

i. His Predecessor, on 27-01-2021, inspected the business premises of M/S New Bismillah Medical Store Situated at Samma Satta Road Khanqa Shareef and took samples of three different type of drugs on Form No. 04 for the purpose of test and analysis and sent them to Drug Testing Laboratory, Bahawalpur.

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

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

iii. M/S New Bismillah Medical Store Situated at Samma Satta Road Khanqa Shareef provided invoice/ Warranty No. 18378, Dated. 06-06-2020 & 13683 Dated 22-02-2020 issued by M/S Ikhlaq Medicine Company House No. 203-B Muhammadia Colony Bahawalpur who in turn provided invoice/warranty No. 4835, Dated. 01-01-2020 issued by M/S Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township Kohat Road Bannu as a proof of its purchase.

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

v. A copy of test/analysis report was sent to M/S Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township Kohat Road Bannu and they were asked to provide the requisite information in this regard. In response the firm challenged the Drug Testing Laboratory report and the office of Provincial Quality Control Board place the said retesting request in the 18th Committee Meeting of PQCB dated 13.09.2021 and the Committee of PQCB after unanimous decision decided to turn down the said retesting request.

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

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

   b. **Issuance of false warranty**

4. Showcause was issued to accused person(s) vide dated 07.03.2022

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

Summary:

Manufacturing Date: 10.2019

Expiry Date: 10.2021

Sampling Date (Form 4): 07.01.2021

Sent to DTL (Form 6): 03.02.2021

Date of receipt in DTL: 03.02.2021

DTL Report Date (Form 7): 03.04.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 27.07.2021

Date of Retesting Request of Firm: 05.05.2021

Fate of Retesting Request: Turn Down (Particulate Matter)

Investigation Report Dated: 04.01.2022

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 35

PQCB R-580/2020

Tehsil and District Layyah

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Trison Research Laboratories Pvt Ltd. Plant: 27-A, P.S.I.E Sargodha** through its Chief Executive Mubasher Javed 2. Mubasher Javed Chief Executive/Warrantor/Production Manager 3. Fatima Tahir W/O Tahir Haseeb Quality Control Incharge of M/s Trison Research Laboratories Pvt Ltd. Plant: 27-A, P.S.I.E Sargodha

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs Layyah reported that: -

i. His predecessor, on 16-1-2020, inspected the business premises of M/s Khan Medicine Company Opposite police station city Layyah and took four 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. 56245 dated: 16-01-2020, 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>Capsule TRIX (Piroxicam 20mg)

Mfg. date: Sep-2019

Exp. Date: Sep-2021

Reg.# 063308</td><td>35038</td><td>M/s Trison Research Laboratories Pvt Ltd. Plant: 27-A, P.S.I.E Sargodha</td><td>01-57000391/DTL

Dated 16-3-2020</td><td>
Analysis with specifications applied: BP 2018

<u>Description</u>:

<u>Stated:</u> White to off white colored homogenous powder filled in red colored shells.

<u>Determined:</u> yellow to light yellow color homogeneous powder filled in shells consisting of red color body and cap packed in ALU-PVC blister of 10 units with a labelled outer carton

(Does not comply)

Blister of the product states “Trison specification” as a finished Drug Product Specifications while the outer carton states “BP Specifications” Which is false claim. (Misbranded, does not Comply)

<u>Weight variation:</u>
<table>
<tr><td>Average weight</td><td>211.61mg</td></tr>
<tr><td>Limits</td><td><u>+</u>10% (NMT 2 Capsules)</td></tr>
</table>
Comply

<u>Dissolution Test:</u>

Does not comply with the specifications as described below:

Tolerance Limit: NLT 80% (Q) where Q is 75% of the labeled amount of Piroxicam.
<table>
<tr><th>Level</th><th>Units</th><th colspan="6">% Release (Each individual unit NLT 80%)</th><th colspan="2">Remarks</th></tr>
<tr><td>S1</td><td rowspan="3">6</td><td colspan="6" rowspan="2"></td><td rowspan="3">Does not comply</td><td rowspan="3">The product does not comply at S1.</td></tr>
<tr><td>Determined</td></tr>
<tr><td></td><td>U#1</td><td>U#2</td><td>U#3</td><td>U#4</td><td>U#5</td><td>U#6</td></tr>
<tr><td></td><td></td><td>41.97</td><td>40.95</td><td>43.50</td><td>44.40</td><td>44.02</td><td>42.48</td><td></td><td></td></tr>
</table>
As criteria of S2 i.e no unit is <Q-15% and S3 i.e NMT 2 Units are <Q-15% and no unit is <Q-25% met on S1 Stage therefore the sample was not proceeded to next stages.

The Quantity Q, is specified amount of dissolved active substance, expressed as percentage on the label claim.

<u>Assay (Piroxicam)</u>:
<table>
<tr><td>Stated</td><td>20mg/Capsule</td></tr>
<tr><td>Determined</td><td>20.85 mg/Capsule</td></tr>
<tr><td>Percentage</td><td>104.26%</td></tr>
<tr><td>Limit</td><td>95-105%</td></tr>
</table>
<u>Result:</u> The above sample is Substandard and Misbranded on the basis of tests performed.
</td></tr>
</table>

iii. M/s Khan Medicine Company Layyah provided invoice/ warranty No. 1320 dated 12-12-2019 issued by M/s Liaqat Traders Medicine Market Ghanta Ghar Multan who in turn provided invoice/warranty No. 847 Dated 23-09-2019 issued by M/s Trison Research Laboratories Pvt Ltd Plant 27-A, P.S.I.E Sargodha as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Liaqat Traders Medicine Market Ghanta Ghar Multan and they were asked to provide requisite information in this regard

v. A copy of test/analysis report was sent to by M/s Trison Research Laboratories Pvt Ltd Plant 27-A, P.S.I.E Sargodha and they were asked to provide the requisite information in this regard.

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

vii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>NIH Test Report No. & Date</th><th>NIH Test Report Results</th></tr>
<tr><td>TRIX Capsules 20mg</td><td>35038</td><td>M/s Trison Research Laboratories Pvt Ltd. Plant: 27-A, P.S.I.E Sargodha</td><td>0203-P/2020
dated: 15-02-2021</td><td>
Analysis with specifications applied: B.P-2017
<u>Description:</u>
Yellow colored granular powder contained In red colored soft gelatin capsules shells packed in blister packing further contained in an outer carton.
<u>Identification:</u> Piroxicam identified.
<u>Weight Variation:</u>
Complies with B.P-2017.
<u>Dissolution:</u>
<table>
<tr><td>Determined</td><td>58.52%</td></tr>
<tr><td>Limit</td><td>Not less than 75% of the label amount</td></tr>
</table>
Does not comply with B.P-2017
<u>Assay:</u>
<table>
<tr><td rowspan="2">Piroxicam</td><td>Stated</td><td>Found</td><td>Limit</td><td>Percentage</td></tr>
<tr><td>20mg/Capsule</td><td>20.372mg/Capsule</td><td>95-105%</td><td>101.860%</td></tr>
</table>
Complies with B.P-2017.
<u>Result:</u> The sample is of <u>Substandard</u> quality on the basis of tests performed.
</td></tr>
</table>

viii. Copy of NIH report was sent to M/s Trison Research Laboratories Pvt Ltd. Plant: 27-A, P.S.I.E Sargodha.

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 Substandard and Misbranded Drug.**

b. **Issuance of false warranty**

3. Revised Show cause notice(s) issued to the accused vide 28-06-2021.

Reply of the Firm:

Refer to your letter No. PQCB/R-580/2020 received by us on 02-07-2022 regarding the subject cited above. (Copy enclosed)

We, hereby verifying the names of the Prima Facie involved in the manufacturing of the said drug as per your direction. Names are as follows:

- Mubasher Javed (CEO/Production Manager/Warrantor)
  Address: House # 31/1 Al Noor Town, Walton road Post Office, Tehsil Lahore Cantt., District Lahore.
- Fatima Tahir W/O Tahir Haseeb (Quality Control Manager)
  Address: Street # 1 Shadab Town Sargodha.

4. Personnel Hearing notice(s) issued to accused person(s) 06-07-2022.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 247th meeting held on 21-07-2022:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **247th meeting held on 21-07-2022** under the Chairmanship of vice chairperson of Provincial Quality Control Board, Punjab in the presence of Board members as mentioned. Mr. M Aamir Shakeel Secretary DQCB District Layyah and Mr Qalandar Khan Drug Inspector Tehsil Layyah were present. No one among the nominated accused were present however, Irfan (Director) appeared before the Board on the behalf of M/s Trison Research Laboratories Pvt Ltd. Plant: 27-A, P.S.I.E Sargodha. Representative of the firm stated that we have improved our specifications and recent batches of said product declared of standard quality from Drugs Testing Laboratory Bahawalpur. He submitted that problem may arise due to insolubility of capsule shells but now the source of capsule shells has changed. He admitted that issue regarding dissolution is also observed in retention samples. He added that Fatima Tahir W/O Tahir Haseeb was Quality Control Manager at the time of manufacturing of said batch.

6. The Board after detailed scrutiny of the record, due deliberation & discussion directed M/s Trison Research Laboratories to submit the appointment letter of Fatima Tahir W/O Tahir Haseeb (Quality Control Manager) and ascertain the name of Quality Control Manager who was involved in the manufacturing of said Batch. The Board further directed concerned Drugs inspector to **Reinvestigate the Case** in the light of information provided by the representative of firm.

7. Revised Show cause notice(s) issued to the accused on 20-01-2023.

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

Case is placed before the Board for Decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 36

PQCB/R-246/2021

Tehsil Khiarpur Tamewali & District Bahawalpur

Misbranded & Sub-Standard (Assay and Physical Description

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan** through its Managing Director Farhat Qadeer Dar. 2. Farhat Qadeer Dar — Managing Director 3. Liaqat Ali — Production Manager 4. Tanveer Ali — Quality Control Manager 5. Muhammad Amjad — Warrantor 6. Tasaddaq Riaz — Marketing Incharge of **M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He, on 30-12-2020, inspected the business premises of M/S United Medical Store, Aleemia Bazar Main Bahawalpur Road, Tehsil Khairpur Tamewali, District Bahawalpur and took four different types of drug samples on Form No. 04 for the purpose of test and analysis.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Suspension. Unidol [Paracetamol 120mg/5ml, 60ml Paediatric Suspension]	UD014	M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan	01-77002917/DTL Dated. 27-02-2021	**Analysis with specifications applied: USP 2020.** **Composition:** Each 5ml Contains: Paracetamol BP 120mg **Description:** Pink Color suspension containing **sedimental visible crystals which are not dispersed on shaking. (Observed upon Physical Inspection). (Does not comply with specifications).** **The label of the product does not bear the name of Pharmacopoeia or document according to which product is manufactured. (The product is misbranded).** **PH (USP):** **Limit 4.0-6.9** **Determined 5.470** **Identification (USP):** Paracetamol is identified. **Assay:** **Paracetamol:** Stated 120mg/5ml **Determined 87.30mg/5ml** **Percentage 72.75%** Limit 90.0-110.0% **(Does not comply with specifications) Result:** The sample is declared **Substandard**, on the basis of **Assay and Physical Description** test and **Misbranded** as defined under clause (vi) of Subsection (s) of section 3 of the Drugs Act 1976.

iii. M/S United Medical Store, Aleemia Bazar Main Bahawalpur Road, Tehsil Khairpur Tamewali, District Bahawalpur provided Invoice/warranty No R 202188 dated 30-10-2020 issued by M/S UK Pharma, House No. 93/11, Bahawal Colony, Bahawalpur who in turn provided invoice/warranty No. 672, dated 05-10-2020 issued by M/S Falkan Traders, Bilal Chowk,Samnabad, Faisalabad who in turn provided invoice/warranty No. 4624, Dated. 24-09-2020 issued by M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S UK Pharma, House No. 93/11, Bahawal Colony, Bahawalpur.

v. A copy of test/analysis report was sent to M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan and they were asked to provide the requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Showcause was issued to accused person(s) vide dated 17-12-2021

Reply of Show Cause Notice:

M/S Unipharma stated that:

a. Product specifications are mentioned along with composition of product. But we will further elaborate it as per rule.
b. We will recall unidol Susp Batch No. UD-014 as early as possible to avoid any hazardous effects to patients and further improve the quality of product reviewing its manufacturing method and other parameters regarding raw material and formulation with process validations and will forward after complete stability studies.
c. Our company fully appreciate Government efforts to ensure quality of drugs and look forward to receive guidance to further improve the standard of our drugs.

4. Personnel Hearing notice(s) issued to accused person 12.09.2022

Case was placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its **250th** meeting held on **22-09-2022** under the chairmanship of Secretary Primary & Secondary Healthcare Department, Punjab. Mr. Attiq-ur-Rehman Secretary DQCB District Bahawalpur and Mr. Muhammad Ahmad Mehmood Drug Inspector Tehsil Khairpur Tamewali were present along with original record of the case. Drug Inspector Drug Inspector Tehsil Khairpur Tamewali briefed the Board about facts of the case and asked for permission for prosecution against the accused persons. No one among the nominated accused appeared before the Board on the behalf of **M/S Unipharma (Pvt) Ltd, 4.5km Manga Raiwind Road, Lahore, Pakistan.**

7. The Board after discussion decided to **adjourn** the case due to non-appearance of accused persons in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

8. Personnel Hearing notice(s) issued to accused person(s) dated 20-04-2023.

Case is placed before the Board for Decision

Summary:

Manufacturing Date: 09-2020

Expiry Date: 08-2022

Sampling Date (Form 4): 30.12.2020

Sent to DTL (Form 6): 01.01.2021

Date of receipt in DTL: 01.01.2021

DTL Report Date (Form 7): 27.02.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 21.04.2021

Date of Retesting Request of Firm: N/A

Fate of Retesting Request: N/A

Investigation Report Dated:18.11.2021

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 37

PQCB R-587/2021

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.

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 258th meeting held on 05-04-2023

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th Meeting** held on **05-04-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Adil Jameel Awan, Secretary DQCB, District Rajanpur joined the meeting through zoom link. Mr. Kaleem Bhutta, Drug Inspector Tehsil Jmapur, District Rajanpur, was present along with the original case record. Muhammad Adnan Tahir (Quality Control Manager) among the nominated accused of **M/S Venus Pharma, 23-km, Multan Road, Lahore, Pakistan** was present.

6. The case was left-over due to time constraint.

7. Personal Hearing notice(s) issued to accused person(s) on 20-04-2023.

PQCB's 259th meeting held on 18-04-2023

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **259th Meeting held on 18-04-2023** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice Chairperson, PQCB). Mr. Adil Jameel Awan, Secretary DQCB, District Rajanpur joined the meeting through zoom link. Mr. Kaleem Bhutta, Drug Inspector Tehsil Jampur, District Rajanpur, was present along with the original case record. No one among the nominated accused of M/S Venus Pharma, 23-Km. Multan Road, Lahore, Pakistan was present.

9. Secretary PQCB apprised the Board that the firm has submitted a written request for adjournment of the case. Keeping in view the facts of the case and adjournment request 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/ final opportunity of personal hearing to the accused person.

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

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. 38

DISTRICT DERA GHAZI KHAN

PQCB/R-310/2022

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

ATTENDANCE:

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

BRIEF FACTS OF THE CASE

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

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

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

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

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

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

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

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

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

b. **Issuance of false warranty**

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

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

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

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

5. Case is placed before the Board for Decision

Summary:

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

PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 39

DISTRICT DERA GHAZI KHAN

PQCB/R-311/2022

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

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Z-Jans Pharmaceuticals (Pvt.) Ltd. 148-A, Industrial Estate, Hayatabad, Peshawar Pakistan** through its Chief Executive Officer/ Managing Director Zahid Khan 2. Zahid Khan — Chief Executive Officer/ Managing Director 3. Hashim Khan — Quality Assurance Manager 4. Falak Naz — Quality Control Incharge 5. Muhammad Rafiq — Production Incharge 6. Waqar Ahmad — Warrantor Of **M/s Z-Jans Pharmaceuticals (Pvt.) Ltd. 148-A, Industrial Estate, Hayatabad, Peshawar Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He, on 15-02-2022, inspected the business premises of M/s Waheed Pharmacy Block No. 13 Railway road Dera Ghazi Khan and took sample of six different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum No. 0000118669 dated 16-02-2022.

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

iii. M/s Waheed Pharmacy Block No. 13 Railway road Dera Ghazi Khan submitted Invoice/warranty No. 96498 dated 01-12-2021 issued by M/s Liaqat Traders Medicine Market Ghanta Ghar Multan as a proof of its purchase of the said drug.

iv. Warrantor Portion of the drug sample was sent to M/s Liaqat Traders Medicine Market Ghanta Ghar Multan who in turn provided invoice/ warranty no.125-1121-01 dated 15-11-2021 issued by M/s Z-Jans Pharmaceuticals (Pvt.) Ltd. 148-A, Industrial Estate, Hayatabad, Peshawar Pakistan as a proof of its purchase of the said drug.

v. A copy of test report was sent to M/s Z-Jans Pharmaceuticals (Pvt.) Ltd. 148-A, Industrial Estate, Hayatabad, Peshawar Pakistan and they were asked to provide requisite information in this regard.

vi. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its 253rd meeting held on 29-11-2022, after due deliberation and discussion unanimously decided to **Turn Down** the subject request for retesting and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

<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>Albenza (Albendazole 100 mg/5 ml) Suspension 10 ml.
Mfg.date:
Mar-2021
Exp. date:
Mar-2024
Regn No.
043730</td>
<td>S-0218</td>
<td>M/s Z-Jans Pharmaceuticals (Pvt.) Ltd. 148-A, Industrial Estate, Hayatabad, Peshawar Pakistan</td>
<td>TRA No. 01-94002256/DTL
Dated:-15-06-2022</td>
<td><u>Result of Test/ Analysis with specifications applied:</u> MS
<u>Description</u>: Off-white to cream color 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 Specification on the label of immediate container as well as on outer unit carton. But in U.S.P, 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:</u> Albendazole
<table>
<tr><td>Stated</td><td>Determined</td><td>Percentage</td><td>Limit</td></tr>
<tr><td>100 mg/5 ml</td><td>92.30 mg/5 ml</td><td>92.30%</td><td>90-110%</td></tr>
</table>
(Complies)
<u>PH</u>:
Range: 4.5-5.5
Determined: 4.103 at 25^{o}C (Does not Comply)
<u>RESULT:</u> The above sample is <u>Mis-Branded</u>, as defined under section 3(s) (iv) of the Drugs Act, 1976 and is <u>Substandard</u> on the basis of PH test.</td>
</tr>
</table>

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

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

b. **Issuance of false warranty**

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

<u>Reply of the firm to Show cause notice vide letter no. nil dated nil:</u>

With due respect it is stated that we again check our product namely SUSP Albenza B.Nos-0218 and found it of standard quality on both physical and analytical basis. As we have submitted all the evidences to the honorable Board before the product in question is of manufacturer Specs, as mention in our testing SOP submitted to you earlier the PH limit is 3.5-4.5 according to which our product PH lies in limit. The finished product specs is already been changes to Manufacturer Specs from USP. Outer carton is hereby attached for information. We hereby endorse the qualified staff.

Sp you are therefore requested to please handle the case humbly.

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

Case is placed before the Board for Decision

<u>Summary:</u>

- **Manufacturing Date: 03-2021**
- **Expiry Date: 03-2024**
- **Sampling Date (Form 4): 15-02-2022**
- **Sent to DTL (Form 6): 16-02-2022**
- **Date of receipt in DTL: 21-02-2022**
- **DTL Report Date (Form 7): 15-06-2022**
- **Time Extension: Granted in 243rd meeting dated 12-05-2022**
- **1ST DI Communication with firm on dated: 01-07-2022**
- **Date of Retesting Request of Firm: 05-07-2022**
- **Fate of Retesting: Turned down in 253rd meeting dated 29-11-2022**
- **Investigation Report Dated: 07-01-2023**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD: