Health & Population Department
PROVINCIAL QUALITY CONTROL BOARD, PUNJAB.

274 Meeting of PQCB

Date: 21-12-2023

Time: 11:00 AM

Venue

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

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ITEM No. 1

REGULAR CASES

Case No. 1

PQCB/R-116/2022

Tehsil Arifwala, District Pakpattan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s The Searle Company Limited, 32km Multan Road Lahore, Pakistan,** through its Director Ejaz Ahmad. 2. Ejaz Ahmad — Director 3. Anees Ejaz — Production Head 4. Saima Muzaffar — Head of Quality Control/Warrantor of M/s The Searle Company Limited, 32km Multan Road Lahore, Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Arifwala, District Pakpattan reported that: -

i. His predecessor, on 11-03-2022 inspected the business premises of M/s Dua Medical Store, shop no. 1, Bahawalnagar Road Near Go Petroleum Services, Qaboola, Tehsil Arifwala, District Pakpattan and took drug sample on Form No. 4 for the purpose of test/analysis vide memo no. 121126 dated 12-03-2022.
ii. The subject drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Tablet. Nuberol Forte [Paracetamol:650mg Orphenadrine Citrate: 50MG] **Mfg**. Date: 08-2021 **Exp**. Date: 08-2024 **Regn**. No: 027196	C0570	M/S THE SEARLE COMPANY LIMITED., 32-KM, MULTAN ROAD, LAHORE-PAKISTAN.	01-85001559/DTL 19-04-2022	**Results of test/analysis with Specifications applied: MS** **COMPOSITION**: Each tablet contains: Paracetamol BP 650mg and Orphenadrine Citrate BP 50mg DESCRIPTION: White to off-white colored, elongated biconvex tablet, having break line on one side and "SEARLE" engraved on other side. Packed in blister pack of 5 tablets , enclosed in outer carton **WEIGHT VARIATION (MS)** ***Limit:*** Average weight ± 5%. (Not more than 02 tablets sample should deviate from the average weight by more than ± 5%. None should deviate

				through ± 10%). **(THE SAMPLE DOES NOT COMPLY THE APPLIED SPECS)** ***Determined Average Weight:*** 785.27mg ***Minimum Deviation:*** 89.42% ***Minimum Deviation:*** 107.57% ***Determined:*** 02 out of 20 units are out of average weight ± 10% and 05 out of 20 units are out of average weight ± 5%. **IDENTIFICATION (MS):** Paracetamol and Orphenadrine Citrate are identified. **ASSAY (MS)** **Stated** **Determined** **Percentage** Paracetamol 650mg/Tab 680.29mg/Tab 104.66% Orphenadrine Citrate 50mg/Tab 53.40mg/Tab 106.80% **LIMIT**: 90.0-110.0% **RESULT**: The sample is declared **SUB-STANDARD** on the basis of **PHYSICAL TEST I.E., WEIGHT VARIATION TEST**.

****

S. No.	1	2	3	4	5	6	7	8	9	10
Weight (mg)	840.1	785.6	812.5	788.6	827.4	814.6	844.7	707.0	762.4	803.4
S. No.	11	12	13	14	15	16	17	18	19	20
Weight (mg)	808.1	707.3	808.4	794.6	790.6	702.2	783.7	824.5	705.6	794.1

iii. M/s Dua Medical Store, shop no. 1, Bahawalnagar Road Near Go Petroleum Services, Qaboola, Tehsil Arifwala provided invoice/ Warranty No. 8300474826 dated 17-02-2022 issued by M/s IBL Operations Pvt Ltd., Lalazar Colony Street no. 2Near Punjab Cadet School, Pakpattan as proof of their purchase.

iv. Warrantor Portion was sent to M/s IBL Operations Pvt Ltd., lalazar Colony Street no. 2Near Punjab Cadet School, Pakpattan.

v. M/s IBL Operations Pvt Ltd., lalazar Colony Street no. 2 Near Punjab Cadet School, Pakpattan provided Warranty/Delivery challan No. 4901890394 dated 31-01-2022 from

Multan Hub to Pakpattan sell, Warranty/Delivery challan No. 4901689499 dated 18-01-2022

from Sovereign Hub to Multan Hub and also provided 1012062044 dated 28-08-2021 issued by M/s The Searle Company Limited, 32km Multan Road Lahore, Pakistan.

vi. A copy of Test/ Analysis report was sent to M/s The Searle Company Limited, 32km Multan Road Lahore- Pakistan and they were directed to provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its 248th meeting held on 04-08-2022 allowed to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Test Report No.**	**NIH Test Report Result**
Tablet Nuberol Forte	C0570	M/s The Searle Company Limited, 32km Multan Road Lahore-Pakistan	0224-P/2022 dated: 12-09-2022	**Reference: British Pharmacopoeia-2017** **WEIGHT VARIATION** **Determined:** Nine out of 20 units masses deviate from 5% of average mass and one out of twenty units deviated by 10% of the average mass. **Limit:** NMT 02 of the units masses deviate from the 5% of average mass and none deviates by 10% of the average mass. **Does not Comply with the Manufacturer specifications.** **CONCLUSION:** The sample is of **Sub-Standard** quality on the basis of tests performed.

viii. A Copy of NIH report was sent to M/s The Searle Company Limited, 32km Multan Road Lahore- Pakistan vide letter dated 23-09-2022.

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

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

3 Show cause notice issued to the accused dated 31-10-2022

Firm submitted written reply to show cause notice dated 15-11-2022

We are pleased to hereby confirm the names as mentioned in aforesaid letter and further to attach

the required documents for your kind review.

4 Personal hearing notice issued to the accused dated 11-12-2023

Summary:

Manufacturing Date: 08-2021

Expiry Date: 08-2024

Sampling Date: 11-03-2022

Sent to DTL (Form 6): 12-03-2022

Date of receipt in DTL: 15-03-2022

DTL Report Date: 19-04-2022

1ST DI Communication with firm on dated: 29-04-2022

Date of Retesting Request of Firm: 11-05-2022

Fate of Retesting Request: allow (248-M dated 04-08-2022)

Sample received in NIH: 17-08-2022

NIH report date: 12-09-2022

Investigation Report Dated: 30-09-2022

Case is placed before the Board for the decision

PROCEEDING & DECISION BY THE BOARD:

Case No. 2

R-681/2021

(Bahawalpur Saddar)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Dyson Research Laboratories Pvt. Ltd., 28th Km Ferozepur Road, Lahore, Pakistan** through its Chief Executive Officer, Haji Mahmood Ahmad Virk 2. Haji Mahmood Ahmad Virk — Chief Executive Officer 3. Zafar Mustafa — Director 4. Jehanzeb Rauf Kahlon — Director 5. Tahir Sharif — Director/ Warrantor 6. Musharaf Nawaz — Production Incharge 7. M. Zeeshan Naeem — Quality Control Incharge **of M/s Dyson Research Laboratories Pvt. Ltd., 28th Km Ferozepur Road, Lahore, Pakistan.**

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 02-08-2021 inspected the business premises of M/s Mazhar Pharmacy situated at Adda Musafir Khana Bahawalpur (Saddar), took three 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, Bahawalpur vide memorandum no. 103232 dated 03-08-2021.
ii. The subject drug sample, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report No. & Date	DTL Test Report Result
Syrup. Dysofer-F [Iron (III) hydroxide polymaltose complex eq. to Elemental Iron: 50mg/5ml, Folic Acid: 0.43mg/5ml]	79057	M/s Dyson Research Laboratories Pvt. Ltd., 28 th Km Ferozepur Road, Lahore, Pakistan.	01-77005054/ DTL Dated 25-11-2021	**Analysis with specifications applied:** MS **COMPOSITION:** Each 5ml Contains: Iron (III) Hydroxide Polymaltose Complex equivalent to Elemental Iron ……. 50mg Folic Acid …… 0.43mg **DESCRIPTION:** Dark chocolate syrup sealed in amber color plastic bottle having white plastic. Stated volume is 120 ml. **pH (MS)**

Mfg Date:

Sep 2020

Expiry Date:

Sep 2022

Regn No.

067867

Limit: ……5.0 – 8.0

Determined:…… 6.744

IDENTIFICATION (MS): Elemental Iron and Folic Acid are identified.

ASSAY (MS):

Assay (MS)	**Stated**	**Determined**	**Percentage**
Elemental Iron	50mg/ 5ml	50.265mg/ 5ml	100.53%
			LIMIT: 90-115%
Folic Acid	0.43mg/5ml	**0.1934mg/ 5ml**	**44.97%**
			LIMIT: 90-125%
			(Does not comply with Specifications)

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

iii. M/s Mazhar Pharmacy situated at Adda Musafir Khana Bahawalpur (Saddar) provided Invoice/Warranty No. 9655 dated 28-07-2021 issued by M/s Decent Pharma (Distributor) House No. 121-Shadab Colony Road, Sabzazar, Bahawalpur as a proof of its purchase of the subject drug sample.

iv. Warrantor portion of drug sample was sent to M/S Decent Pharma (Distributor) House No. 121-Shadab Colony Road, Sabzazar, Bahawalpur who provided Invoice/Warranty No. 6016-ATL/WAR dated 21-06-2021 issued by M/s Atlantic Pharma, 339-Block E, Johar Town, Lahore as a proof of its purchase of the subject drug sample.

v. M/s Atlantic Pharma, 339-Block E, Johar Town, Lahore provided Invoice/Warranty No. 111-18-05-049896 dated 13-09-2020 issued by M/s Dyson Research Laboratories Pvt. Ltd., 28th Km Ferozepur Road, Lahore, Pakistan.

vi. A copy of test/analysis report was sent to M/S Dyson Research Laboratories Pvt. Ltd., 28th Km Ferozepur Road, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis reports of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vii. Pursuant to firm's request, the Provincial Quality Control Board in its 240th meeting held on 15-03-2022, after due deliberation and discussion unanimously decide to turn down the firm's request for retesting of the subject sample.

viii. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976

and Rules framed there under by the way of: -

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

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

REPLY OF SHOW CAUSE NOTICE:

1. This is in reference to the Show Cause Notice No. PQCB/R-681-2021 dated 23- 01-2023, received by us on 27-01-2023, whereunder your good-self has directed M/s Dyson Research Laboratories (Pvt.) Ltd. (the "Company") to show cause as to why any legal action, including but not limited to, the initiation of prosecution before the Honorable Drug Court as-well as cancellation/suspension of the drug manufacturing license and drug registration, may not be taken against it for allegedly issuing a false warranty and manufacturing a substandard drug in contravention of the provisions of the Drug Laws and the rules framed thereunder.

2. At the very outset, it is submitted that the Company is one of the leading national pharmaceutical companies in the country and is engaged in the manufacturing of premium quality pharmaceutical products. It is a matter of fact that no complaint in relation to the pharmaceutical products manufactured by the Company has been received from any quarter which affirms their excellent quality, efficacy and safety. It is in this backdrop that the Company seeks to refute the erroneous and incorrect findings rendered by the Government Analyst Drug Testing Laboratory Bahawalpur vide TRA No. 01-77005054/DTL dated 25-11-2021 (the "DTL Report") whereby the product, namely, Syrup Dysofer-F Batch No. 79057 has allegedly been declared as "substandard" on the basis of the results of the Assay Test.

3. Firstly, it is essential to highlight that the entire manner in which the Product has been tested by the Government Analyst is riddled with glaring infirmities and discrepancies. It is a matter of fact that the mandatory requirement stipulated under Section 22(2) of the Drugs Act, 1976 has not been dispensed with hence the DTL Report is void ab initio and completely incapable of being relied upon. Even otherwise, a thorough and detailed investigation has been carried out by the Company on its retained samples wherein no anomaly has been observed and it has been confirmed that the Product is of standard quality.

[Copy of the results of the tests conducted on the retained sample are enclosed herewith as "Enclosure I"]

4. In addition to the foregoing, it is pertinent to highlight that the Company has a stringent testing regime and all of its pharmaceutical products are subjected to the same prior to their release in the market. A similar exercise was carried out by the Company in the present case and the Product was only given clearance for release once it was subjected to a rigorous testing protocol whereby it was affirmed that the same is of standard quality. In view thereof, it is certain that the alleged variation observed by the Government Analyst in the DTL Report has solely occurred due to the inability of third parties including but not limited to the staff of the pharmacy to maintain and store the Product in accordance with the specific storage conditions listed on its label claim, more particularly, the temperature requirement,

[Copies of the Certificate of Analysis along with the label claim of the Product are enclosed herewith as "Enclosure II-III"]

5. Since the DTL Report entails grave legal as-well as regulatory consequences for the Company it is essential to ascertain whether the storage conditions were maintained by third parties in order to prevent the miscarriage of justice. In this regard, no independent exercise has been carried out by the Drug Inspector who has miserably failed to dispense with the requirement stipulated under Section 32(3) of the

Drugs Act, 1976. As such, it shall be completely against the dictates of justice to penalize the Company and its officials for the negligence and omissions of third parties which have resulted in the contravention of the Drugs Act, 1976.

6. Without any prejudice to the foregoing, it may be noted that the Product has already been declared as of standard quality by the Government Analyst Drug Testing Laboratory Multan vide TRA No. 01-94000347/DTL dated 13-01-2022. More importantly, eight (08) separate batches of Syrup Dysofer-F have also been declared of standard quality by the National Institute of Health Islamabad. The details of the same are reproduced hereunder:

i) Syrup Dysofer-F Batch No. 79048 declared of standard quality by the NIH vide TRA No. 081-P/2021 dated 26-03-2021.

ii) Syrup Dysofer-F Batch No. 79049 declared of standard quality by the NIH vide TRA No. 083-P/2021 dated 26-03-2021.

iii. Syrup Dysofer-F Batch No. 79050 declared of standard quality by the NIH vide TRA No. 082-P/2021 dated 26-03-2021.

iv. Syrup Dysofer-F Batch No. 79051 declared of standard quality by the NIH vide TRA No. 080-P/2021 dated 26-03-2021.

v) Syrup Dysofer-F Batch No. 79052 declared of standard quality by the NIH vide TRA No. 084-P/2021 dated 26-03-2021.

vi) Syrup Dysofer-F Batch No. 79053 declared of standard quality by the NIH vide TRA No. 079-P/2021 dated 26-03-2021.

vii) Syrup Dysofer-F Batch No. 79054 declared of standard quality by the NIH vide TRA No. 078-P/2021 dated 26-03-2021.

> [Copy of DTL Multan Report is enclosed herewith as "Enclosures IV" Copies of the NIH Reports along with the TRA No. TRA No. 01-94000347/DTL dated 13-01-2022 are enclosed herewith as "Enclosures V-XI"]

7. Notwithstanding the foregoing and despite the absolute innocence of the Company and its officials, please note the following information and documents as per your requirement:

i) Mahmood Ahmed Virk (CEO)

ii) Umar Nisar (Quality Control In-charge)]

iii) Ghazanfar Ali (Production

iv) Tahir Sharif (Warrantor).

v) Drug Manufacturing License.

vi) Drug Registration Certificate.

8. In view of the foregoing, it is reiterated that the Company and its officials have not contravened the provisions of the Drug Laws and the rules framed thereunder rather have shown strict compliance thereof. The alleged deviation observed by the Government Analyst which has been made the basis for initiating the case against the Company and its officials has solely occurred due to the inability of the third parties to store/maintain the Product in accordance with the specific storage conditions. Hence, it shall be a great travesty of justice to subject the Company to adverse consequences on the basis of the negligence and

omission of a third party.

9. Accordingly, it is very kindly requested that the titled Show Cause Notice and any subsequent proceedings may be withdrawn in the interest of justice and equity and the case be consigned to record.

Comparison of Different Batches Highlighted by Firm in Reply of SCN

Sr.	Product Name	Batch No.	Assay (DTL) Elemental Iron Limit: 90%-115% Folic Acid Limit: 90%-125%	Assay (NIH) Elemental Iron Limit: 90%-115% Folic Acid Limit: 90%-125%
1	Syrup Dysofer-F	79048	Elemental Iron: 103.20% **Folic Acid: 76.2%**	Elemental Iron:112.817% Folic Acid: 105.68%
2	Syrup Dysofer-F	79049	Elemental Iron: 98.52% **Folic Acid: 74.8%**	Elemental Iron: 113.93% Folic Acid: 118.0%
3	Syrup Dysofer-F	79050	Elemental Iron: 102.04 % **Folic Acid: 75.12%**	Elemental Iron: 114.52% Folic Acid: 107.96%
4	Syrup Dysofer-F	79051	Elemental Iron: 105.56% **Folic Acid: 77.08%**	Elemental Iron: 111.70% Folic Acid: 100.26%
5	Syrup Dysofer-F	79052	Elemental Iron: 110.25% **Folic Acid: 78.0%**	Elemental Iron: 113.25% Folic Acid: 107.71%
6	Syrup Dysofer-F	79053	Elemental Iron: 92.65% **Folic Acid: 77.37%**	Elemental Iron: 110.58% Folic Acid: 108.010%
7	Syrup Dysofer-F	79054	Elemental Iron: 102.04% **Folic Acid: 73.90%**	Elemental Iron: 113.93% Folic Acid: 112.91%
Batch under Discussion	Syrup Dysofer-F	79057	Elemental Iron: 100.53% **Folic Acid: 44.97%**	

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **271st meeting** held on **01-11-2023** under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson). Jahangir Khan, Secretary DQCB District Bahawalpur attended the meeting online via Zoom Link and Mr. Imtiaz Ahmad, Drug Inspector, Bahawalpur Saddar was present along with original case record. No one among nominated accused, appeared before the Board on the behalf of M/s Dyson Research Laboratories Pvt. Ltd., 28th Km Ferozepur Road, Lahore, Pakistan.

6. The Board after discussion decided to **adjourn** the case and to provide another but final opportunity to appear before the Board in the best interest of justice.

Summary:

Manufacturing Date: 09.2020

Expiry Date: 09.2022

Sampling Date (Form 4): 02.08.2021

Sent to DTL (Form 6): 03.08.2021

Date of receipt in DTL: 04.08.2021

DTL Report Date (Form 7): 25.11.2021

Time Extension: Granted in 19th Committee Meeting dated 21.10.2021

1ST DI Communication with firm on dated: 03.12.2021

Date of Retesting Request of Firm: 13.12.2021

Fate of Retesting Request: Turn Down in 240th Meeting dated 15.03.2022

Investigation Report Dated: 22.12.2022

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

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 3

PQCB/R-669/2021

(Tehsil Ahmadpur East, District Bahawalpur)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, National Industrial Zone, Rawat, Islamabad-Pakistan** through its Managing Director/CEO, Muhammad Iqbal 2. Muhammad Iqbal — Managing Director/CEO 3. Jamshed Ali — Production Manager 4. Zahid Usman — Quality Control Manager/ Warrantor **of M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, National Industrial Zone, Rawat, Islamabad-Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Ahmad Pur East, District Bahawalpur reported that: -

i. He, on 24-12-2020 inspected the business premises of M/s Subhan Allah Pharmacy, Opposite THQ Hospital Ahmadpur East, District Bahawalpur, took three different types of drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 81246 dated 28-12-2020.
ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory **Bahawalpur** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Injection. Dexicort [Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate: 4mg/ml] **Mfg Date:** 06-2020 **Expiry Date:**	20F138	M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, National Industrial Zone, Rawat, Islamabad-Pakistan.	01-77002851/DTL dated: 26-02-2021	**Result of test/ analysis with specifications applied:** USP 2020 **COMPOSITION:** Each ml contains: Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate …… 4mg **DESCRIPTION:** Colorless liquid in transparent glass sealed ampoule. (Stated volume: 01ml) 19 out of 25 ampoules were seen with visible particulate matter. **(Does not comply with the parenteral specifications)** **VOLUME (USP):**

05-2022 **Regn No.** 097759				Limit: -------- NLT nominal volume Determined: 1.12 ml **pH (USP):** Limit: ----------7.0 – 8.5 Determined: ------ 7.935 **STERILITY (USP):** The product is sterile. **IDENTIFICATION (USP):** Dexamethasone Phosphate is identified. **ASSAY (USP):** **Dexamethasone phosphate** Stated: 4 mg/ ml Determined: 4.57 mg/ ml Percentage: 114.37% Limit: 90.0 – 115.0% **RESULT:** The sample is declared **SUB-STANDARD** on the basis of PHYSICAL TEST.

iii. Chemist of M/s Subhan Allah Pharmacy, Opposite THQ Hospital Ahmadpur East, District Bahawalpur, provided invoice/warranty bearing numbers 1496 dated 15-10-2020 issued by M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, National Industrial Zone, Rawat, Islamabad-Pakistan as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent to M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, National Industrial Zone, Rawat, Islamabad-Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, National Industrial Zone, Rawat, Islamabad-Pakistan with the 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 238th meeting held on 09-02-2022, after due deliberation and discussion unanimously decide to **turn down** the firm's request for retesting of the subject sample.

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

a. **Manufacturing for sale / Stocking for sale/ selling of Substandard drug**
b. **Issuance of false warranty**

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

REPLY OF SHOW CAUSE NOTICE:

That reference to your show cause notice vides letter no.PQCB/R-669/2021, which is received on 08-05-2023, related to **Dexicort injection 4mg/ 1ml B# 20F138**,has been declared Subs- standard by the DTL Bahawalpur.

It is stated, the DTL Bahawalpur vide test analysis report No. TRA.01-77002851/DTL dated 26/02/2021 has decaled as under:

PRODUCT: DEXICORT(dexamethasone sodium phosphate) INJ 4mg/1ml

DESCRIPTION: colorless solution filled in a sealed, transparent, glass ampoules of 1ml in a labeled hard carton.25 ampoules holding in beehives are packed in an outer hard carton (25x1ml ampoules)

IDENTIFICATION: dexamethasone sodium phosphate is identified.

ASSAY:	STATED	DETERMINED	%AGE
	4mg/ml	4.57 mg/ml	(114.37%)
			(Limits = 90 - 115%)

PH 7.935 (Limits: 7.0-8.5)

VOLUME: 1.12ml limit: NLT NOMINAL VOLUME

Sterility: The product is sterile

RESULT: The sample is sub-standard quality on the basis of **VISIBLE PARTICULATES**.

In this regard it is stated That our request of re-testing was turned down by the Board in its 238th meeting held on 09-02-2022, and in the process, the right of appeal of the firm went loss/deprived.

We manufacture our all products under the keen observation of our Quality Assurance and Quality Control Department which after performing all the Pharmacopeial tests releases the batch for marketing however, after receiving the test report of DTL Bahawalpur We have checked our said batch again against white and black background approximately for 05 seconds (75 AMPOULES) we have not found any visible particles.

Your Cooperation in this regard will be highly appreciated.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **271st meeting** held on **01-11-2023** under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson). Mr. Jahangir Khan, Secretary DQCB District Bahawalpur attended the meeting online via Zoom Link and Mr. Imran Javed, Drug Inspector, Ahmadpur East was present along with original case record. No one among nominated accused appeared before however Asim Malik (Advocate) appeared before the Board on the behalf of M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, National Industrial Zone, Rawat, Islamabad-Pakistan. He submitted before the Board a written request for adjournment.

5. The Board after discussion decided to **adjourn** the case on the request of the firm in the best

interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

Summary:

Manufacturing Date: 06.2020

Expiry Date: 05.2022

Sampling Date (Form 4): 24.12.2020

Sent to DTL (Form 6): 28.12.2020

Date of receipt in DTL: 29.12.2020

DTL Report Date (Form 7): 26.02.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 26.11.2021

Date of Retesting Request of Firm: 02.12.2021

Fate of Retesting Request: Turn Down in 238th Meeting dated 09.02.2022

Investigation Report Dated: 02.03.2023

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

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 4

PQCB/R-491/2022

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

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan** through its Chief Executive Officer Muhammad Iqbal 2. Muhammad Iqbal — Chief Executive Officer 3. Muhammad Qaiser — Managing Director 4. Zahid Usman — Quality Control Manager/ Warrantor 5. Jamshed Ali — Production Manager Of **M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He, on 08-03-2022, inspected the business premises of M/s A.R Pharma situated at shop khata no. 227/229 street no. 4 Balakh-e-Serwar City Dera Ghazi Khan, and took sample of two different types of drugs on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Multan vide memorandum no. 0000120899 dated 09-03-2022.

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

iii. M/s A.R Pharma situated at shop khata no. 227/229 street no. 4 Balakh-e-Serwar City Dera Ghazi Khan submitted Invoice/warranty no. 3948 dated 10-01-2022 issued by M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan and they were asked to provide the requisite information in this regard.

v. A copy of test/analysis report was sent to M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan and they were asked to provide the requisite information in this regard.

vi. The company challenged the report of DTL Multan in the appellate laboratory and the case was placed in 248th meeting of Provincial Quality Control Board held on 04-08-2022 where the Board after due deliberation and discussion unanimously decided to Turndown firm's request of the re-testing request of the subject drug sample and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

vii. Drug Inspector requested for grant of permission for prosecution against above mentioned accused

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

<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>Dexicort (Dexamethasone sodium phosphate equivalent to dexamethasone phosphate 4mg/ml) Injection 1 ml.

Mfg.date:

Dec-2021

Exp. date:

Nov-2023

Regn No.

097759</td><td>21L751</td><td>M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan</td><td>TRA No. 01-94002702/DTL

Dated:-09-05-2022</td><td><u>Result of Test/ Analysis with specifications applied</u>: USP 2021

<u>Description:</u> Colorless solution filled in a sealed, transparent, glass ampoule of 1 ml with yellow 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*1 ml Ampoules).

<u>Visible Particulates:</u>

<u>Stated:</u> ‘’Inspected unit must be free from visible particulates when examined without magnification against a black background and against a white background approximately for 05 seconds’’.

<u>Determined:</u> “When examined against white and black background, 08 (eight) out of 20 ampoules contain visible particulates”.

(DOES NOT COMPLY)

<u>Extractable Volume:</u> Limit: NLT stated

Determined: 1.0 ml (Complies)

<u>PH</u>: Range: 7.0-8.5 at 25^{o}C

Determined: 8.35 at 25^{o}C (Complies)

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

<u>Identification</u>: Dexamethasone sodium phosphate identified.

<u>Assay</u>

<u>Dexamethasone phosphate:</u>
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>4 mg/ ml</td><td>3.65 mg/ ml</td><td>91.30%</td><td>90-115%</td></tr>
</table>
</td></tr>
</table>

				(Complies) **RESULT:** The above sample is **Sub-Standard,** on the basis of Visible Particulates.

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

3. Show cause notice(s) issued to accused person(s) dated 25-08-2023.

4. Personal Hearing notice(s) issued to accused person(s) dated 10-10-2023.

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 **270th** meeting held on **19-10-2023** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab. Mr. M. Asif Abbas, Secretary DQCB, District Dera Ghazi Khan and Mr. Faisal Mahmood Khan, Drug Inspector Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan were present along with the original case record. No one among the nominated accused persons of **M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan** was present. However, Counsel of the firm Asim Malik (Advocate) and Hafiz Arsalan Aslam (Legal Consultant) appeared before the Board on behalf of the firm and requested for adjournment.

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 but final opportunity of personal hearing to the accused persons.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 12-2021**
- **Expiry Date: 11-2023**
- **Sampling Date (Form 4): 08-03-2022**
- **Sent to DTL (Form 6): 09-03-2022**
- **Date of receipt in DTL: 11-03-2022**
- **DTL Report Date (Form 7): 09-05-2022**
- **Time Extension: NA**
- **1ST DI Communication with firm on dated: 19-05-2022**
- **Date of Retesting Request of Firm: 24-05-2022**
- **Fate of Retesting: Turned down in 248th meeting 04-08-2022**
- **Investigation Report Dated: 12-04-2023**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 5

PQCB/R-48/2023

Tehsil & District Lodhran

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Iqra Pharmaceuticals Plot No. 2, St. # S-9, National Industrial Zone, Rawat, Islamabad, Pakistan** through its Chief Executive Officer Muhammad Iqbal 2. Muhammad Iqbal — Chief Executive Officer 3. Muhammad Qaiser — Managing Director 4. Zahid Usman — Quality Control Manager/ Warrantor 5. Jamshed Ali — Production Incharge Of **M/s Iqra Pharmaceuticals Plot No. 2, St. # S-9, National Industrial Zone, Rawat, Islamabad, Pakistan.** 6. Khalid Waseem — Proprietor Of **M/s Waseem Medical Store and Super Store, Sukhera Chowk, Galay Wal, Tehsil & District Lodhran.**

BRIEF FACTS OF THE CASE

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

i. He, on 27-10-2022, inspected the business premises of M/s Waseem Medical Store and Super Store, Sukhera Chowk, Galay Wal, Tehsil & District Lodhran, took samples of three 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. 0000146635 dated 31-10-2022.

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

iii. M/s Waseem Medical Store and Super Store, Sukhera Chowk, Galay Wal, Tehsil & District Lodhran submitted Invoice/warranty No.3532 dated 18-10-2022 issued by M/s Iqra Pharmaceuticals Plot No. 2, St. # S-9, National Industrial Zone, Rawat, Islamabad, Pakistan as a proof of its purchase of the said drug.

iv. Warrantor Portion of the drug sample was sent M/s Iqra Pharmaceuticals Plot No. 2, St. # S-9, National Industrial Zone, Rawat, Islamabad, Pakistan and they were asked to provide requisite information in this regard.

v. A copy of test report was sent to M/s Iqra Pharmaceuticals Plot No. 2, St. # S-9, National Industrial Zone, Rawat, Islamabad, Pakistan 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

Difisal SR (Diclofenac sodium 100 mg) sustained release tablet **Mfg.date:** Aug-2021 **Exp. date:** Jul-2023 **Regn No.** 099620	21H368	M/s Iqra Pharmaceuticals Plot No. 2, St. # S-9, National Industrial Zone, Rawat, Islamabad, Pakistan	TRA No. 01-89007744/DTL Dated:-25-02-2023	**Result of Test/ Analysis with specifications applied:** USP 2022 **Description:** Pink color, round tablet plain on both sides, packed in ALU-PVC blister of 10 units in a labeled outer hard carton. Each outer carton contains 03 blisters of 10 units each i.e. 3*10= 30 tablets. **Uniformity of dosage unit (Weight Variation):** Max. AV=L1: 15% **(Complies)** **Identification:** Diclofenac sodium identified. **Assay:** Analysis method: HPLC Diclofenac sodium

Stated	**Determined**	**Percentage**	**Limit**
100mg/tablet	108.52mg/tablet	108.52%	90-110%

(Complies)

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

The percentage of the labelled amount of diclofenac sodium dissolved in 0.05M Phosphate Buffer of PH 7.0 is as under:

Limit: 1st hr (15-35%), 5th hr (45-65%), 10th hr (65-85%), 16th hr (75-95%) & 24th hr (NLT 80%)

Level	**Units**	**% Release at 1st hr (15-35%)**						**Remarks**
L1	6	U#1	U#2	U#3	U#4	U#5	U#6	**(DOES NOT COMPLY)**
Determined	%	92.3	74.7	69.9	72.8	102.8	99.8	
L1	6	**% Release at 5th hr (45-65%)**						
Determined	%	108.7	110.9	110.1	97.1	106.0	107.9	
L1	6	**% Release at 10th hr (65-85%)**						
Determined	%	111.4	108.5	107.6	111.4	109.0	111.7	

				L1	6	**% Release at 16th hr (75-95%)**					
				Determined	%	110.9	114.7	113.6	108.7	109.3	111.4
				L1	6	**% Release at 24th hr (NLT 80%)**					
				Determined	%	113.3	115.2	115.2	114.9	112.5	113.3

***As the criteria of L3 i.e. The average value of 24 units (**L1+L2=L3) lies within each of stated ranges and is NLT the stated amount at the final test time; NMT 2 of the 24 units are more than 10% of the labeled content outside each of the stated ranges; NMT 2 of the 24 units are >10% of the labeled content below the stated amount at the final test time; and none of the units are >20% of labeled content outside each of the stated ranges or >20% of the labeled content below the stated amount at the final test time is achieved at L1. So, the results conform at L1 stage.

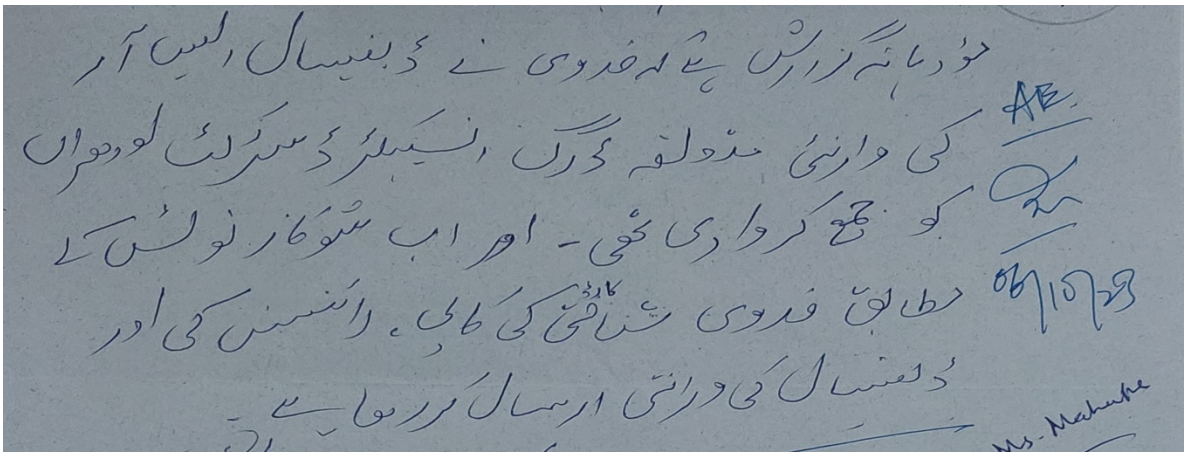
RESULT: The above sample is **Sub-standard**, on the basis of Dissolution Test.

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

Names of accused persons	**Offences**
1. **M/s Iqra Pharmaceuticals Plot No. 2, St. # S-9, National Industrial Zone, Rawat, Islamabad, Pakistan** through its Chief Executive Officer Muhammad Iqbal 2. Muhammad Iqbal Chief Executive Officer 3. Muhammad Qaiser Managing Director 4. Zahid Usman Quality Control Manager/ Warrantor 5. Jamshed Ali Production Incharge Of **M/s Iqra Pharmaceuticals Plot No. 2, St. # S-9, National Industrial Zone, Rawat, Islamabad, Pakistan**	a. **Manufacture for Sale/ Sale of the Substandard drug** b. **Issuance of false warranty**
6. Khalid Waseem Proprietor Of **M/s Waseem Medical Store and Super Store, Sukhera Chowk, Galay Wal, Tehsil & District Lodhran.**	a. **Sale of drugs in absence of Qualified Person**

3. Show cause notice(s) issued to accused person(s) dated 18-09-2023.

Reply of M/s Waseem Medical Store and Super Store, Sukhera Chowk, Galay Wal, Tehsil & District Lodhran to show cause notice vide letter no. nil received in the office of PQCB dated 06-10-2023:



4. Personal Hearing notice(s) issued to accused person(s) dated 11-12-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 08-2021**
- **Expiry Date: 07-2023**
- **Sampling Date (Form 4): 27-10-2022**
- **Sent to DTL (Form 6): 31-10-2022**
- **Date of receipt in DTL: 01-11-2022**
- **DTL Report Date (Form 7): 25-02-2023**
- **Time Extension: Granted in 256th meeting dated 19-01-2023**
- **1ST DI Communication with firm on dated: 08-03-2023**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Nil**
- **Investigation Report Dated: 08-04-2023**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 6

PQCB/R-370/2022

Tehsil & District Lodhran

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan** through its Chief Executive Officer Muhammad Iqbal 2. Muhammad Iqbal — Chief Executive Officer 3. Muhammad Qaiser — Managing Director 4. Jamshed Ali — Production Manager 5. Zahid Usman — Quality Control Manager/ Warrantor **Of M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan.** 6. Jamal Rasheed — Proprietor/ Warrantor 7. Shumaila — Qualified Person Of **M/s Trade Link, Plot No. 7/212,S. Abdul Tawab Road D.M.C.H.S, Karachi.** 8. Malik Zulfiqar Ahmad — Proprietor/ Warrantor 9. Muhammad Amjad Sohail — Qualified Person Of **M/s Pakistan Surgical Medicine Street Town Hall Multan.** 10. Shoukat Hussain — Proprietor Of **M/s Shoukat Medicine Company, Street No. 2, Shahzad Town, Near Commerce College, Lodhran.**

BRIEF FACTS OF THE CASE

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

i. He, on 11-08-2022, inspected the business premises of M/s Shoukat Medicine Company, Street No. 2, Shahzad Town, Near Commerce College, Lodhran, took sample of drug on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum no. 0000136654 dated 15-08-2022.

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

iii. M/s Shoukat Medicine Company, Street No. 2, Shahzad Town, Near Commerce College, Lodhran submitted Invoice/warranty No. 10492 dated 07-04-2022 issued by M/s Pakistan Surgical Medicine Street Town Hall Multan as a proof of its purchase of the said drug.

iv. Warrantor Portion of the drug sample was sent to M/s Pakistan Surgical Medicine Street Town Hall Multan who in turn provided invoice/ warranty No. 04 dated 21-03-2022 issued by M/s Trade Link, Plot No. 7/212S. Abdul Tawb Road D.M.CH.S, Karachi who in turn submitted invoice/ warranty No. 3834

dated 22-12-2021 issued by M M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan.

v. A copy of test report of the subject drug sample was sent to M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan and they were asked to provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 254th meeting held on 13-12-2022 decided to turn down the subject request for retesting of the drug sample and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

Name of drug	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Glydo 2% (Lidocaine HCl 40mg/2ml) Injection 2 ml. **Mfg.date:** Oct-2021 **Exp. date:** Oct-2023 **Regn No.** 097726	21J528	M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan.	TRA No. 01-94005337/DTL Dated:-15-10-2022	**Result of Test/ Analysis with specifications applied:** USP 2022 **Description:** Colorless solution filled in a sealed, transparent, glass ampoule of 2 ml with black printed label, yellow colored neck ring in a labeled outer hard carton. 100 ampoules holding in beehives are packed in a unit outer hard carton (100*2ml Ampoules). **Visible Particulates:** **Stated:** ''Inspected unit must be free from visible particulates when examined without magnification against a black background and against a white background approximately for 05 seconds'' **Determined:** ''When examined against white and black background, 36 (thirty six) out of 60 ampoules contain visible particulates''. **(DOES NOT COMPLY)** **Extractable Volume**: Limit: NLT Stated Determined: 2.04 ml **(Complies)** **PH:** Limit: 5.0-7.0 at 25^{o}C Determined: 6.35 at 25^{o}C **(Complies)** **Sterility**: It conforms to sterility test **(Complies)** **Identification:** Lidocaine HCl Identified. **Assay:** Lidocaine HCl Stated | Determined | Percentage | Limit

				40mg/2ml	38.98mg/2ml	97.46%	95-105%

(Complies)

Result: The above sample is **Sub-Standard**, on the basis of Visible Particulates.

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: -

Names of accused persons	Offences
1. **M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan** through its Chief Executive Officer Muhammad Iqbal 2. Muhammad Iqbal — Chief Executive Officer 3. Muhammad Qaiser — Managing Director 4. Jamshed Ali — Production Manager 5. Zahid Usman — Quality Control Manager/ Warrantor **Of M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan.**	a. **Manufacture for Sale/ Sale of the Substandard drug** b. **Issuance of false warranty**
6. Jamal Rasheed — Proprietor/ Warrantor 7. Shumaila — Qualified Person Of **M/s Trade Link, Plot No. 7/212,S. Abdul Tawab Road D.M.CH.S, Karachi.**	a. **Stocking for sale/ Sale of Substandard drug** b. **Issuance of false warranty**
8. Malik Zulfiqar Ahmad — Proprietor/ Warrantor 9. Muhammad Amjad Sohail — Qualified Person Of **M/s Pakistan Surgical Medicine Street Town Hall Multan.**	a. **Stocking for sale/ Sale of Substandard drug** b. **Issuance of false warranty**
10. Shoukat Hussain — Proprietor Of **M/s Shoukat Medicine Company, Street No. 2, Shahzad Town, Near Commerce College, Lodhran.**	a. **Sale of the Substandard drug in absence of Qualified Person.**

3. Show cause notice issued to accused person(s) dated 24-05-2023 & 25-05-2023.

Reply of Tradelink Pharma to show cause notice vide letter no. nil dated 09-06-2023:

With due respect it is stated that we M/s Trade Link "Plot No. 7/212, S. Abdul Tawab Road D.M.C.H.S Karachi receive a show cause notice No. PQCB/R-370/2022 dated 24-05-2023 via Pakistan Post No. RGL21171822 received on dated 03-06-2023, regarding the sample collection and substandard issue of sold product manufactured by M/s Iqra Pharmaceuticals RCCI Rawat "Glydo 2% Injection Registration No. (097726) Batch No. 21J528

Mfg Date: OCT-2021 EXP Date: OCT-2023, supplied under the invoice Bill Warranty No. 04 dated 31-03-2022.

This is to update the respected department that we are only the sale distributors of the sampled

product and have no concern with the manufacturing of the above mentioned product, for reference distribution letter is attached.

Also we receive a stock return letter of above mentioned substandard product from the manufacturer Dated (15/11/2022) "Copy of letter is attached"

On the bases of that we take stock return from Pakistan Pharma, and returned back to the company.

Sir we are sending the reply regarding the received Show Cause Notice from your kind authority, our valid DSL copy is also attached with the reply.

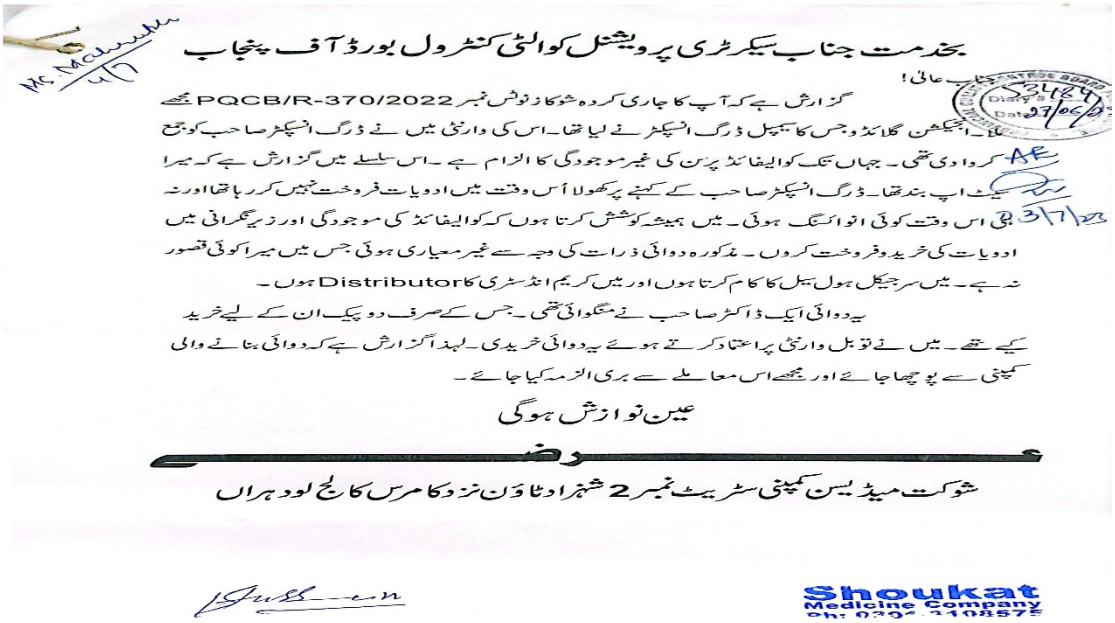
<u>Reply of Pakistan Surgical to show cause notice vide letter no. PQCB/R-370/2022 dated 15-07-2023</u>

With due respect it is stated that we M/s Pakistan Surgical Medicine "Street Town Hall Multan" receive a show cause notice No. POCB/R-370/2022 dated 24-05-2023 via Pakistan Post No (RGL21171824) received on the Shop address on dated (26-06-23), regarding the sample collection and substandard issue of sold product manufactured by M/s Iqra Pharmaceuticals RCCI Rawal "Glydo 2% Injection Registration No. (097726) Batch No. 21J528 Mfg Date: OCT-2021 EXP Date: OCT-2023, supplied to M/s Shoukat Medicine Company Street No 2. Shahzad Town Near Commerce College Lodhranunder the invoice Bill Warranty No. 10492 dated 07-04-2022.

This is to update the respected department that we are only the sale distributors of M/s Trade Link Karachi of the sampled product and have no concern with the manufacturing of the above mentioned product, also we receive a stock return letter of above mentioned substandard product from M/s Trade Link "Plot No. 7/212, S. Abdul Tawab Road, D.M.C.H.S Karachi under the Courier Slip No. (3284) DATED 29-10-2022"Copy of letter and courier slip is attached"

Sir we are sending the reply regarding the received Show Cause Notice from your kind authority, our valid DSL and CNIC copies of mentioned persons in notice are attached with the reply, requested to please consider the request and grant us the warning for above mentioned case.

<u>Reply of Shoukat Medicine Company to show cause notice (received in the office of PQCB dated 27-06-2023):</u>



بخدمت جناب سیکرٹری پروویشنل کوالٹی کنٹرول بورڈ آف پنجاب

جناب عالی!

گزارش ہے کہ آپ کا جاری کردہ شوکاز نوٹس نمبر PQCB/R-370/2022 مجھے [illegible] انجکشن گلائڈو جس کا سپیشل ڈرگ انسپکٹر نے لیا تھا۔ اس کی وارنٹی میں نے ڈرگ انسپکٹر صاحب کو جمع کروا دی تھی۔ جہاں تک کوالیفائڈ پرسن کی غیر موجودگی کا الزام ہے۔ اس سلسلے میں گزارش ہے کہ میرا سیٹ اپ بند تھا۔ ڈرگ انسپکٹر صاحب کے کہنے پر کھولا اُس وقت میں ادویات فروخت نہیں کر رہا تھا اور نہ اس وقت کوئی انوائسنگ ہوئی۔ میں ہمیشہ کوشش کرتا ہوں کہ کوالیفائڈ کی موجودگی اور زیر نگرانی میں ادویات کی خرید و فروخت کروں۔ مذکورہ دوائی ذرات کی وجہ سے غیر معیاری ہوئی جس میں میرا کوئی قصور نہ ہے۔ میں سرجیکل ہول سیل کا کام کرتا ہوں اور میں کریم انڈسٹری کا Distributor ہوں۔

یہ دوائی ایک ڈاکٹر صاحب نے منگوائی تھی۔ جس کے صرف دو پیک ان کے لیے خرید کیے تھے۔ میں نے تو بل وارنٹی پر اعتماد کرتے ہوئے یہ دوائی خریدی۔ لہذا گزارش ہے کہ دوائی بنانے والی کمپنی سے پوچھا جائے اور مجھے اس معاملے سے بری الزمہ کیا جائے۔

عین نوازش ہوگی

عرض

شوکت میڈیسن کمپنی سٹریٹ نمبر 2 شہزاد ٹاؤن نزد کامرس کالج لودھراں

Shoukat Medicine Company Ph: 0300-3108575

4. Personal Hearing notice(s) issued to accused person(s) dated 23-10-2023.

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 **271st** meeting held on **01-11-2023** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab. Mr. Misbah-Ud-Din, Secretary DQCB, District Lodhran attended the meeting online via zoom link and Dr. Naveed Aslam, Drug Inspector Tehsil & District Lodhran was present along with the original case record. No one among the nominated accused persons of **M/s Iqra Pharmaceuticals, Plot No. 2, ST. # S-9, National Industrial Zone, Rawat, Islamabad-Pakistan** was present. However, Counsel of the firm Asim Malik (Advocate) appeared before the Board on behalf of the firm and submitted written request for adjournment.

6. The Board after due deliberation and discussion unanimously decided to **adjourn the case** on request of the firm in best interest of justice. 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) dated 11-12-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: Oct-2021**
- **Expiry Date: Oct-2023**
- **Sampling Date (Form 4): 11-08-2022**
- **Sent to DTL (Form 6): 15-08-2022**
- **Date of receipt in DTL: 18-08-2022**
- **DTL Report Date (Form 7): 15-10-2022**
- **Time Extension: NA**
- **1ST DI Communication with firm on dated: 01-11-2022**
- **Date of Retesting Request of Firm: 11-11-2022**
- **Fate of Retesting: Turned down in 254th meeting dated 13-12-2022**
- **Investigation Report Dated: 08-02-2023**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 7

PQCB/R-791/2021

Tehsil Arifwala, Pakpattan

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/warrantor, Pervaiz Iqbal Siddiqui 2. Pervaiz Iqbal Siddiqui — Managing Partner/Warrantor 3. Malik Muhammad Asif — Production Incharge 4. 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 Arifwala, District Pakpattan reported that: -

i. The then Drug Inspector, on 29-09-2021 inspected the business premises of M/s Shan medical store Machilli Bazar Arifwala, took following drug on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memorandum no. 108188 dated 30-09-2021**.**
ii. The subject drug sample, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**	**DTL Test Report Result**
Sugar Coated Tablet Valron-P 75 tablet [Diclofenac Potassium 75mg USP] **Mfg Date**: 09-2020	T-14420	M/S Venus Pharma, 23-Km Multan Road Lahore-Pakistan	01-85000162/ DTL Dated 04-11-2021	**Analysis with specifications applied: USP 2020** **COMPOSITION:** Each Sugar-coated Tablet contains: Diclofenac Potassium ……..75mg **DESCRIPTION (MS)**: Chocolate brown colored biconvex tablet, plain on both sides. Packe 10 tablets. **IDENTIFICATION (USP):** Diclofenac Potassium is identified **ASSAY (USP):** Diclofenac Potassium Stated: 75mg/tab Determined: 69.11mg/tab Percentage: 92.1454% Limit: 90-110%

Exp. Date: 09-2022 **Regn No**. 078831				**DISSOLUTION TEST (USP):** **Tolerance limit:** NLT 75% (Q) in 60min. each unit is equal to or greater than Q+5% (i.e., 8 are less than Q-15% (i..e, 60%) and no units is less than Q-25% (i.e.,. 50%)

STAGE	**Unit Tested**	**ACCEPTANCE CRITERIA**						
	06	Each unit is equal to or greater than Q+5% (i.e., 80%). NMT 2 units are less than Q-15% (i. e, 60%) and no units is less than Q-25% (i.e., 50%)						**Averag**
		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	
S1	Diclofenac Potasium	16.96%	17.34%	16.77%	18.29%	18.67%	16.77%	17.47%

Result: all 6 units are less than Q-25% (i.e., 50%) and average drug release is 17.47%.

RESULT: The sample is declared **Substandard** on the basis of Dissolution Test.

iii. M/s Shan medical store Machilli Bazar Arifwala provided Invoice/Warranty No. 74098 dated 29-09-2021 issued by M/s Lahore Drug House H/ no. 50-B/II Kerbala Road, Sahiwal as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Lahore Drug House H/ no. 50-B/II Kerbala Road, Sahiwal.

v. M/s Lahore Drug House H/ no.50-B/II Kerbala Road, Sahiwal, provided Invoice/Warranty No. 191 dated 06-08-2021 along with authority letter issued by M/s Venus Pharma, 23-Km Multan Road Lahore-Pakistan

vi. A copy of test/analysis report was sent to M/s Venus Pharma, 23-Km Multan Road Lahore-Pakistan with directions to explain their position and provide requisite information in this regard. In response, Firm challenged DTL Report and requested for retesting from NIH, Islamabad. The Board in its 238th meeting dated 09-02-2022, allowed subject retesting request of the firm. National Institute, Islamabad, declared subject drug **substandard.** The detail is as below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Report No & Date**	**NIH Test Report Result**
Tablet Valron-P (S.C) (Diclofenac	T-14420	M/S Venus Pharma, 23-Km Multan Road Lahore-Pakistan	027-P/2022 Dated 22-04-2022	**Reference: USP-43** **DISSOLUTION TEST:** **Determined:** All the six tablets are deviated

Potassium 75mg)				from the limit **<u>Limit</u>**: Not less than 75% (Q) of the labelled amount of Diclofenac Potassium is dissolved. **Does not comply with USP-43** **<u>Conclusion</u>:** The sample is of **<u>Substandard</u>** quality on the basis of the tests performed.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976/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**

<u>Summary:</u>

Manufacturing Date: 09-2020

Expiry Date: 09-2022

Sampling Date: 29-09-2021

Sent to DTL (Form 6): 30-09-2021

Date of receipt in DTL: 02-10-2021

DTL Report Date: 04-11-2021

Time extension granted: N/A

1ST DI Communication with firm on dated: 16-11-2021

Date of Retesting Request of Firm: 27-11-2021

Fate of Retesting Request: allow (238-M dated 09-02-2022)

Sample received in NIH: 21-02-2022

NIH report date: 14-05-2022 **(**Reporting days: 61 days**)**

Investigation Report Dated: 16-05-2023

3 Show cause notice issued to the accused

Firm submitted reply to show cause notice vide letter dated 11-07-2023

In response to the show Cause Notice issued by the secretary (Drug Inspector / Pharmacist) is submitted.

1. That the constitution of Islamic Republic of Pakistan Impose clear restriction on the Provincial Quality Control Board, Punjab, in the words:-

Obedience of the constitution and Law is the inviolable obligation of every citizen wherever he may be".

And

No action detrimental to the life liberty, body"

“Reputation property of any person shall be taken except in accordance with law....

And

Article 189 and 201 of the constitution of Islamic Republic of Pakistan 1973, Imposed clear Restrictions on each and every organ of the state including the courts and this board and all the authorities, any question of Law decided or Enunciates A Principle of Law shall be binding on this Board also"

2. Honorable Supreme Court of Pakistan Pleased to Laid Down the Principle of Law that"-

I. "it is an elementary principle that it a mandatory condition of the exercise of Jurisdiction by a Court, Tribunal or Authority is not fulfilled, then the entire proceedings which follow become illegal and suffer from want of jurisdiction. Any Order passed in continuation of these proceedings in appeal or revision equally suffer from illegality and are without Jurisdiction ....)
II. ..... the Question of jurisdiction of FORUM is always considered to be very important and any order passed by a Court or a forum, having no jurisdiction, even if is found to be correct on merits, is not sustainable. The jurisdiction of a Court lays down a foundation stone for a Judicial or quasi-judicial functionary to exercise its powers / authority and no sooner the question of Jurisdiction is deterred in negative, the whole edifice built such defective proceedings, is bound to crumble down...."
III. "....it is a fundamental principle of law that a court or tribunal has to decide the lies before it in accordance with Law and parties area not bound to engage a counsel. Justice according to Law is the duty of the which can neither be abdicated in favor of the whims or ignorance of the litigations or their lawyers nor it be avoided or evaded on the pretest that a question of law going to the root of the case was not raised promptly...."
IV. ….it is an old-age fundamental principle of law that justice should not only be done but manifestly and undoubtedly it should seen to have been done. To achieve this objective / goal it is of prime importance that a judge / Person equipped with the authority of decision should not be having any sort of personal interest in the outcome of the matter under issue before him. The conduct of the proceedings should not generate any reasonable apprehension in the mind of a person that the deciding officer has harboured any grudge or bias against him.... ")
V. "...it is basic principle that if a mandatory condition for the exercise of jurisdiction by a Court is not fulfilled, then the entire proceedings which follow become illegal and suffer from want of jurisdiction as law laid down by this Court in Mansib Ali's case etc.,....

3. That Under Section 22(4) of the Drugs Act 1976, the DTL Test Report No. TRA 01-85000162/DTL dated: 04/11/2021 cannot be used against M/s. Venus Pharma, so far as NIH Test

Report No. 027-P/2022 dated: 22/04/2022 is concerned also legally value less cannot be used against M/s. Venus Pharma for the following:-

a. **The person signed the Report named Ikram-ul-Haq (Acting Chief) Under the Law No authority is given to the acting Chief to Sign such Report under Section 22(5) of the Drugs Act 1976.**

b. Said Ikram-ul-Haq not legally competent / authorized / empowered to signed the Test Report until and unless he was so authorized through Notification duly published in the official gazette, where as Ikram-ul-Haq was never so appointed.

c. No Lawful order is in existence as required Under Section 14 of the Drugs Act 1976, for the establishment to set up NIH for the purposes of Section 14 Drugs Act.

d. Under the Drugs Act 1976, and for the purposes of Drugs Act 1976, that is for Test/ Analysis of Drugs by any Laboratory or institution Federal or Provincial Government Analyst are essential, who performed the Test / Analysis nowhere mentioned, so it can be Presumed that Report Prepared without Test.

4. Under Rule 16 of the (Federal Inspector, Federal Government Analyst and Federal Drug Laboratory) Rules 1976.

"It is essential / necessary / mandatory for the Federal Government Analyst to give the details of FULL PROTOCOLS OF TEST"

FULL PROTOCOLS OF TEST MEANS:-

“Report should be Self-contained so that its authenticity could be tested if it is disputed."

The Honorable Lahore High Court Lahore Pleased to held that:-

*** the Report and the Certificate of the national institute of health not being in accordance with law, could not have forward basis of the decision of the Provincial Quality Control Board, Punjab,"**

The Test Report No. **027-P/2022 dated: 22/04/2022 signed on 61 days from the receipt** of Sample.

The full proiocols of Test not given in the Report ie., the details of the method used, the steps taken to reach the conclusion.

The Report of NIH without the Lawful and full protocols of Test, there Fore, as held by the Honorable high Courts of Lahore; Peshawar: Karachi; and Quetta, the Test Report No. 027-P/2022 dated: 22/04/2022 is illegal and cannot be used against Venus Pharma.

5. The Drug Inspector concerned, in spite of clear demand for the supply of essential and necessary documents related with the case vile letters dated: 27/11/2021; 06/12/2021, 22/01/2022 send through TCS and duly received by the Drug inspector and PQCB, Punjab. But the copies of required documents yet not Provided even the Drug Inspector AVOID to mentioned the dates when M/s. Shan

Medical Store Provided the warranty of M/s. Lahore Drug House, and on which date sample portion was supplied to him. Difficulty M/s. Shan Medical Store Violates the Mandatory requirements of Section 32(3)(B) (Provisos)

As such further proceeding by the Drug Inspector are without Lawful authority and without Jurisdiction.

6. That the proceedings against M/s. Venus Pharma are unlawful; illegal; without Lawful Justification as such unsustainable under the Law and the constitution of Islamic Republic of Pakistan 1973.

It in humbly requested that, in the light of above facts and applicable Law, the show Cause Notice may kindly be withdrawn and proceedings against M/s. Venus Pharma may be dropped.

4 Personal Hearing Notice issued to accused person(s) dated 23-10-2023

PREVIOUS PROCEEDING & DECISION BY THE BOARD

5 Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **271st meeting** held on **01-11-2023** under the chairmanship of Vice chairperson. Mr. Sarfraz Ali Secretary DQCB, Pakpattan vial zoom link attended meeting and Dr Liaqat Provincial Inspector of drugs Tehsil Arifwala was present along with original case record. Among the nominated accused person, Adnan Tahir (Quality Control Manager) of M/s Venus Pharma, 23-Km Multan Road Lahore-Pakistan appeared before the Board and submitted written request of adjournment vide letter dated 25-10-2023 that counsel of the firm is not available.

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

7 Personal Hearing Notice issued to accused person(s)

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 8

PQCB/R-783/2021

Tehsil Dera Ghazi Khan (Rural) District Dera Ghazi Khan

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. 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 Dera Ghazi Khan (Rural), District Dera Ghazi Khan reported that:-

i. The then drug inspector, on 02-10-2021, inspected the business premises of M/s Baloch Medical Store Jhoke Road Kot Chutta Dera Ghazi Khan, took sample 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. 0000108750 dated 08-10-2021.

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

iii. M/s Baloch Medical Store Jhoke Road Kot Chutta Dera Ghazi Khan submitted Invoice/warranty No. 440 dated 15-09-2021 issued by M/s Venus Pharma, 23-km, Multan Road, Lahore-Pakistan as a proof of its purchase of the said drug.

iv. Warrantor Portion of the drug sample was sent to M/s Venus Pharma, 23-km, Multan Road, Lahore-Pakistan and they were asked to provide requisite information in this regard.

v. A copy of test report was sent to M/s Venus Pharma, 23-km, Multan Road, Lahore-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 Committee of Provincial Quality Control Board in its 241st meeting held on 31-03-2022, after due deliberation and discussion unanimously decided to **turn down the subject request for retesting of the sample** and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

Name of drug	**Batch No.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Dexamethasone	DS-	M/s Venus	TRA No. 01-	**Result of Test/ Analysis with specifications applied:** USP

<table>
<tr>
<td>(Dexamethasone sodium phosphate equivalent to dexamethasone phosphate 4mg/ml) Injection 1 ml

Mfg.date:

Aug-2021

Exp. date:

Aug-2023

Regn No.

012089</td>
<td>0821W</td>
<td>Pharma, 23-km, Multan Road, Lahore-Pakistan</td>
<td>94000106/DTL

Dated:-26-11-2021</td>
<td>2021

<u>Description:</u> Colorless solution filled in sealed and transparent glass ampoule with yellow printed label and red neck ring in a labeled outer hard carton. 25 ampoules holding in beehives are packed in a unit outer hard carton (25*1ml Ampoules).

<u>Visible Particles:</u>

<u>Stated:</u> “Inspected units must be free from visible particles when examined without magnification against a black background and against a white background approximately for 05 seconds”.

<u>Determined</u>: “When examined against white and black background, 03 (three) out of 20 ampoules contain visible particles”.

(DOES NOT COMPLY)

<u>Extractable Volume</u>: Limit: NLT stated

Determined: 1.06 ml (Complies)

<u>PH:</u> Limit: 7.0-8.5

Determined: 7.72 (Complies)

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

<u>Identification:</u> Dexamethasone sodium phosphate identified.

<u>Assay:</u> Dexamethasone phosphate

<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>4mg/ml</td><td>4.08mg/ml</td><td>102.24%</td><td>90-115%</td></tr>
</table>
(Complies)

<u>RESULT:</u> The above sample is <u>Substandard</u>, on the basis of visible particles.</td>
</tr>
</table>

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

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

3. Show cause notice(s) issued to accused person(s) dated 23-08-2023.

Reply of firm to show cause notice vide letter dated 08-09-2023

REPLY TO THE SHOW CAUSE NOTICE No. POCB/R-783/20211

TEST REPORT No. 01-94000106/DTL DATED: 26/11/2021 DEXAMETHASONE Iml INJECTION BATCH No. DS0821W.

With Due Respect:

(1) FIRST:QURAN AND SUNNAH

SECOND:CONSTITUTION OF PAKISTAN, 1973.

THIRD:THE DRUGS ACT 1976 AND CASE LAW.

FOURTH:Pharmacopias.

FIFTH:TEST REPORT: SUBJECT TO SECTION 11(5) (b) (c) DRUGS ACT 1976.

(2) UNFORTUNATELY PQCB, PUNJAB (without merits) NEVER CONSIDER THE QURAN: SUNNA'H; 1973 CONSTITUTION THE LAW: CASE LAW: SECTION 11(5) (b) (e) DRUG ACT 1976:

PQCB PUNJAB,FAR AWAY FROM THE INJUNCTIONS OF ISLAM AND ISLAMIC TEACHINGS.

PQCB PUNJAB, NOT AWARE ABOUT ARTICLES 4: 5: 9, 10-A OF 1973 CONSTITUTION.

PQCB PUNJAB NOT KNOW THE APPLICATION OF SECTION 11(5)(b)(e) OF DRUGS ACT.

PQCB PUNJAB NOT CONSIDER THE CASE LAW, THE PRINCIPLES OF LAW LAID DOWN BY THE SUPREME COURT AND THE HIGH COURTS VIOLATE ARTICLE 189 AND 201 OF 1973 CONSTITUTION.

(3) SHOW CAUSE NOTICE No. POCB/R-783/2021 DATED 21/08/2023, ISSUED, DR. MUHAMMAD MUNAWAR HAYAT AS SECRETARY, POCB PUNJAB, WITHOUT LAWFUL JUSTIFICATION: WITHOUT JURISDICTION, WITHOUT TAKING INTO CONSIDERATION THE ABOVE REFERRED PROVISIONS OF CONSTITUTIN AND LAW,

FOR THE REASONS:

(a) POWERS of the PQCB under Sub-Section (5) (b) (e) only can be exercised by the Board. Not by any other official or Authority.

(b) The PQCB without scrutinizing the Report:

(i) of Drug Testing Laboratory and

(ii) of Drug Inspector.

Cannot decide any matter and cannot pass an order.

(4) In Para 2 of the notice under the column of DTL Test Report Result. According to the Test or Analysis:-

VOLUME: Complies, (Pass) 100% upto Standard

PH (B.P): Complies, (Pass) 100% upto Standard

STERILITY (B.P):Complies, (Pass) 100% upto Standard

IDENTIFICATION (B.P):Complies, (Pass) 100% upto Standard

ASSAY (B.P):Complies, (Pass) 100% upto Standard

Whereas, the sample was declared Sub-Standard unlawfully; illegally; without lawful Authority and without Jurisdiction with malice and for the achievements of ulterior motives, even the Bahawalpur and Multan DTL 's are fully prejudice towards the Pharma Industries in Lahore Particularly. The Govt. Analyst having no Authority Under the Law, for Observations.

(5) That it is also unfortunate aspect that the Drug Inspectors and the Government Analyst in Punjab not only subordinates and favorite persons. Even given full favor and protection of their unlawful acts" by PQCB under the Chairmanship of Chairman Chairperson, to whom all are subordinate directly or impliedly.

(6) PQCB, unlawfully conform the illegal, fake Test Report of so called Govt. Analyst Such Test Report rightly held as "MALICE IN LAW" by the Honorable Division Bench of Lahore High Court, Lahore while dismissed the Inter Court Appeals of PQCB, PUNJAB, which Judgment is still binding on PQCB, PUNJAB, and is final, why this POCB Not follow the Judgment Including the order of Peshawar. Quetta and Karachi High Courts

(7) The PQCB, Punjab not taken into consideration the submission and documents submitted by M/s. Venus Pharma and received, by the PQCB, Panjab

How PQCB included the reasons which are not part of the documents submitted by the particles. Why irrelevant references are given to protect the unlawful and illegal Report of DTL Multan who is prejudice against the Pharma Unit, of Lahore, and why fearful from sending the samples for Re-Test under Section 22(5) of the Act.

(8) How the Secretary, PQCB, Punjab, having divine powers which are incorporated in the so-called orders signed by Dr. M. Munawar Hayat, Drug Inspector as Secretary PQCB who was also given the Powers of Govt. Analyst/Director DTL Having no Power to interfere into PQCB proceedings, why allowed to interfere as such Show Cause Notice is without Lawful Authority. Not appointed Secretary, PQCB, under the law, the Drug Act 1976, whereas, under the Rule making Power Secretary PQCB cannot be appointed?

(9) In the circumstances, the DTL Test Report No. 01-94000106/DTI. Multan Dated: 26/11/2021 is at the face of it is unlawful and illegal cannot be used as evidence against M/s. Venus Pharma for clear violations, Even, the Person who signed the Impugned Test Report ever appointed as Provincial Govt. Analyst as required under Section 16 of the Drugs Act 1976, if so Please Provide the copy of Gazette Notification.

(10) The PQCB, Punjab, consist of How many Chairman and Members? Lawful or unlawful; Law knowing or not, however during meeting always observed when ever appeared in the meeting that about 30/35 persons, ladies and gents found sitting, why? in what capacity, such proceedings cannot be presumed as the Proceeding of a lawful PQCB, Punjab in such circumstances, How such PQCB. Punjab can listen and decide the cases independently. The contents of such orders are without consideration of submissions made on behalf of the Companies. The Boards are Chairman, Members and only Secretary No one else.

(11) The PQCB, must be agree with the law, that after the challenge of DTL Test Report under Section 22(4) for Re-Test u/s 22(5) the DTL Test Report Becomes ineffective. As Such, now. Presently No Test Report is in the field to use against M/s. Venus Pharma.

(12) All the replies to Drug Inspectors in connection with this case Please, consider as integral part of this Reply. The copies requested that be provided yet not provided. Please provide all the relevant documents related with the case, Including the Report of Drug Inspector u/s 19(6) of the Drug Act, the Order under section 11(1), (2) and (3) of the Drugs Act 1976, copies of Gazette Notification u/s 16 of related Govt. Analyst.

It is requested in the circumstances that entire Proceedings against M/s. Venus Pharma being without Lawful Authority liable to be Vitiated, as Such dropped the entire Proceedings to meet the ends of Justice. Show Cause Notice No. PQCB/R-783/2021 Dated 23/08/2023 be recalled and entire proceeding be dropped

SHAIKH MUHAMMAD NAWAZ Advocate

FOR VENUS PHARMA

4. Personal Hearing notice(s) issued to accused person(s) dated 23-10-2023.

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 271st meeting held on 01-11-2023 under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab. Mr. M. Asif Abbas, Secretary DQCB, District Dera Ghazi Khan attended the meeting online via zoom link and Mr. Muhammad Farhan, Drug Inspector Tehsil Dera Ghazi Khan (Rural), District Dera Ghazi Khan was present along with the original case record. Among the nominated accused persons Adnan Tahir, Quality Control Incharge of **M/s Venus Pharma, 23-KM, Multan Road, Lahore-Pakistan** appeared before the Board and submitted written request for adjournment vide letter dated 25-10-2023 stating that Counsel of the firm is not available.

6. 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 but final opportunity of personal hearing to the accused persons.

7. Personal Hearing notice(s) issued to accused person(s) dated 11-12-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: Aug-2021**
- **Expiry Date: Aug-2023**
- **Sampling Date (Form 4): 02-10-2021**
- **Sent to DTL (Form 6): 08-10-2021**
- **Date of receipt in DTL: 08-10-2021**
- **DTL Report Date (Form 7): 26-11-2021**
- **Time Extension: NA**
- **1ST DI Communication with firm on dated: 16-12-2021**
- **Date of Retesting Request of Firm: 22-12-2021**
- **Fate of Retesting: Turned down in 241st meeting dated 31-03-2022**
- **Investigation Report Dated: 19-04-2023**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 9

PQCB/R-306/2022

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

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. Adnan Tahir — Quality Control Incharge 4. Malik Muhammad Asif — Production Incharge Of **M/s Venus Pharma, 23-KM, Multan Road, Lahore-Pakistan** 5. Muhammad Irshad Hussain — Proprietor 6. Muhammad Saleem Akhtar — Qualified Person Of **M/s Masha Allah Medical Store Peer Qatal Road Dera Ghazi Khan.**

BRIEF FACTS OF THE CASE

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

i. He, on 12-11-2021, inspected the business premises of M/s Masha Allah Medical Store Peer Qatal Road Dera Ghazi Khan and took sample 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. 0000110898 dated 13-11-2021.
ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:
iii. M/s Masha Allah Medical Store Peer Qatal Road Dera Ghazi Khan submitted Invoice/warranty No. 729 dated 01-11-2021 issued by M/s Venus Pharma, 23-KM, Multan Road, Lahore-Pakistan as a proof of its purchase of the said drug.
iv. Warrantor Portion of the drug sample was sent to M/s Venus Pharma, 23-KM, Multan Road, Lahore-Pakistan and they were asked to provide requisite information in this regard.
v. A copy of test report was sent to M/s Venus Pharma, 23-KM, Multan Road, Lahore-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 246th meeting held on 05-07-2022, 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>B-Complex (B1…10mg/ml, B2…2mg/ml, B6…5mg/ml, Nicotinamide…75mg/ml, Pantothenic acid…5mg/ml) Injection 2 ml.

Mfg.date:

Sep-2021

Exp. date:

Sep-2023

Regn No.

014721</td>
<td>H-38921</td>
<td>M/s Venus Pharma, 23-KM, Multan Road, Lahore-Pakistan</td>
<td>TRA No. 01-94000598/DTL

Dated:-08-03-2022</td>
<td><u>Result of Test/ Analysis with specifications applied:</u> MS

<u>Description:</u> Light yellow to yellow color solution filled in sealed, amber glass ampoule of 2 ml with printed label and yellow color neck ring packed in a labeled outer hard carton. Each outer carton contains 25 ampoules of 2 ml i.e. (2 ml * 25 Ampoules).

<u>Visible Particles:</u>

Stated: ‘’Inspected units must be free from visible particles when examined without magnification against a black background and against a white background approximately for 05 seconds’’

Determined: ‘’When examined against white and black background, 14 out of 20 ampoules contain visible particles.’’

(DOES NOT COMPLY)

<u>Extractable Volume</u>: Limit NLT stated

Determined: 2 ml (Complies)

<u>PH</u>: Limit: 4.0-5.0

Determined: 4.68 (Complies)

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

<u>Identification</u>: Thiamine HCl, Pyridoxine HCl, Riboflavin and Nicotinamide Identified.

<u>Assay:</u>

Thiamine
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>10 mg/ml</td><td>9.90 mg/ml</td><td>99.02%</td><td>90-110%</td></tr>
</table>
(Complies)

Pyridoxine HCl</td>
</tr>
</table>

Stated	Determined	Percentage	Limit
5 mg/ml	4.93 mg/ml	98.65%	90-110%

(Complies)

Nicotinamide

Stated	Determined	Percentage	Limit
75 mg/ml	73.88 mg/ml	98.51%	90-110%

(Complies)

Riboflavin

Stated	Determined	Percentage	Limit
2 mg/ml	2.15 mg/ml	107.3%	90-110%

(Complies)

RESULT: The above ample is declared **Substandard,** on the basis of Visible Particles.

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

Names of accused persons	**Offences**
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. Adnan Tahir Quality Control Incharge 4. Malik Muhammad Asif Production Incharge Of **M/s Venus Pharma, 23-KM, Multan Road, Lahore-Pakistan**	a. **Manufacture for Sale /Sale of Substandard Drug** b. **Issuance of false warranty**
5. Muhammad Irshad Hussain Proprietor	a. **Stocking for**

6. Muhammad Saleem Akhtar Qualified Person Of **M/s Masha Allah Medical Store Peer Qatal Road Dera Ghazi Khan.**	**sale/ sale of Substandard drug** b. **Delayed submission of Invoice/ Warranty**

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

Reply of firm to show cause notice vide letter no. nil dated 27-04-2023:

Subject: REPLY TO THE SHOW CAUSE NOTICE NO.PQCB/R-306/2022 DATED: 06.02.2023 IS UNLAWFUL IN CONTINUATION OF SO CALLED ORDER DATED: 05.07.2022, "TURNED DOWN THE REQUEST FOR RE-TEST" UNDER SECTION 22(5) OF THE DRUGS ACT 1976 WHILE EXERCISE THE DISCRETIONARY POWERS, TEST REPORT NO.TRA 01-94000598 MULTAN DATED: 08.03.2022.

With due Respect submitted that:-

So called Order dated 05.07.2022 written by a story writer with irrelevant references showing the prejudice mind of the writer or PQCB, Punjab.

Under the law viz the Drugs Act 1976, the Show Cause Notice under reply, is without lawful authority and without jurisdiction, having no legal value:-

(1) THE CONSTITUION OF ISLAMIC REPUBLIC OF PAKISTAN 1973 BOUND DOWN THIS BOARD ALSO IN THE WORDS:-

"Obedience to the Constitution and Law is the inviolable obligation of every citizen wherever he may be....."

including every Member, Chairman, Secretary etc. of this Board.

(2) THE CONSTITUTION OF ISLAMIC REPUBLIC OF PAKISTAN 1973 BOUND DOWN INCLUDING THIS BOARD THAT:-

"No action detrimental to the life, liberty. body, reputation or property of any person shall be taken except in accordance with law....."

(3) THE CONSTITUTION OF ISLAMIC REPUBLIC OF PAKISTAN 1973 BOUND DOWN ALL THE SUBORDINATE COURTS AND AUTHORITIES INCLUDING THIS BOARD, OF ALL THE ORDERS, DECIDES A QUESTION OF LAW OR ENUNCIATES A PRINCIPLE OF LAW SHALL BE BINDING ON THIS BOARD ALSO."

It is expected and presumed that, THIS BOARD DEFIDATLY AWAIR about EACH AND EVERY WORD OF THE DRUGS ACT 1976 AND THE CONSTITUTION FOR FAIR AND INDEPENDENT DECISIONS, IN ACCORDANCE WITH LAW

"IGNORANCE OF LAW IS NO EXCUSE"

THE SHOW CAUSE NOTICE NUMBER PQCB/R-306/ 2022 DATED 06.02.2023 (BASED ON TEST REPORT NO.TRA 01-94000598/DTL, DATED 08.03.2022). DISCLOSING / INDICATING CLEAR VIOLATIONS OF MANDATORY REQUIREMENTS OF THE DRUGS ACT 1976, THE 1973 CONSTITUTION AND PRINCIPLES OF LAW SETTLED AND LAID DOWN BY THE HONOURABLE SUPREME COURT OF PAKISTAN FOLLOWED BY THE HONOURABLE HIGH COURTS OF PAKISTAN, HAVING THE BINDING FORE FOR, PQCB, PUNJAB.

THE SHOW SHOW CAUSE NOTICE IS WITHOUT APPLICATION OF LAW; FACTS AND FAIR AND INDEPENDENT MIND, LIABLE AND REQUIRED TO BE QUASHED FOR THE FOLLOWING AMONGST OTHER:-

REASONS:

(a) Para 1(ii) of Show Cause Notice indicating violation of Section 22(2), 22(3), 22(4). 22(5) and Section 16 of the Drugs Act, 1976.

(b) Para 1(iii) of Show Cause Notice indicating violation of Section 19(3) read with Section 32(3) of the Drugs Act, 1976.

(c) Para 1(vii) of Show Cause Notice indicating violation of Section 22(4) of the Drugs Act, 1976.

(d) Pare 2(a)(b) of Show Cause Notice indicating violation of Sections 11(5)(b): 23/27 of Drugs Act read with Section 24-A of General Clauses Act.

(e) Violation of para / clauses 5 and 6 of FORM 7.

(f) Violation of Section 11(5)(b) read with Section 19(6) and Section 22(5) of the Drugs Act, 1976.

(g) Violation of Rule 20(8) OF THE Punjab Drug Rules, 2007.

(h) PQCB, Punjab relied upon Test Report No.TRA 01-84000598/DTL dated 08.03.2022 against the law laid down by the Honourable Single Judge of the Honourable Lahore High Court, Lahore declared such Reports having no legal value, then the PQCB, Punjab file appeal in the Lahore High Court, Lahore and the Honourable Division Bench of the Lahore High Court, Lahore pleased to dismiss the appeal of this PQCB, Punjab wherein clearly HELD that such Test Reports are:-

"MALICE IN LAW"

That Judgment having the binding force on PQCB, Punjab and all the Govt. Analyst committed the contempt of Honourable Lahore High Court, Lahore. The Honourable Peshawar High Court; Balochistan High Court and Karachi High Court also held such Reports in clear violation of law.

Alongwith contempt of Honourable High Courts, the Govt. Analyst and all others supporting such Reports are punishable under Section 27(5) of the Drugs Act, 1976.

Note: Violation of one mandatory provision of law, Vitiates Quashed the entire proceedings, as principle of law settled by the Honourable Supreme Court of Pakistan, and "THE IGNORANCE OF LAW IS NO EXCUSED,"

(4) Section 27(4) of the Drugs Act 1976 read with Schedule VI of the DRAP Act 2012,

"..... whoever ..... contravenes any of the provisions of this Act or the Rules shall be punishable with imprisonment..... and with fine…" and under Section 27(5) of the Drugs Act 1976, if a Provincial Inspector or an official of the Provincial Drug Testing Laboratory:-

(a) is guilty of any willful breach or neglect any provision of this Act or the Rules.....

(b) (c) (d)

"Shall, without prejudice to any other action in accordance with law, be liable to imprisonment for a term which may extend to three years not less than Six months and with find.....

IMPORTANT and ESSENTIAL:

In para 1(iv) of the Show cause Notice, contravention of Drug Act 1976 is clearly admitted and clear breach of the Provision of Drug Act 1976 also claimed as such the concerned Drug Inspector and all others who support this contravene and the breach of law are punishable under Sub-Section (4) of Section 27 and Sub-Section (5) of Section 27 of the Drugs Act 1976..

(5) How, Secretary, PQCB, Punjab, can use the words in para 2 of the Show Cause Notice that "Company have contravened the Provisions of Section 23/27 of the Drugs Act." which means Secretary, PQCB. Punjab already decided for serious actions against the facts and applicable law and case law.

Whereas, legal action is required under the law against all the persons who committed the violation of law, the mandatory requirements of law, and all others who give coverage and support such contraventions as submitted above.

(6) In reply to para 3 of your Show Cause Notice, it is submitted:

(1) Secretary PQCB. having No lawful authority and Jurisdiction to issue the Show Cause Notice as such the Show Cause Notice under reply is without lawful authority and without Jurisdiction, for this reason the proceedings against M/s Venus Pharma are without Jurisdiction.

(ii) In para 3(i) of your Show Cause Notice, How Secretary, PQCB confirm the contravention? Whereas, No contravention committed by M/s Venus Pharma Specially when the allegation based on guise and surmises. And the violations of mandatory requirements of law committed by the Drug Inspector; The Government of Punjab, The Govt. Analyst etc. Therefore, No action under any of the Provision of Law can be initiated/ taken against M/s Venus Pharma.

(iii) This Board / PQCB Punjab proceedings under Section 11(5)(b) of the Drugs Act 1976. Under Section 11(5)(b) of the Drugs Act 1976, PQCB having No lawful authority and Jurisdiction as mentioned in para 3(ii) of the Show Cause Notice.

(iv) Respected Secretary PQCB. Punjab, para 3(iii) of your Show Cause Notice is unwarranted by law

Therefore, para 3(i), (ii) and (iii) disclosing the prejudice mind of the Secretary, PQCB. And such designation given to a Drug Inspector is against the settled principle i.e A Drug Inspector is not a fit person for the job of Secretary, PQCB

(7) The Show Cause Notice No PQCB/ R-306/2022 dated 06.02.2023 is without lawful authority, without jurisdiction, unlawful, illegal, without lawful jurisdiction and unsustainable under the law

In the circumstances entire proceedings against M/s Venus Pharma are unlawful, illegal, without lawful authority and without jurisdiction, as such the Show Cause Notice under reply is liable to be withdrawn and proceeding against M/s Venus Pharma are also liable to be dropped, it is also prayed that legal action / prosecution be initiated against the Drug Inspector and other responsible persons, including the Secretary, PQCB to meet the ends of justice.

Shaikh Muhammad Nawaz Advocate,

For M/s Venus Pharma, Lahore.

4. Personal Hearing notice(s) issued to accused person(s) dated 23-10-2023.

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 **271st** meeting held on **01-11-2023** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab. Mr. M. Asif Abbas, Secretary DQCB, District Dera Ghazi Khan attended the meeting online via zoom link and Mr. Faisal Mahmood Khan, Drug Inspector Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan was present along with the original case record. Among the nominated accused persons Adnan Tahir, Quality Control Incharge of **M/s Venus Pharma, 23-KM, Multan Road, Lahore-Pakistan** appeared before the Board. Among the nominated accused persons Muhammad Irshad Hussain, Proprietor of **M/s Masha Allah Medical Store Peer Qatal Road Dera Ghazi Khan** appeared before the Board. Representative of the firm submitted written request for adjournment was received vide letter dated 25-10-2023 that

Counsel of the firm is not available.

6. 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 but final opportunity of personal hearing to the accused persons.
7. Personal Hearing notice(s) issued to accused person(s) dated 11-12-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: Sep-2021**
- **Expiry Date: Sep-2023**
- **Sampling Date (Form 4): 12-11-2021**
- **Sent to DTL (Form 6): 13-11-2021**
- **Date of receipt in DTL: 17-11-2021**
- **DTL Report Date (Form 7): 08-03-2022**
- **Time Extension: Granted in 238th meeting dated 09-02-2022**
- **1ST DI Communication with firm on dated: 28-03-2022**
- **Date of Retesting Request of Firm: 07-04-2022**
- **Fate of Retesting: Turned down in 246th meeting dated 05-07-2022**
- **Investigation Report Dated: 26-12-2022**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 10

PQCB/R-151/2021

(DHQ Teaching Hospital Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Kohinoor Industries, 160-B, S.I.T.E. Sahiwal, Pakistan** through its Managing Director, Noman Shahid. 2. Noman Shahid Managing Director 3. Nadeem Akram Warrantor 4. Naveed Iqbal Abid Quality Control Incharge 5. Hafiza Hina Ashraf Production Incharge **of M/S Kohinoor Industries, 160-B, S.I.T.E. Sahiwal, Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He, on 25-05-2021, inspected the premises of Main Medicine Store DHQ Teaching Hospital, District Sahiwal and took one drug sample on Form No. 04 for the purpose of test and analysis.
ii. Following drug samples, after test/ analysis, was declared **Substandard** by Government Analyst Drug Testing Laboratory, **Bahawalpur** as detailed below:

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report

TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Medi Gauze [30cm x 30cm. 4Ply]</td><td>730123</td><td>M/s Kohinoor Industries, 160-B, S.I.T.E Sahiwal, Pakistan</td><td>01-25007434/DTL

Dated. 23-06-2021</td><td>Analysis with specifications applied:

BP 2020/BPC 1973

<u>Description:</u> Medi Gauze consist of cotton cloth of plain weave folded into square in such a way that no cut edges are exposed and stiched around the open sides, bleached to good white, clean and reasonably free from weaving defects. Tape is stiched into one corner and at one side distinctly colored multi filament yarn is incorporated. (Stated=30cm x 30cm)

<u>Warp (BPC 1973):</u>

<table><tr><td>Limit</td><td>Avg 73/10cm (SD=1.33)</td></tr><tr><td>Determined</td><td>Avg 73/10cm</td></tr></table>
<u>Weft (BPC 1973):</u></td></tr>
</table>

Limit	Avg 57/10cm (SD=1.33)
Determined	Avg 54/10cm

Weight/Unit Area (BPC 1973):

Limit	**Avg 15gm/m^2 (SD=0.33)**
Determined	**Avg 20.61gm/m^2**

Does not comply with the specifications.

Sinking Time (BPC 1973):

Limit	Not more than 10 seconds
Determined	Avg 2 Seconds

Acidity/ Alkalinity (BPC 1973):

Limit	**Phenophthalein= No pink color** **Methyl Orange= Yellow color**
Determined	**Pink color appeared on addition of phenolphthalein. (Alkaline in nature).**

Does not comply with the specifications.

Sterility (BP 2020):

The Product is sterile.

Result:

The sample is declared **Substandard**, on the basis of **Acidity /Alkalinity and Weight per unit area test.**

iii. Store Keeper of Main Medicine Store DHQ Teaching Hospital, District Sahiwal provided Invoice/warranty No 01-21-1528 dated 24-05-2021 issued by M/s Kohinoor Industries, 160-B, S.I.T.E Sahiwal, Pakistan as a proof of its purchase.
iv. Warrantor portion of drug sample was sent to M/s Kohinoor Industries, 160-B, S.I.T.E Sahiwal, Pakistan.
v. A copy of test/analysis report was sent to M/s Kohinoor Industries, 160-B, S.I.T.E Sahiwal, Pakistan

and they were asked to provide the requisite information in this regard.

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

    a. **Manufacturing for sale / Stocking for sale/ selling of Substandard drug**
    b. **Issuance of false warranty**

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

REPLY OF SHOW CAUSE NOTICE:

It is further stated that, TRA No. 01-25007434-DTL. dated 23-06-2021 shows Gauze specs within range as wrap & weft are within limits, however alkalinity and acidity varied due to testing method, which was discussed in DTL. Bahawalpur and Multan as samples of water and testing solution was also taken there and test was performed and discussed. However, later unfortunately it was declared substandard. It is requested to retest the alkalinity as per standard.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **271st meeting** held on **01-11-2023** under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson). Mr. Ahmad Awais, Secretary DQCB District Sahiwal attended the meeting online via Zoom Link and Mr. Umair Majeed, Drug Inspector, DHQ Teaching Hospital Sahiwal was present along with original case record. No one among nominated accused appeared before the Board on the behalf of M/s Kohinoor Industries, 160-B, S.I.T.E. Sahiwal, Pakistan. The firm submitted a written request for adjournment in the office of the Secretary, Provincial Quality Control Board, Punjab.

6. The Board after discussion decided to **adjourn** the case on the request of the firm in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

Summary:

Manufacturing Date: 05.2021

Expiry Date: 05.2024

Sampling Date (Form 4): 25.05.2021

Sent to DTL (Form 6): 25.05.2021

Date of receipt in DTL: 28.05.2021

DTL Report Date (Form 7): 23.06.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 14.07.2021

Date of Retesting Request of Firm: No

Fate of Retesting Request: N/A

Investigation Report Dated: 16.08.2021

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

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 11

PQCB/R-563/2022

Teaching Hospital Dera Ghazi Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan** through its Managing Director Noman Shahid 2. Noman Shahid — Managing Director 3. Dr. Khurram Shehzad — Production Incharge/ Plant Manager 4. Naveed Iqbal Abid — Quality Control Manager 5. Muhammad Nadeem Akram — Warrantor Of **M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Teaching Hospital Dera Ghazi Khan reported that:-

i. He, on 21-12-2021, inspected the premises of Surgical Main Store Teaching Hospital Dera Ghazi Khan, 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. 0000113632 dated 21-12-2021.
ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:

iii. Store Keeper, Surgical Main Store Teaching Hospital Dera Ghazi Khan submitted Invoice/warranty No. 12-21-1532 dated 19-12-2021 issued by M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan as a proof of its purchase of the said drug.
iv. Warrantor Portion of the drug sample was sent to M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan and they were asked to provide requisite information in this regard.
v. A copy of test report was sent to M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-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 245th meeting held on 16-06-2022, 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.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results

Kohinoor Leader Absorbent Cotton Wool 500g **Mfg.date:** Dec-2021 **Exp. date:** Dec-2024 **Regn No.** 005416	105474	M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan	TRA No. 01-94001223/DTL Dated:-03-02-2022	**Result of Test/ Analysis with specifications applied:** BPC 1973 **Description:** **Stated:** Well-carded cotton fibres bleached to good white, free from pieces of thread and reasonably free from leaf, shell and foreign matter. It does not shed any appreciable quantity of dust when gently shake. **Sinking Time**: Limit: NMT 15 seconds (BPC/MOH) Determined: 13.33 seconds **(Comply)** **Water Holding Capacity**: Limit: NLT 20g/g (BPC/MOH) Determined: 20.541 g/g (Comply) **Alkalinity: Limit: Should show no pink color with phenolphthalein indicator. (BPC/MOH)** Determined: Filtrate gives pink color with phenolphthalein indicator. **(Does not comply)** **Acidity: Limit: Should show yellow color with methyl orange (BPC/MOH)** Determined: Filtrate gives yellow color with methyl orange indicator **(Comply)** **RESULT:** The above sample is **Sub-Standard** on the basis of test performed.

2. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (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 18-09-2023.

Firm's letter no. KCi/91073 dated 30-09-2023

Request for grant to Revision Petition against order dated 18-09-2023

Case No. POCB/R-563/2022

Respectfully state that the

The respected Board decided to Turn Down our retesting request vide letter no. KCL63105 on dated 17-02-2023. In the 245" meeting held on 16-06-2022 and our Production Incharge of Kohinoor Industries was present before the respected board & argued that we have tested this product Absorbent Cotton Wool (BPC) 500 gm under batch no. 105474 with complete Test Protocol & with procedural details & found its standard quality as

per BPC Specs in all parameters even in Alkalinity test & no pink color produce with phenolphthalein indicator, but it is a big agitate for us after receiving this DTL report to shows that sinking time is not meeting as per BPC Standard & fluorescence was observed in TRA No. 01- 94001223/DTI.. Hence we have received standard quality DTL reports though out all DTL Labs of Province. (Reports attached)

That the balance of convenience also lies in favor of the Applicants. Please review the petition & accept our stance that our products Lender Absorbent Cotton Wool having batch no. 105474 are fit for external use & give us warring under this Order No. PQCB/R-563/2022. In future we will remain more vigilant under these regards.

4. Personal Hearing notice(s) issued to accused person(s) dated 07-11-2023.

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 **272nd meeting** held on **22-11-2023** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department/Vice Chairperson PQCB. Mr. M. Asif Secretary DQCB, Dera Ghazi Khan attended the meeting online via zoom link and Mr. Faisal Mehboob, Drug Inspector Teaching Hospital Dera Ghazi Khan was present along with original case record. No one among the nominated accused person of **M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan** was present. However a written request for adjournment was received vide letter no. Ref.No: DCI/96107 dated 20-11-23.

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

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 12-2021**
- **Expiry Date: 12-2024**
- **Sampling Date (Form 4): 21-12-2021**
- **Sent to DTL (Form 6): 21-12-2021**
- **Date of receipt in DTL: 28-12-2021**
- **DTL Report Date (Form 7): 03-02-2022**
- **Time Extension: NA**
- **1ST DI Communication with firm on dated: 10-02-2022**
- **Date of Retesting Request of Firm: 17-02-2022**
- **Fate of Retesting: Turned Down in 245th meeting dated 16-06-2022**
- **Investigation Report Dated: 11-05-2023**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 12

PQCB/R-602/2021

(Tehsil Chichawatni, District Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Jaens Pharmaceutical Industries, 28km, Lahore-Sheikhupura Road Sheikhupura, Pakistan** through its Director Syed Javed Ali. 2. Syed Javed Ali — Director 3. Anjum Saeed — Production Incharge 4. Syed Shahbaz Ali Shah — Quality Control Incharge/ Warrantor 5. Muhammad Irshad — Marketing Incharge **of M/S Jaens Pharmaceutical Industries, 28km, Lahore-Sheikhupura Road Sheikhupura, Pakistan.**

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 28-09-2021, inspected the business premises of M/S Goheer Medical Store, Adda 90-More Tehsil Chichawatni, District Sahiwal and took subject drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo. No.0000108090, dated. 29-09-2021.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Drops. Predsin Eye Suspension [Prednisolone Acetate 5mg U.S.P, Chloramphenicol BP 2mg] **Mfg Date:** April-2021 **Exp Date:** April -2023	Y0161	M/S Jaens Pharmaceutical Industries, 28km, Lahore-Sheikhupura Road Sheikhupura, Pakistan	01-85000147/DTL Dated. 27-11-2021	**Analysis with specifications applied: USP 2020/MS.** **Composition:** Each ml contains: Prednisolone Acetate U.S.P……..5mg Chloramphenicol B.P……2mg **Description:** Pale Yellow Color liquid in dropper plastic bottle packed in outer carton. (Stated Volume is 10ml).

Registration No.

032637

pH (MS):

Limit	5.5-7.5
Determined	6.723

Sterility (USP):

The product is sterile.

Identification (MS):

Chloramphenicol and Prednisolone Acetate are identified.

Assay (MS):

Chloramphenicol:

Stated	2mg/ml
Determined	**2.5186mg/ml**
Percentage	**125.93%**
Limit	90-110%

Prednisolone Acetate:

Stated	5mg/ml
Determined	**5.7665mg/ml**
Percentage	**115.33%**
Limit	90-110%

Does not complies with the applied specifications.

Result:

The sample is declared **Substandard** on the basis of **Assay Test of Chloramphenicol and**

				Prednisolone Acetate.

iii. M/S Goheer Medical Store, Adda 90-More Tehsil Chichawatni, District Sahiwal provided Invoice/warranty No S0B-0065353, dated 16-09-2021 issued by M/S Naeem Medicine, 123-H Burewala who inturn provided invoice/warranty No. 1046, dated. 30-04-2021 issued by M/S Jaens Pharmaceutical Industries, 28km, Lahore-Sheikhupura Road Sheikhupura, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Naeem Medicine, 123-H Burewala and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Jaens Pharmaceutical Industries, 28km, Lahore-Sheikhupura Road Sheikhupura and they were asked to provide the requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>NIH Test Report No.</th><th>NIH Test Report Result</th></tr>
<tr><td>Eye Suspension Predsin 10ml</td><td>Y0161</td><td>M/S Jaens Pharmaceutical Industries, 28km, Lahore-Sheikhupura Road Sheikhupura, Pakistan</td><td>0153-P/2022 dated 17-08-2022</td><td>Analysis with specifications applied:

MS

<u>Assay:</u>

<u>Prednisolone Acetate:</u>

<table>
<tr><td>Stated</td><td>5mg/ml</td></tr>
<tr><td>Found</td><td>2.682mg/ml</td></tr>
<tr><td>Limit</td><td>90-120%</td></tr>
<tr><td>Percentage</td><td>53.64%</td></tr>
</table>

<u>Chloramphenicol:</u>

<table>
<tr><td>Stated</td><td>2mg/ml</td></tr>
<tr><td>Found</td><td>3.3236mg/ml</td></tr>
<tr><td>Limit</td><td>90-130%</td></tr>
</table>
</td></tr>
</table>

				Percentage	**166.18%**
				Does not comply with manufacturer specifications. **Remarks:** The sample is of Substandard quality on the basis of test performed.	

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

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

a. **Issuance of false warranty**

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

REPLY OF SHOW CAUSE NOTICE:

With reference to your letter bearing no. PQCB/R-602/2021 dated 15-11-2022, received to us on 30-11-2022, on the subject captioned above wherein we are directed **to explain our position** and submit **certain documents/information** regarding quality of Drop "**Predsin Eye Suspension**" bearing batch no. Y0161 (hereafter referred as **the product sampled**) manufactured by M/S JAENS Pharmaceutical Industries (Pvt.) Ltd. declared substandard by Government Analyst NIH vide test report no. 0153-P/2022 dated 17-08-2022 (hereafter referred as **the Impugned NIH report**) on the basis of assay.

In this regard, it is humbly submitted that:

REPLY + EXPLANATION by M/S JAENS Pharmaceutical Industries (Pvt.) Ltd. through its Chief Executive Officer:

1. M/S JAENS Pharmaceutical Industries (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. Our product Drop "**Predsin Eye Suspension**" got registered in June 2004 and since then we have produced 327 batches and no complaint regarding quality of the product has been received till now except this one.

Detail of manufactured batches is attached herewith as Annexure A

3. As far as the allegation of substandard nature of the product sampled is concerned, the Batch Manufacturing Record prepared at the time of manufacturing of the product sampled by the Production department of The Company headed & operated. with full independence & sole responsibility by the Production Incharge depicts that they got issued the Active Pharmaceutical Ingredients i.e. Prednisolone Acetate & Chloramphenicol in the standard described quantity as per manufacturing order and used the same quantity in production of the product sampled. So use of less amount of API of

Prednisolone Acetate and excess amount of Chloramphenicol in the manufacturing of the product sampled in out of question.

Copy of raw material stock register, Production/ Manufacturing Order, & dispensing card is attached herewith as Annexure **B, C & C1** respectively.

4. While the Quality Control department of The Company headed & operated with full independence & sole responsibility by the Quality Control Incharge tested all the required quality parameters of the said product during manufacturing at bulk stage and found the amount of Active Pharmaceutical Ingredients (APIs) at bulk stage of the product sampled within the prescribed limits.

Copy of analytical report of the product sampled at bulk stage along with the UV prints is attached herewith as Annexure D

5. It is also pertinent to mention here that at the time of batch release of the product sampled, the Quality Control department of The Company headed & operated with full independence & sole responsibility by the Quality Control Incharge tested all the required quality parameters of including assay and found them satisfactory as per MS requirements. Relying on these satisfactory reports, the product sampled was released to be sold.

Copy of Certificate of Analysis of finished product along with UV Prints is attached herewith as Annexure E.

6. Later on, upon the receipt of government analyst report DTL Bahawalpur vide TRA No 01-85000147/DTL Bahawalpur dated 27-11-2021, the Quality Control department of The Company headed & operated with full independence & sole responsibility by the Quality Control Incharge even tested retained sample of the product sampled kept under prescribed conditions in our well-equipped state of art quality control laboratory and found all the parameters including assay satisfactory as per MS requirements.

Copy of Certificate of Analysis of **retained sample** along with UV prints is attached herewith as Annexure F

7. 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 28-12- 2021 in respect of DTL Bahawalpur 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. 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 describing the appointment of the government analyst who prepared and signed the impugned NIH report in respect of the product sampled or such class of drugs or such area of jurisdiction. 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 notice. So the impugned DTL/NIH report is illegal, without lawful authority which has no essence in the eye of law and is inadmissible against The Company and its employees due to non appointment of government analyst who prepared and signed the impugned report within the meaning of the Drugs Act 1976.

ii. That the impugned NIH report is badly time barred as the sample of the product sampled was

received at NIH on 09-06-2022 while the impugned NIH report was issued on 17-08-2022 after 68 days of receipt of the sample of the product sampled in sheer violation of section 22(2) of the Drugs Act 1976. Hence the impugned NIH report is without lawful authority & jurisdiction as it doesn't meet the mandatory statutory requirement of section 22 of the Drugs Act 1976.

iii. The both reports i.e. DTL Bahawalpur report & the Impugned NIH report 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 the product sampled by the two government analysts is as follows:

Therapeutically active ingredient	**Government Analyst DTL Multan results**	**Chief-Appellate Laboratory NIH, Islamabad**
Prednisolone Acetate	115.33% Limit 90%-110%	53.64% Limit 90%-120%
Chloramphenicol	125.93% Limit 90%-110%	166.18% Limit 90%-130%

It is imperative to mention here that the grievance of The Company in respect of the DTL Bahawalpur report was only to the extent of the application of wrong specification limit range of Prednisolone Acetate and Chloramphenicol i.e. 90%-110% each ingredients by government analyst DTL Bahawalpur instead of 90%-120% and 90% -130% respectively.

Copy of DTL Bahawalpur report & method of analysis containing the product specifications is attached herewith as Annexure G & G1

Otherwise the results of assay, as determined by the government analyst DTL Bahawalpur, of the product sampled Le. Prednisolone Acetate and Chloramphenicol were well within the limits ie. 115.33% against the actual limit of 90%-120% and 125.93% against the actual limit of 90%- 130% respectively impliedly showing the product sampled of standard quality,

While the Federal Government Analyst vide the impugned NIH report determined the assay of the product sampled i.e. Prednisolone Acetate and Chloramphenicol 53.64% against the actual limit of 90%-120% and 166.18% against the actual limit of 90%-130% respectively not only entirely contrary to the results of the DTL Bahawalpur report but also in sheer violation of Rule 16 of Drugs (Federal Inspectors, etc.) Rules 1976.

As per Rule 16 of Drugs (Federal Inspectors, etc.) Rules 1976;

The Federal Government Analyst is duty bound to supply the result of test or analysis with full protocol of the test applied on form # 6.

But in the case in hand, as far as assay of the product sampled is concerned, the Federal Government Analyst didn't disclose the full protocol of assay test performed of Prednisolone Acetate and Chloramphenicol as follows:

- For the purpose of assay test, concentration of both standard and sample solution must be the same. Any deviation in the concentration of either solution will affect the result of assay test.

Prednisolone Acetate assay test:

- The federal government analyst did not disclose the amount of weighed quantity of the

product sampled taken by for the purpose of preparation of the sample solution which is not only sheer violation of rule 16 of Drugs (Federal Inspectors, etc.) Rules 1976 but also creates serious doubts that sample solution was not prepared by the analyst having same concentration as that of standard solution which resulted in low assay result of Prednisolone Acetate.

Chloramphenicol assay test:

- The federal government analyst did not disclose the amount of weighed quantity of the product sampled taken by for the purpose of preparation of the sample solution which is not only sheer violation of rule 16 of Drugs (Federal Inspectors, etc.) Rules 1976 but also creates serious doubts that sample solution was not prepared by the analyst having same concentration as that of standard solution which resulted in high assay result of Chloramphenicol.

Copy of The Impugned NIH report is attached herewith as Annexure H.

Thus Non provision of full protocol of test analysis by The Federal Government Analyst shakes the credibility of the result of assay test performed and makes the impugned NIH report faulty and illegal on account of its non conformity nature to mandatory requirement of Rule 16 of Drugs (Federal Inspectors, etc.) Rules 1976. So on the basis of defective & faulty federal government analyst report, the product sampled can't be termed/considered as substandard.

8. 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 product sampled taken on form # 4 was not provided by the Drug Inspector to the manufacturer/warrantor 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. 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. POCB 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.

iii. Without prejudice to all aforementioned arguments, it is also important to mention here that the product sampled bears storage condition as "store at cool temperature". While the concerned Drug Inspector at the time of sampling made on 28-09-2021 from M/S Goheer Medical store did not mention the storage temperature at which this product was stored there. He also did not observe/mention the storage condition of the product sampled at Provincial Quality Control Board where it was kept stored for the period of 9-10 months till its dispatch to NIH despite the results of both reports were totally at variance to each other. It is pertinent to mention here that the storage of any pharmaceutical product at prescribed temperature storage condition is critically important to maintain its physico-chemical properties/stability. Thus the alleged anomaly stated in

the impugned NIH report is most likely caused by the improper storage condition either at PQCB or NIH. Therefore the company cannot be held liable regarding the quality of the product stored at improper storage conditions.

9. 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 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.
10. **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. 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.

11. **That PARA 3 of SCN alleges that**

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

i. You should not be prosecuted for committing above said contravention(s) in the Drug Court.
ii. The licensing Authority/ Drug Registration Authority should not be recommended for cancellation/ suspension of your Drug Manufacturing / Sale License and Drug Registration.
iii. Other suitable legal action [s] should not be taken against you.

<u>Comments/ Explanation</u>

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, section 22 of Drugs Act 1976 and Rule 16 of Drugs (Federal Inspectors, etc.) Rules 1976 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.

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

- Mr. Anjum Saeed Production Incharge
- Syed Shahbaz Ali Shah Quality Control Incharge
- Syed Shahbaz Ali Shah Warrantor

of M/S JAENS Pharmaceutical Industries (Pvt) Ltd.

II. Please also note that **Mr. Syed Javed Ali** Director M/S JAENS Pharmaceutical Industries (Pvt) Ltd. has no concern with the operations of the Company being silent share holder and he has no nexus with the issues (allegations) under consideration in the said show cause as all routine manufacturing and quality control/assurance operations are done **without his prior knowledge and consent.** So, in the light of above, it is requested that name of **Mr. Syed Javed Ali** Director M/S JAENS Pharmaceutical Industries (Pvt) Ltd. 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.

III. Further also note that **Mr. Muhammad Irshad** Regional Marketing Manager also has neither any nexus with manufacturing of the product sampled and its quality aspects as his job description is related to only promotional activities of the drug to the healthcare professionals nor he is involved in the sale of the product sampled. So, in the light of above, it is requested that name of **Mr. Muhammad Irshad** Regional Marketing Manager of M/S JAENS Pharmaceutical Industries (Pvt) Ltd. 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.

13. That in addition to above, the undersigned reserves its right to submit further assistance/arguments/contradictory evidence to this honorable forum at personal hearing stage if happened.
14. Please also find the relevant person's contact no.; Mr. Babar Khan Manager Regulatory Affairs 0345-6383708.
15. We do hereby verify the following information as required by you

- Copy of Drug Manufacturing License is attached herewith as **Annexure J**
- Copy of Product Registration Certificate is attached herewith as **Annexure K**
- Copy of Batch Manufacturing Record is attached herewith as **Annexure M**

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.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **271st meeting** held on **01-11-2023** under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson). Mr. Ahmad Awais, Secretary DQCB District Sahiwal attended the meeting online via Zoom Link and Mr. Talib Hussain, Drug Inspector, Tehsil Chichawatni, District Sahiwal was present along with original case record. No one among nominated accused appeared before the Board on the behalf of M/s Jaens Pharmaceutical Industries, 28km, Lahore-Sheikhupura Road Sheikhupura, Pakistan. The firm submitted a written request for adjournment in the office of the Secretary, Provincial Quality Control Board, Punjab.

6. The Board after discussion decided to **adjourn** the case on the request of the firm in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

Summary:

Manufacturing Date: 04.2021

Expiry Date: 04.2023

Sampling Date (Form 4): 28.09.2021

Sent to DTL (Form 6): 29.09.2021

Date of receipt in DTL: 30.09.2021

DTL Report Date (Form 7): 27.11.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 22.12.2021

Date of Retesting Request of Firm: 28.12.2021

Fate of Retesting Request: Allowed in 244th meeting dated 31.05.2022. Substandard by NIH

Investigation Report Dated: 24.09.2022

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

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 13

PQCB R-123/2022

Tehsil Choubara, District Layyah

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Jaens Pharma, 28 km, Sheikhupura Road, Sheikhupura** through its Director Syed Javed Ali 2. Syed Javed Ali Director 3. Anjam Saeed Production Incharge 4. Syed Shahbaz Ali Shah Quality Control Incharge/Warrantor of **M/S Jaens Pharma, 28 km, Sheikhupura Road, Sheikhupura**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Chaubara, District Layyah reported that: -

i. He, on 04-12-2021, inspected the business premises of M/S Rizwan Medical Store, Tehsil Chaubara, District Layyah and took 03 different types of drug samples on Form No.04 and sent to Drug Testing Laboratory Multan for the purpose of test/analysis. The subject sample was sent vide memorandum no. 112507 dated 06-12-2021.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Multan as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
DEXER EYE DROPS (DEXAMETHASONE 1mg /ml + CHLORAMPHENICOL 5mg/ml)	B0297	JAENS pharmaceutical industries (pvt) LTD. 28-KM, Lahore Sheikhupura road Sheikhupura.	01-94000873/DTL MULTAN DATED 06-04-2022

Specification applied: MS

Description: Clear, colorless to slightly pale colored solution in a 5 mL of white plastic labelled bottle with a dropper and a white plastic lid packed in a labelled outer carton.

Determined: 04 out of 05 units contains 1.5ml, 1.5ml, 2.0ml and 2.0ml instead of 5ml.

(DOES NOT COMPLY)

Identification Chloramphenicol Identified.

Assay

Assay	Stated	Determined	Percentage	Limits	Comments

Chloramphenicol	5mg/ml	5.99mg/ml	119.71%	90-130%	**Complies**

Note: Assay of Dexamethasone cannot be performed due to insufficient quantity for analysis as provided in the method of analysis by the firm.

Result: The above sample is **Sub-Standard** on the basis of description**.**

iii. M/S Rizwan Medical Store, Tehsil Chaubara, District Layyah provided invoice/ warranty no. 1585 dated 14-07-2021 issued by M/S Al-Shaafi Pharma Distributors, 377-A, TDA Block, Bypass Road, Layyah, as a proof of purchase of subject drug sample.
iv. Warrantor portion was sent to M/S Al-Shaafi Pharma Distributors, 377-A, TDA Block, Bypass Road, Layyah.
v. Al-Shaafi Pharma Distributors, 377-A, TDA Block, Bypass Road, Layyah in turn provided Invoice/warranty no. 1118, dated: 28-05-2021.
vi. A copy of test/analysis report was sent to M/S Jaens Pharma, 28 km, Sheikhupura Road, Sheikhupura to explain their position and provide requisite information in this regard.
vii. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.
viii. The retesting request was placed in PQCB's 247th meeting. The Board after due deliberation unanimously decided to **Turn Down** the subject request for retesting of the sample.

NOTE:

The firm filed a writ petition no. 10275 0f 2023 against PQCB order dated: 21-07-2022, wherein the firm's request for retesting was turned down by the Board.

The writ petition has been dismissed clubbed with writ petition no.77305-22 in the Lahore High Court, Lahore vide orders dated 16-01-2023. The order sheet concluded as;

"……For what has been stated above, this writ petition and the connected writ petitions having no merit are dismissed".

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 20-01-2023.

Personal hearing notice(s) issued to accused person(s) on 11-12-2023.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:04-2021**
- **Exp. Date: 04-2023**
- **Sampling date (Form 4): 04-12-2021**

- **Sent to DTL (Form 6): 06-12-2021**
- **Date of receipt in DTL: 09-12-2021**
- **DTL Report Date (Form 7): 06-04-2022**
- **Time Extension to DTL for analysis: granted in 237th meeting, dated: 30-12-2021.**
- **DI 1st intimation to firm: 11-04-2022**
- **Retesting request if any: Yes**
- **Fate of Retesting Request: Turned Down in 247th meeting, dated: 21-07-2022**
- **Investigation report Dated: 29-09-2022**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 14

PQCB R-426/2021

Tehsil Kabir Wala, District Khanewal

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Fozan Pharmaceutical Industries (Pvt) LTD, 36-A Industrial Estate, Hayatabad, Peshawar** through its Managing Director Syed Muhammad Naveed 2. Syed Muhammad Naveed Managing Director 3. Rahat Ullah Production Incharge 4. Muhammad Saleem Quality Control Incharge/Warrantor of M/s Fozan Pharmaceutical Industries (Pvt) LTD, 36-A Industrial Estate, Hayatabad, Peshawar

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Kabirwala, District Khanewal reported that:-

i. He, on 18-08-2021, inspected the business premises of M/s Al-Imran Medical Store, Pull Rango, Tehsil Kabirwala District Khanewal and took three different types of drug sample on Form No. 04 for the purpose of test and analysis and sent them to Drugs Testing Laboratory Multan.

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

Name of drug	**Batch no.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Tablet ALPOFOZ [Alprazolam: 0.5mg]	P-80	M/s Fozan Pharmaceutical Industries (Pvt) LTD, 36-A Industrial Estate, Hayatabad, Peshawar	TRA No.01-89006592/DTL dated: 21-12-2021	**Analysis with specifications applied: USP 2021** **Description:** Pink to light pink color oblongated tablet having line of bisection on one side & plain on other side packed in ALU-PVC blister of 10 units in a labeled outer carton. Each outer carton contains 03 blisters of 10 units (3 x 10= 30 Tablets) **Identification:** Alprazolam identified. **Analysis Method: HPLC** **Assay:** Alprazolam

				Stated	0.5mg/Tablet
				Determined	**0.253mg/Tablet**
				Percentage	**50.71% (Does not comply)**
				Limit	90-110%
				(Result: The above sample is **Substandard** on the basis of the Assay Test.	

iii. M/s Al-Imran Medical Store, Pull Rango, Tehsil Kabirwala District Khanewal provided bill/ Warranty No. 64485 dated 08-08-2021 issued by M/s Millat Drug Agency, Ghanta Ghar Market, Multan who in turn provided invoice/warranty No. 27 Dated 01-08-2021 issued by M/s National Pharma Town Hall medicine Market, Ghanta Ghar Multan who in turn provided invoice/warranty No. Nil Dated 19-07-2021 issued by M/s Irfan Traders, Al-Mansoor Medicine Market, Namak Mandi Peshawar who in turn provided invoice/warranty No. 11,465 Dated 15-07-2021 issued by M/s Fozan Pharmaceutical Industries (Pvt) LTD, 36-A Industrial Estate, Hayatabad, Peshawar as a proof of its purchase.

iv. Warrantor portion was sent to M/s Millat Drug Agency, Ghanta Ghar Market, Multan and they was asked to explain its position in this regard.

v. A copy of test/analysis report was sent to M/s Fozan Pharmaceutical Industries (Pvt) LTD, 36-A Industrial Estate, Hayatabad, Peshawar and they was asked to provide requisite information in this regard.

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

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

   b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 28-06-2022
4. Personnel Hearing notice(s) issued to accused person(s) 06-07-2022.

PREVIOUS PROCEEDINGS AND 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 Asif Nawaz Secretary DQCB District Khanewal and Mr. M. Illyas Asim Drug Inspector Tehsil Kabirwala, District Khanewal were present. No one among the nominated accused appeared before the Board of M/s Fozan Pharmaceutical Industries (Pvt) LTD, 36-A Industrial Estate, Hayatabad, Peshawar
6. Secretary PQCB apprised the Board that request for adjournment has been received from the firm stated that their technical team was on the way but due to bad weather their vehicle got accident so they cannot join the meeting today and, in their absence, case cannot be presented technically.

7. 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
8. Personal hearing notice(s) issued to accused person(s) on 23-10-2023.

PQCB's 271st meeting held on 01-11-2023:

9. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **271st** meeting held on **01-11-2023** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab. Mr. Naveed Hussain, Secretary DQCB, District Khanewal attended the meeting online via zoom link and Mr. M. Ilyas Asim, Drug Inspector, Tehsil Kabir Wala, was present along with the original case record. No one among the nominated accused **of M/s Fozan Pharmaceutical Industries (Pvt) LTD, 36-A Industrial Estate, Hayatabad, Peshawar** was present. The firm submitted written request for adjournment stating that the technical staff is not available on the date of hearing due to their advance commitments and are busy in Export Inspection.
10. The Board after due deliberation and discussion unanimously decided to **adjourn the case** in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused.

Personal hearing notice(s) issued to accused person(s) on 11-12-2023.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:07-2021**
- **Exp. Date: 07-2023**
- **Sampling date (Form 4): 18-08-2021**
- **Sent to DTL (Form 6): 23-08-2021**
- **Date of receipt in DTL: 23-08-2021**
- **DTL Report Date (Form 7): 21-12-2021**
- **DI 1st intimation to firm: 27-12-2021**
- **Retesting request if any: No**
- **Investigation report Dated: 24-04-2022**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 15

PQCB/ R-540/2018, R-788/2019, R-382/2021

PRODUCT SPECIFIC INSPECTION REPORT OF

M/S DON VALLEY PHARMACEUTICALS, 31-KM FEROZEPUR ROAD, LAHORE

Members of Inspection Committee:

1	**Prof. Dr. Muhammad Jamshaid** (Member PQCB)	**Convener**
2	**Dr. Mahmood Ahmad** (Member PQCB)	Member
3	**Dr. Muhammad Imran Ashraf** (Member PQCB)	Member
4.	**Mr. Rana Abdul Mateen** (DDC PQCB)	Coordinator

Date of Inspection:

Inspection was conducted on 05-10-2023 with reference to PQCB Order No. **PQCB/ R-540/2018, R-788/2019, R-382/2021** dated 27-06-2023. Samples of drug were;

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Film coated Tablet, Dyramid (Ofloxacin 200mg)	5635	M/s Don Valley Pharmaceuticals, Lahore	01-17000576/DTL dated: 19-02-2018	Result: the sample is sub-standard on the basis of DISSOLUTION TEST performed as per USP 2017.
Tablet Ulsin 40mg	7961	M/s Don Valley	01-129004634/DTL	Result: The sample is sub-

[Famotidine USP 40mg]		Pharmaceuticals, Lahore	dated: 23.08.2019	standard on the basis of DISSOLUTION TEST performed as per USP 2018.
Tablet. Pensulid [Nimesulide B.P. 100mg]	EY-20-007	M/s Don Valley Pharmaceuticals, Lahore-Pakistan.	01-73006957/DTL dated: 04-02-2021	Result: The sample is sub-standard on the basis of DISSOLUTION TEST performed as per MS.

Brief about Manufacturing Unit:

A National pharmaceutical company duly certified with **ISO 9001:2015, 14001:2015, 45001:2018, 22000:2018 & ISO/IEC 17025:2017** and also complied with the latest **cGMP** and **cGLP** Standards.

Manufacturing Unit	M/s Don Valley Pharmaceuticals (Pvt.) Ltd.
Location/Address	31-km Ferozepur Road, Lahore
DML No. and Validity (Date of DML renewal)	000395 30.01.2019
Approved Sections	Oral Liquid, Tablet, Capsule, Injectable (Dry Powder), Cream & Ointment and Sachet sections
Management	1. **Dr. Shahla Javed Akram** CEO 2. **Saad Javed Akram** Managing Director 3. **Abdul Shabeer** Director Finance
Firm's Representatives	1. **Muhammad Ashfaq** Quality Control Manger 2. **Mst. Shabana** Production Manger 3. **Muhammad Jahangir** Quality Assurance Manger

OBSERVATIONS:

1. Retesting date was not mentioned on the label of APIs Containers in the Raw Material Store.
2. Active and In-active materials were placed at the same place in the quarantine area without distinguishing the label of Active & In-Active.
3. Single Weighing Balance was used in the Sampling Booth and Dispensing Area in In-Active General Store.
4. Firm has been improved the RAW Material Sources.
5. Firm has been improved the testing methodology and added a new 14 head dissolution apparatus.
6. Firm has been made a separate in process Quality Control Lab for QA Department that lies in production area to check the Disintegration, Tablet Hardness, Tablet Friability, Thickness and weight variation after every 30 minutes

7. Three new HPLC (Shimadzu) have been purchased by Firm which are CFR 21 compliance.
8. More stringent measures have been taken for Line clearance.

SR.No.	Material Name	Old Source	New Source.
1	Cross Carmelose Sodium	Hubei Yuancheng saichuang technology.	Maple Biotech Ltd.
2	Starch	ICI	Rafan Maize
3	Mg-Stearate	Coin Power Int. China	Huzhou City Linghu Xingwaug Chemical Co. Ltd.
4	Aerosil 200	Hubei Yuancheng saichuang technology.	Hubei Huifu Nanomaterial Co. Ltd
5	PVP-K 30	Jiaozuo zhongwei special product pharma	Boai NKY Medical holding Ltd

Batch Processing Record of Specific Product

1. Batch Number: 5635, 7961 & EY-20-007
2. BMR Record: available.
3. list of Equipment: available
4. Vendor Qualification of Raw Material: available

Recommendations

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

- The firm has to make the Policy for Quality Control of APIs.
- The firm has to distinguish the area for Active and In-Active materials separately in the Quarantine Area.
- The firm has to purchase Primary Standards of APIs and more weighing balances for sampling and compounding booths.
- The printing area is very well established separately. More printing machines are however, required to be installed to meet the manufacturing requirements.
- The dissolution apparatus should be equipped with autosampler.
- Data loggers should be available for temperature and humidity control records at all critical areas.
- Root cause analysis for fail batches and market complaints should be conducted by the firm.

Conclusion

After careful evaluation of record and physical verification of the plant and equipment involved at the time of production, the panel is of the opinion that the drug in question declared as substandard due to some problems at the stage of QC analysis (Dissolution Apparatus). The firm is advised to follow strictly the Good Manufacturing Processes with letter and spirit. Moreover, the quality control department should be improved and instruments should be routinely validated and validation record be maintained.

M/s Don Valley Pharmaceuticals submitted following response in terms of Corrective & Preventive Actions taken with respect to the PSI report vide letter no. Tablets/Dv-001-2023 dated 01-11-2023:

CORRECTIVE AND PREVENTIVE ACTIONS REPORT OF PRODUCT SPECIFIC INSPECTION REPORT OF DYRAMID, ULSIN AND PENSULID TABLET

Sr.No	Recommendation By PQCB Team	Don Valley Pharmaceuticals Action Plan	Status
1	The firm has to make the policy for Quality Control of APIs	**APIs** have been treated with controlled procedure.	SOPs Attached
2	The firm has to distinguish the area for Active and In-Active materials in the Quarantine Area.	We are planning to construct **new Quarantine area** for active and inactive material.	In construction plan of 2024
3	The firm has to **purchase primary standards of API's** and more weighing balance for sampling and compounding booths.	Some of the working standards have been purchased. We have purchased **weighing balance** for sampling booth.	Invoice attached
4	The printing area is very well established separately. More printing machines are however, required to be installed to meet the manufacturing requirements.	We have already four printing machines with QR code facility. Now we are going to purchase **two more Printer** for unit cartons.	Quotation has been attached
5	The dissolution apparatus should be equipped with auto sampler.	We have already **two dissolution apparatus** in working. But after the recommendation we are going to purchase a new Dissolution Apparatus with Auto sampler facility.	Attached
6	Data loggers should be available for temperature and humidity record at all critical areas.	**Data loggers** for stores and sample retention room have been in purchased.	Quotation attached
7	Root cause analysis for fail batches and market complaints should be conducted by the firm.	CAPA has been made by the firm.	Attached

Case No. 00

PQCB/ R-540/2018

Jehanian, Khanewal

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore,** through its Chief Executive Officer Dr. Shehla Javed Akram 2. Dr. Shehla Javed Akram — Chief Executive Officer 3. Shabana Kashif W/o Kashif Islam Sheikh — Production Incharge 4. Tariq Mehmood — Quality Control Incharge 5. Muhammad Yamin — Warrantor of **M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore**.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Jehanian, District Khanewal reported that: -

i. His predecessor, on 31-10-2017, inspected the business premises of M/s Khalil Pharmacy, Main Bazar Thatta Sadiq Abad Tehsil Jehanian and took sample of below mentioned drugs on Form No. 04 for the purpose of test and analysis.

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

iii. M/s Khalil Pharmacy, Main Bazar Thatta Sadiq Abad Tehsil Jahanian provided invoice/ Warranty No. 971 dated 20-10-2017 issued by M/s Rayyan Pharma, Medicine Market Town Hall Multan as a proof of its purchase.

iv. Warrantor portion was sent to M/s Rayyan Pharma, Medicine Market Town Hall Multan with directions to explain their position in this regard.

v. M/s Rayyan Pharma, Medicine Market Town Hall Multan provided invoice/warranty No. 1709-8641 dated 19-09-2017 issued by M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore as a proof of its purchase.

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Film coated Tablet,	5635	M/s Don Valley Pharmaceuticals, 31-Km Main	TRA No.01-17000576/DTL	**Analysis with specifications applied: USP 2017** **Dissolution Test**

Dyramid (Ofloxacin 200mg)		Ferozepur Road, Lahore	dated: 19-02-2018	Does not comply with specifications as described below: Tolerance limit: NLT 80% (Q) of the labelled amount of Ofloxacin dissolved.

Level	**No. Tested**	**Acceptance Criteria** **Each Unit Should not less than Q+5%**						**Average**
S1	6	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	S1
Determined %age		40.11	34.24	36.41	37.72	35.54	38.59	
S2	Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15%.							
	6	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 5	S1+S2
Determined %age		24.78	23.69	25.87	23.37	23.69	82.94	35.58%
S3	Average of 24 units (S1+S2+S3) is equal to or greater than Q, and NMT 2 Units are less than Q-15% and no unit is less than Q-25%							
	6	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 5	S1+S2+
Determined %age		24.35	26.19	87.17	26.41	26.41	25.33	32.74%
	6	Unit 7	Unit 8	Unit 9	Unit 10	Unit 11	Unit 12	
Determined %age		22.83	22.72	23.26	24.56	24.78	24.89	

Assay (Ofloxacin)

Stated	200mg/Tab
Determined	205.36mg/Tab

				Percentage	102.68%
				Limit	90%-110%
				Result: The above sample is **Sub-standard** on the basis of dissolution.	

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) vide 17-05-2021

Reply of the Firm to Show-Cause Notice:

With reference to your Letter No. PQCB/R-540/2018 dated 17/05/2021, received by us on 24/05/2021. It is to inform that your office Letter No. PQCB/R-540/2018 dated 17/05/2021 was somehow mixed with other documents due to the negligence of our staff that's why couldn't reply timely; as soon as we found the letter we are replying. Moreover, it is to inform that we didn't receive any such letter or report from the provincial inspector of drugs in which Dyramid Tablet (our product) B#5635 was declared as substandard and it is informed that batch is already expired since August, 2019. So, we request you to please dispose of this case.

4. Personal hearing notice(s) issued to accused person(s) on 17-03-2022.

PREVIOUS PROCEEDINGS OF THE CASE:

PQCB's 241st meeting held on 31-03-2022:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **241st meeting held on 31-03-2022** under the Chairmanship of Secretary Primary & Secondary Healthcare Department, Punjab. Mr. Junaid Mahmood Secretary DQCB District Khanewal and Shehroze Khan Drug Inspector Tehsil Jehanian were present. No one among the nominated accused were present however, Imran Abbass (Area Sales Manager) appeared before the Board on the behalf of M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore and requested to adjourn the case.
6. Secretary PQCB apprised the Board that request for adjournment has been received in subject case from the Firm due to non-availability of their technical staff i.e Shabana Kashif (Production Incahrge) and Dr. Shehla Javed Akram is not present in Lahore on 31-03-2022. 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 30-08-2022.

PQCB's 250th meeting held on 22-09-2022:

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **250th meeting held on 22-09-2022** under the Chairmanship of Secretary Primary and Secondary Healthcare Department, Punjab. Mr. M Anwar ul Haq Member DQCB, District Khanewal and Mr. Shehroze Khan Drug Inspector Tehsil Jahanian, District Khanewal were present along with

original case record. No one among the nominated accused, of **M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore,** was present. However, Mr. Shoib Safdar, counsel of the firm alomg with M Ishfaq (Quality Control Manager) and M. Imran (Sales Manager) on behalf of **M/s Don Valley Pharmaceuticals, 31-Km Main Ferozepur Road, Lahore,** were present. Technical representatives of the firm told the board that the technical staff has been changed and they were unable to produce any authority letter by the firm to attend the meeting at the time of hearing.

9. In view of the preceding facts, the Board after due deliberation and detailed discussion unanimously decided to **Adjourn the case** due to absence of accused technical staff of the firm. The board further decided to provide another but final opportunity of personal hearing to the accused persons.
10. Personal hearing notice(s) issued to accused person(s) on 19-06-2023.

PQCB's 263rd meeting held on 27-06-2022:

11. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **263rd meeting** held on **27-06-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Mr. Asif Nawaz, Secretary DQCB, District Khanewal attended the meeting online via zoom link and Mr. Shehroz Khan, Drug Inspector Tehsil Jehanian, District Khanewal was present along with the original case record. No one among the nominated accused persons was present. However, Mr. M. Ishfaq (Quality Control Manager) along with Adv. Shaoib Safdar and Adv. Hamna Shakeel, Representatives of M/s Don Valley Pharmaceuticals (Pvt) Limited 31-Km Main Ferozpur Road, Lahore-Pakistan appeared before the Board and submitted that non-compliance of the dissolution test of the subject Tablet Dyramid is incomprehensible as assay of the subject drug sample is well within its official limit. Firm further stated that the retention sample tested by them is found to be complying in terms of all parameters. Firm requested the Board for a lenient view apprising the Board that they have improved their system by installing new updated instruments for testing i.e., increasing the number of HPLCs to four and using 14/12-basket assembly for dissolution test.
12. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample i.e, Film coated Tablet, Dyramid (Ofloxacin 200mg), batch no. 5635 has been declared substandard by the Drugs Testing Laboratory, Multan on the basis of dissolution test as the sample fails to comply the specifications of release at all three stages i.e., S1, S2 and S3. The Board also observed that according to the DTL report the subject drug sample is complying the specifications for assay test. The Board was of the view that assay and dissolution test are key parameters, both of which should comply the limits in order to attain required efficacy from the drug.
13. The Board after giving due heed to firm's arguments and reassurances of improvement in their system, was of the view that failure of sample to comply the release limit of S1, S2 and S3 Stage as per acceptance criteria at S3 of average of 24 units (S1+S2+S3) is equal to or greater than Q (80%), and NMT 2 Units are less than Q-15% (65%) and no unit is less than Q-25% (55%), enforces the need to rule out any deviation in the quality control or assurances procedures and hence, needs an inspection of the subject drug sample's practiced production & quality control standards. Therefore, the Board after due deliberation and detailed discussion decided to **pend the case** and conduct **Product Specific Inspection (PSI)** of **M/s Don Valley Pharmaceuticals (Pvt) Limited 31-Km Main Ferozpur Road, Lahore-Pakistan.** For this purpose, the Board constituted a committee comprising of following members with directions to submit report after conducting product specific inspection for further consideration by the Board.

1	**Prof. Dr. Muhammad Jamshaid** (Member PQCB)	**Convener**
2	**Dr. Mahmood Ahmad**	Member

	(Member PQCB)	
3	**Dr. Muhammad Imran Ashraf** (Member PQCB)	Member
4.	**Mr. Rana Abdul Mateen** (DDC PQCB)	Coordinator
5.	**Technical Member of PPMA**	Facilitator

8. The Board further directed the committee to submit report.

Personal hearing notice(s) issued to accused person(s) on 11-12-2023

Case is placed before the board for decision.

Summary:

Manufacturing Date: 08-2017

Expiry Date: 08-2019

Sampling Date (Form 4): 31-10-2017

Sent to DTL (Form 6): 31-10-2017

Date of receipt in DTL: 10-11-2017

DTL Report Date (Form 7): 1 9 - 0 2 - 2 0 1 8

Time Extension: granted by Board in 176th meeting, dated: 12-15-2017

1ST DI Communication with firm on dated: 09-05-2018

Date of Retesting Request of Firm: No request

Investigation Report Dated: 16-04-2021

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 16

PQCB/R-788/2019

Ravi Town, District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore,** through its Chief Executive Officer, Dr. Shehla Javed Akram. 2. Dr. Shehla Javed Akram Chief Executive Officer. 3. Muhammad Yamin Production Manager/Warrantor. 4. Zia ul Haq Quality Control In-Charge Of M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Ravi Town, and Lahore reported that:-

i. His predecessor, on 22-05-2019, inspected the premises of Main Medicine Store, Government Said Mitha Hospital, Said Mitha Bazar, Lahore and took sample of Tablet Ulsin, Batch no. 7916, manufactured by M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore vide on Form 4 for the purpose of test/analysis.

ii. The sample was forwarded to Drug Testing Laboratory Lahore vide Memo number 19 DI/RT dated 23-05-2019 for test/analysis.

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

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Tablet Ulsin 40mg [Famotidine USP 40mg] **Mfg. Date**: 04-2019 **Exp. Date**: 04-2021 **Reg #** 021518	7961	M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore	01-129004634/ DTL dated: 23 Aug 2019	**Result of test/ analysis with specifications applied:** USP 2018 **PHYSICAL DESCRIPTION:** Green coloured elliptical tablets "D.V" engraved on one side in green blister packing of Unit 10. **WEIGHT VARIATION:** Sample meets acceptance criteria for uniformity of mass or weight. Limit ± 7.5% of 102 mg (Average weight=103.2mg) **IDENTIFICATION:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Famotidine identified).

ASSAY:

Stated: 40mg/Tab

Determined: 41.96 mg/capsule

Percentage 104.9%

Limit: 90-110%

DISSOLUTION TEST: Does not comply with the USP Specifications as detailed below:

Tolerance Limit: NLT 80% (Q) of the labelled amount of famotidine is dissolved.

S1: Each unit is NLT Q+5%

S2: Average of 12 units (S1+S2) is ≥ Q, and no unit is < Q-15%

S3: Average of 24 units (S1+S2=S3) is ≥ Q, NMT two units are < Q-15%, and no unit is < Q-25%

LEVEL	NUMBER TESTED	ACCEPTANCE CRITERIA						REMARKS
1	6	**Each individual unit should NLT 85% (Q+5%)**						**Does not comply**
		1	**2**	**3**	**4**	**5**	**6**	
Determined (%)		**22.4**	**25.9**	**22.8**	**21.3**	**25.4**	**19.9**	

The sample fails to comply the dissolution test, performed as per USP, as all 6 units showed release less than Q -25% (i.e. 55%) and remained intact at the bottom of vessels after dissolution at S1. Hence, not proceeded to S2 and S3

.RESULT:

The above sample is SUB-STANDARD on the basis of DISSOLUTION TEST performed as per USP.

iv. The Store Keeper, Main Medicine Store, Government Said Mitha Hospital, Said Mitha Bazar, Lahore provided Invoice No. 3018 dated 08-05-2019 issued by M/S IS Enterprises 229-A New Sample Road, Railway Colony, Mughal Pura, Lahore, who in turn provided invoice/warranty bearing No. 1905-12859 dated 08-05-2019 issued by M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore.

v. The Warrantor portion was sent M/s IS Enterprises 229-A New Sample Road, Railway Colony, Mughal Pura, Lahore.

vi. A copy of test/analysis report was sent to M/S Don Valley Pharmaceuticals and they were asked to provide requisite information in this regard.

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

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

3. Showcause was issued to accused person(s) dated 27.02.2023.

Reply of the Firm to the Show Cause Notice:

Reply to the Show Cause Notice bearing reference No. PQCB/R-788/2019 dated 27-02-2023.

1. This is in response to the Show Cause Notice bearing reference No. POCB/R- 788/2019 dated 2 7-02-2023 wherein your good office has instructed M/s Don Valley Pharmaceuticals ("Don Valley") to show cause as to why any legal action, including but not limited to initiation of prosecution before the Honorable Drug Court and the cancellation/suspension of the Drug Manufacturing License, Drug Sale License along with the registration of the Drug, may not be taken against Don Valley and its concerned officials for allegedly contravening the provisions of the Drug laws and the rules framed thereunder.
2. Firstly, at the outset, Don Valley does not agree with the findings of the Government Analyst Drug Testing Laboratory, Lahore rendered vide TRA No. 01-129004634/DTL dated 23-08-2019 (DTL Report") where under its product, namely, Tablet Ulsin 40mg Batch No. 7961 ("Product") has allegedly been declared as "substandard" on the basis of the result of the Dissolution Test. In view thereof, Don Valley seeks to refute the inaccurate findings of the Government Analyst, inter alia, on the following grounds:
i. A perusal of the DTL Reports reveals that the Government Analyst has failed to mention the testing protocols employed to test the Product. As such, the variation is likely to have occurred due to several reasons including but not limited to a non-calibrated apparatus used at the time of testing. It is a matter of fact that a non-calibrated dissolution apparatus causes significant fluctuations in the temperature and RPM of the apparatus resulting in inaccurate and incorrect findings in relation to the dissolution of the Product.
ii. In addition to the foregoing, it may also be noted that no evidence has been brought on record to substantiate the fact that the pH of the phosphate buffer was maintained properly by the Government Analyst. More so, the DTL Report is completely silent vis-à-vis the condition of the media solution used to test the Product. The quality and/or condition of the media solution has a direct and substantial bearing on the dissolution of the Product.

iii. Even otherwise, all tests carried out by the quality control department of Don Valley at the time of the release of the Product are in compliance with the parameters defined under the United States Pharmacopeia. More importantly, a thorough investigation has also been conducted on the retention samples and in-process batches wherein it has transpired that the same are of standard quality. Accordingly, the findings rendered by the Government Analyst are defective and in incapable of being relied upon.
3. Notwithstanding the foregoing and despite the complete innocence of the Don Valley and its concerned officials in the subject case, please note the following information and documents as per your requirement:
i. Shehla Javed Akram (Chief Executive Officer).
ii. Muhammad Yamin (Production In charge/Warrantor)
iii. Zia-ul-Haq (Quality Control In-charge)
iv. Drug Manufacturing License.
v. Drug Registration Certificate.
4. Accordingly, it is submitted that Don Valley and its concerned officials have not contravened the provisions of the Drug Laws and the rules framed thereunder as has been alleged in the Show Cause Notice under reply. As reiterated earlier, the findings rendered by the Government Analyst are incorrect, defective and without any merit. Therefore, it shall be against the tenets of justice to rely upon such findings and initiate any subsequent proceedings against Don Valley and/or its concerned officials on the basis of the
5. In view of the foregoing, it is very kindly requested that the Show Cause Notice under reply and all subsequent proceedings may be withdrawn in the interest of justice and the case be consigned to record

4. Personal Hearing notice(s) issued to accused person(s) dated 19.06.2023

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 **263rd meeting** held on **27-06-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Mr. Hassan Saeed, Secretary DQCB, Lahore and Mr. Raheem Ahmed, Drug Inspector Ravi Town, Lahore were present along with original case record.No one among the nominated accused persons was present. However, Muhammad Ishfaq, Quality Control Manager, M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore, along with Counsel of the firm, Advocate Shoaib Safdar and Advocate Hamna Shakeel appeared before the Board on the firm's behalf. The representatives of the firm reiterated the statement already furnished in the written reply of show cause by the firm, they further emphasized that as the assay of the product was within limits, and the failure of the product to meet the dissolution test parameters was incomprehensible. They further stated that the firm has added new instruments for improvement in their testing mechanism.

6. The Board, after detailed scrutiny of the DTL report, case record and submissions of the firm, observed that subject drug samples were declared substandard from Drug Testing Laboratory, Lahore on the basis of the dissolution test, performed as per USP, as all 6 units showed release less than Q -25% (i.e. 55%) and remained intact at the bottom of vessels after dissolution at S1. The Board was of considered opinion that assay and dissolution tests are two different parameters and a product needs to comply with both parameters. Further, adding new instruments for quality testing will have no effect on product quality unless the testing mechanisms are reviewed. The Board was of the opinion that all aspects of the product production, including the supply and storage of raw material must be reviewed. Therefore, in order to dig out the root cause of the defect, the Board after due deliberation and discussion, unanimously decided to **pend the case** and constitute a committee comprising of the following members to conduct **Product Specific Inspection (PSI)** of M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-KM, Main Ferozepur Road, Lahore and submit report for consideration by the Board.

1	**Prof. Dr. Muhammad Jamshaid** (Member PQCB)	Convener
2	**Dr. Mahmood Ahmad** (Member PQCB)	Member
3	**Dr. Muhammad Imran Ashraf** (Member PQCB)	Member
4.	**Mr. Rana Abdul Mateen** (DDC PQCB)	Coordinator
5.	**Technical Member of PPMA**	Facilitator

7. The Board further directed the coordinator of the committee to submit report.

Personal Hearing notice(s) issued to accused person(s) dated 11-12-2023.

Summary:

Manufacturing Date: 04-2019

Expiry Date: 04-2021

Sampling Date: 22-05-2019

Sent to DTL (Form 6): 23-05-2019

Date of receipt in DTL: 23-05-2019

DTL Report Date: 23-08-2019

Time Extension: GRANTED IN 210 MEETING

1ST DI Communication with firm on dated: 22-07-2020

Investigation Report Dated: 01-11-2022

PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 17

PQCB/R-382/2021

Tehsil Pattoki, District Kasur

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Don Valley Pharmaceuticals (Pvt) Limited 31-Km Main Ferozpur Road, Lahore Pakistan** through its Chief Executive Officer, Dr. Shehla Javed Akram 2. Dr. Shehla Javed Akram — Chief Executive Officer 3. Shabana Kashif — Production Incharge 4. Tariq Mehmood — Quality Control Incharge 5. Muhammad Yamin — Warrantor Of M/s Donvalley Pharmaceuticals (Pvt) Limited 31-Km Main Ferozpur Road, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 15-12-2020, inspected the business premises of M/s Al-Madina Pharmacy Allama Iqbal Road, Tehsil Pattoki, District Kasur and took following subject drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report No. & Date	DTL Test Report Result
Tablet. Pensulid [Nimesulide B.P. 100mg]	EY-20-007	M/S DONVALLEY Pharmaceuticals (Pvt.) Limited, 31 km, Main Ferozepur Road, Lahore-Pakistan.	01-73006957/DTL dated 04-02-2021	**Analysis with Specifications Applied: MS** PHYSICAL CHARACTERISTICS: YELLOW ROUND BICONVEX TABLET, PLAIN FROM BOTH SIDES IN ALU ALU PACK OF 10 UNITS. AVERAGE WEIGHT: This sample meets the MS acceptance criteria of average weight (316 mg ± 5%) with average weight of 310.5 mg. IDENTIFICATION: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (NIMESULIDE IDENTIFIED) ASSAY OF Nimesulide**:** Stated: 100 mg/ Tab Determined: 94.60 mg/ Tab

Percentage: 94.6%

Limit: 90.0% - 110.0% of the label claim

DISSOLUTION TEST: Does not comply with the MS Specifications as detailed below:-

Tolerance Limit: NLT 80.0% after 60 minutes.

For S1: Each unit is not less than Q + 5%

For S2: Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q – 15%

For S3: Average of 24 units (S1 + S2 + S3) is equal to or greater than Q, not more than 2 units are less than Q – 15%, and no unit is less than Q – 25%

Level	**Number Tested**	**Acceptance Criteria**						**Remarks**
S1	6	Each individual unit should NLT Q + 5% (85%)						**Does not Comply**
		Unit 1	**Unit 2**	**Unit 3**	**Unit 4**	**Unit5**	**Unit 6**	
Determined (%)		**54.2**	58.2	58.2	**48.6**	71.3	**54.9**	

The sample fails to comply the release limits at S1, as 5 out of 6 units showed release less than Q – 15% (65%) and 3 units showed release less than Q – 25% (55%).

RESULT: The above sample is **SUBSTANDARD** on the basis of DISSOLUTION TEST performed as per MS.

iii. Proprietor of M/s Al-Madina Pharmacy Allama Iqbal Road, Tehsil Pattoki, District Kasur provided warranty bearing No. 20647 dated 28-11-2020 issued by M/s Umair Traders, Rehman Plaza, Railway Road, Kasur as a proof of its purchase.

iv. M/s Umair Traders, Rehman Plaza, Railway Road Kasur, in-turn provided warranty bearing No. 2011-17171 dated 19-11-2020 issued by M/s Donvalley Pharmaceuticals (Pvt) Limited 31-Km Main Ferozpur Road, Lahore-Pakistan as a proof of its purchase.

v. Warrantor portion of drug sample was sent to M/s Umair Traders Rehman Plaza, Railway Road Kasur -Pakistan.

vi. A copy of test/analysis report was sent to M/s Donvalley Pharmaceuticals (Pvt) Limited 31-Km Main Ferozpur Road, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 16-03-2022

Firm submitted written reply to the Show Cause Notice vide letter no PENSULID/DV/11/04/22 dated 11-04-2022

In such regards, we wish to state the following That till to date no warrantor/manufacturer portion had received from concerned drug inspector after taking the samples against the requirement of section 19 (3) (ii) of Drug Act, 1976. The test report has passed the sample on all other tests declared on the report including physical description, weight variation. Assay of Pensulid 100mg Tablet BP (Nimesulide) Batch # EY-20-007. After receiving the DTL report we initiate investigation and ***it was identified that DTL Lahore tested the product using the old Method of analysis. The method was changed in July 2020*** *and the information and method has also been sent to provincial Inspector of Drugs tehsil Pattoki District Kasur vide letter No PENSULID/DV/037-2021 dated 25th June 2021 product and the method was sent to DTL Punjab. Tne samples of different batches has also been picked by Drug Inspector and sent to different drug testing Laboratories of Punjab for testing purpose the results were found satisfactory.*

While testing Product Pensulid 100mg Tablet BP (Nimesulide) Batch # EY-20-07 ***DTL Lahore did not request us for provision of new dissolution method and DTL Lahore use the old method which lead to substandard of the product. we have retested our retained samples of the said batch all parameters were found within the specification.*** *This indicates the Product Pensulid 100mg Tablet BP (Nimesulide) Batch# EY-20-07 is of standard quality. In these circumstances it is apparent that there is no need, cause or justification for any further action in the matter and request the case may be closed.*

Furthermore, firm verified the names of the accused persons mentioned in the Show Cause Notice:

1. *Chief Executive Officer (Dr. Shehla Javed Akram)*

2.Production in charge/Warrantor (Muhammad Yamin)

3. Quality Control In charge (Tariq Mehmood)

4. Personal hearing notice(s) issued to accused person(s) dated 19-06-2023

Previous Proceedings and Decision by The Board:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **263rd meeting** held on **27-06-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Ms Mariam Sharif, Secretary DQCB, District Kasur attended the meeting online via zoom link and Mr. Akhtar Ali, Drug Inspector Tehsil Pattoki, District Kasur was present along with the original case record. No one among the nominated accused persons was present. However, Mr. M. Ishfaq (Quality Control Manager) along with Adv. Shaoib Safdar and Adv. Hamna Shakeel, Representatives of M/s Don Valley Pharmaceuticals (Pvt) Limited 31-Km Main Ferozpur Road, Lahore-Pakistan appeared before the Board and submitted that non-compliance of the dissolution test of the subject Tablet Pensulid is incomprehensible as assay of the subject drug sample is well within its official limit. Firm further stated that the retention sample tested by them is found to be complying in terms of all parameters.

Firm requested the Board for a lenient view apprising the Board that they have improved their system by installing new updated instruments for testing i.e., increasing the number of HPLCs to four and using 14/12-basket assembly for dissolution test.

6. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample i.e, Tablet. Pensulid [Nimesulide B.P. 100mg] batch no. EY-20-007 has been declared substandard by the Drugs Testing Laboratory, Lahore on the basis of dissolution test as the sample fails to comply the release limits at S1. Five out of six units showed release less than Q – 15% (65%) and three units showed release less than Q – 25% (55%). The Board also observed that according to the DTL report the subject drug sample is complying the specifications for average weight and assay test. The Board was of the view that assay and dissolution test are key parameters, both of which should comply the limits in order to attain required efficacy from the drug.

7. The Board after giving due heed to firm's arguments and reassurances of improvement in their system, was of the view that failure of sample to comply the release limit of S1 Stage and dissolution of five units less than 65% (Q-15%) and of three units to dissolve even below the limit of 55% (Q-25%) enforces the need to rule out any deviation in the quality control or assurances procedures and hence, needs an inspection of the subject drug sample's practiced production & quality control standards. Therefore, the Board after due deliberation and detailed discussion decided to **pend the case** and conduct **Product Specific Inspection (PSI)** of **M/s Don Valley Pharmaceuticals (Pvt) Limited 31-Km Main Ferozepur Road, Lahore-Pakistan.** For this purpose, the Board constituted a committee comprising of following members with directions to submit report after conducting product specific inspection for further consideration by the Board.

1	**Prof. Dr. Muhammad Jamshaid** (Member PQCB)	**Convener**
2	**Dr. Mahmood Ahmad** (Member PQCB)	Member
3	**Dr. Muhammad Imran Ashraf** (Member PQCB)	Member
4.	**Mr. Rana Abdul Mateen** (DDC PQCB)	Coordinator
5.	**Technical Member of PPMA**	Facilitator

8. The Board further directed the committee to submit report

9. Personal hearing notice(s) issued to accused person(s) dated 11-12-2023

10. Case is placed before the Board for decision.

Summary:

Manufacturing Date: 11-2020

Expiry Date: 11-2022

Sampling Date (Form 4): 15-12-2020

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

Date of receipt in DTL: 16-12-2020

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

Time Extension: Not Time Barred

1st DI Communication with firm on dated: 06-04-2021

Firm's Reply to DI's First Intimation: 25-06-2021

2nd DI Communication with firm on dated: 16-08-2021

Firm's Reply to DI's Second Intimation: 24-08-2021 (Intention for Retesting)

Retesting Request of Firm: Firm showed intention for retesting in response to 2nd letter by Drug Inspector.

Investigation Report Dated: 16-12-2021

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 18

PQCB R-826/2019

Nishtar Institute of Dentistry, Multan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Cotton Craft Pvt Ltd, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore** through its Managing Director Salman Shahid 2. Salman Shahid — Managing Director 3. Hafiz Tariq Mehmood — Production Incharge/Warrantor 4. Nuzhat Kausar Mumtaz — Quality Control Incharge of M/s Cotton Craft Pvt Ltd, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore**.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Nishtar Institute of Dentistry, Multan reported that: -

i. He, on 21-10-2019, inspected the premises of Medicine Store inside Nishtar Institute of Dentistry, Multan and took samples of two different type of drugs on Form No. 04 for the purpose of test and analysis.
ii. Following drug sample, sent vide memorandum no. 1011/Pharmacy/NID dated: 21-10-2019 after test/ analysis was declared **Substandard** by Government Analyst Drug Testing Laboratory, Multan as detailed below:

Name of drug	**Batch no.**	**Name of manufacturer**	**DTL Report TRA No. & Date**	**DTL Test Report Results**
Absorbent cotton wool [Cotton wool 200gm] **Mfg. date:** **05-2019** **Exp. date:** **04-2022**	03E19	M/s Cotton Craft Pvt Ltd, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore.	TRA No.01-56009998/DTL 07-12-2019	**Analysis with specifications applied:** BPC-1973 **Description:** Absorbent cotton wool consists of well carded cotton bleached to good white, free from pieces of threads, leaf and shell and foreign matter. **(Complies)** **Sinking Time:** **Limit** — NMT 10 seconds **Determined** — 6 seconds **(Complies)**

Reg# 006271				**Water holding capacity:** **Limit** NLT 23g/g **Determined** 18.33 g/g **(Does not Comply) (Also on MOH guidelines)** **Weight:** Claimed/Stated: 200gm Determined: 203.6gm **(Complies)** **Acidity/Alkalinity:** It complies with acidity/alkalinity test. **(Complies)** **Result:** The above sample is **Sub-standard** on the basis of water holding capacity test performed.

iii. Drug inspector vide Form 05 seized the above-mentioned substandard stock dated 23-12-2019.

iv. Store keeper Medicine Store inside Nishtar Institute of Dentistry, Multan provided invoice/ warranty No. C1519 dated 20-10-2019 issued by M/s Medi Track Pakistan, Behind Indus Tower, Main Medicine Market, Town Hall, Multan, as a proof of its purchase.

v. Warrantor Portion was sent to M/s Medi Track Pakistan, Behind Indus Tower, Main Medicine Market, Town Hall, Multan.

vi. M/s Medi Track Pakistan, Behind Indus Tower, Main Medicine Market, Town Hall, Multan in turn provided invoice/warranty no. 5124 dated; 19-10-2019 issued by M/s Pakistan Surgical Distributors, Office No. 1st Floor, Ehtisham Chamber, Crossing Ganpat Road, Lahore, who in turn provided invoice/warranty no. Nil dated: 18-10-2019 issued by M/s Cotton Craft Pvt Ltd, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore, as a proof of purchase

vii. A copy of test report was sent to M/s Cotton Craft Pvt Ltd, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore, 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- 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 24-11-2023.

Reply to Show Cause Notice:

- This is with reference to the Show Cause Notice No. **PQCB/R-826/2019** dated 24.11.2023 served to this firm, concerning the sample of **Absorbent Cotton Wool BPC**, 200gm **Batch 03E19**, taken from Medicine

Store inside Nishtar Institute of Dentistry, Multan on 21.10.2019, declared sub-standard by the Provincial Drug Testing Laboratory Multan vide test Analysis report No. TRA-01-56009998/DTL dated 07.12.2019 on the basis of Water Holding Capacity.

In this regard we would like to submit here as under.

The details of DTL report No. TRA-01-56009998/DTL dated 07.12.2019 along-with our explanations/comments are given here under for evaluation and kind consideration at your end please.

Test Performed	**Stated Values**	**Determined/Observed**	
Physical Description	Well-carded cotton fibers bleached to good white, free from pieces of threads and reasonably free from leaf, shell and foreign matter. It does not shed any appreciable quantity of dust when gently shaken	Well-carded cotton fibers bleached to good Complies white, free from pieces of threads and reasonably free from leaf, shell and foreign matter. It does not shed any appreciable quantity of dust when gently shaken	Complies
Sinking time	Not more than 10 Second at 20-25C	Average6.0 seconds	Complies
Water Holding Capacity	NLT 23gm/gm **NLT 20gm/gm-**as per Revised Specification Notification No. F.6-6/2005-Reg-II (South) dated 13.09.2006.	18.33gm/gm	Does not comply
Weight	200gm	203.6gm	Complies
Acidity/Alkalinity	Yellow color with methyl orange	It complies with acidity/alkalinity test	Complies
	No pink color with Phenolphthalein indicator.		

Please observe from the above analysis that according to the Test Analysis Report No. TRA-01-56009998/DTL dated 07.12.2019 the Drug (Medical Device) under reference complies all necessary parameters / test (Description, Sinking time, Weight and Acidity / Alkalinity etc.) required under BPC specifications but the Analyst declared it sub-standard in Water Holding Capacity test, which we understand is not accurate.

Hence our submissions are as under:

Water Holding Capacity: Stated that the water holding capacity is a physical test, normally differ due to temperature of water and if it does with the water having temperature of required limit it must be compiles. In this case we understand it may have happened due to temperature of water otherwise all the test done by the Analyst has been complies and we have no doubt above the quality of our product.

Further we understand the samples is tested in the month of December, 2019 (very cold days) and realize the temperature of fresh water has not been maintained according to the required room temperature (20-25C), due to which the minor shortfall in the water holding capacity can be arises in some case due to coolness of water. Also the difference in standard limit 20gm and the observed of 18.33gm is very minor, which understand is ignorable. Copy of Revised Specification Notification No.F.6-6/2005-Reg-II (South) dated 13th Sep. 2006 is attached herewith for your ready reference.

It is relevant to mention here that we tested the retained sample of the said Batch No.03E19 of Absorbent Cotton Wool BPC 200gm at our Quality Control Lab and observe it is of "Standard Quality" and there is no such shortfalls in the sample as reported by the Analyst in his report. A copy of Test Report performed at our QC Lab dated 24.07.2020 is attached herewith for your ready reference. It is worthwhile to mention here that product under reference has been declared out of specification / substandard on the grounds of Water Holding Capacity otherwise all necessary parameters has been complying. It is stated that this item has many commercial usages other than medical purposes like Cleaning of Machinery, HVAC System & Pipe Fittings, Generator cleaning, Polishing and filling of pillows etc.

It is stated that the Product (Medical Device) under reference is complies all test according to the BPC specifications and observations find by the Analyst for declaring out of specification are unfortunate. Even though if the authority feels it necessary, we are ready to replace the seized stock with the fresh stock of standard quality.

Keeping in view the above said explanation it is stated that the product (Medical Device) under reference complies all tests according to the BPC specifications and observations find by the Analyst for declaring sub-standard is unfortune/ignorable. Hence, it is requested that the stock under reference may kindly be accepted and set aside the case at your end for which shall be highly obliged.

The firm provided the names of technical staff involved in the manufacturing or the subject batch.

Personal hearing notice(s) issued to accused person(s) on 11-12-2023.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:05-2019**
- **Exp. Date: 04-2022**
- **Sampling date (Form 4): 21-10-2019**
- **Sent to DTL (Form 6): 21-10-2019**
- **Date of receipt in DTL: 22-10-2019**
- **DTL Report Date (Form 7): 07-12-2019**
- **DI 1st intimation to firm: 24-12-2019**
- **Retesting request if any: No**
- **Investigation report Dated: 25-10-2023**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 19

PQCB/R-47/2023

Tehsil Kahror Pacca District Lodhran

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Hisun Pharmaceutical Industries, 37-A, R-2, Industrial Estate Gadoon-Pakistan District Swabi** through its Chief Executive Officer Col Rana Munawar Hussain (Rtd) 2. Col Rana Munawar Hussain (Rtd) Chief Executive Officer 3. Muhammad Nawaz Director/ Warrantor 4. Abdullah Abubakkar Production Manager 5. Muhammad Shahid Inayat Quality Control Manager Of **M/s Hisun Pharmaceutical Industries, 37-A, R-2, Industrial Estate Gadoon-Pakistan District Swabi**.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil Kharor Pacca, District Lodhran reported that:-

i. He, on 19-09-2022, inspected the business premises of M/s New Life Medicose situated at Purana Mailsi Road, Kahror Pacca District Lodhran, 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. 0000141009 dated 20-09-2022.
ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:
iii. M/s New Life Medicose situated at Purana Mailsi Road, Kahror Pacca District Lodhran submitted Invoice/warranty No. 72089 dated 10-09-2022 issued by M/s Sharay Pharma, Multan as a proof of its purchase of the said drug.
iv. Warrantor Portion of the drug sample was sent to M/s Sharay Pharma, Multan who in turn provided invoice/ warranty no. 1950 dated 01-09-2022 who in turn provided invoice/ warranty no. 1950 dated 01-09-2022 issued by M/s Marva Trading, 11, First Floor Quadrat Elahi Medicine Market Namak Mandi Peshawar who in turn provided invoice/ warranty no. 253 dated 03-02-2022 issued by M/s Hisun Pharmaceutical Industries, 37-A, R-2, Industrial Estate Gadoon-Pakistan.
v. A copy of test report of the subject drug sample was sent to M/s Hisun Pharmaceutical Industries, 37-A, R-2, Industrial Estate Gadoon-Pakistan 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

<table>
<tr>
<td>Dexphen [Dextromethorphan HBr 6.25mg/5ml & Diphenhydramine HCl 5.0 mg/5ml]

Mfg.date:

Jan-2022

Exp. date:

Jan-2024

Regn No.

047959</td>
<td>S-666</td>
<td>M/s Hisun Pharmaceutical Industries, 37-A, R-2, Industrial Estate Gadoon-Pakistan</td>
<td>TRA No. 01-94006198/DTL

Dated:-17-01-2023</td>
<td><u>Result of Test/ Analysis with specifications applied</u>: MS

<u>Description</u>: Light pink color liquid, contained in amber color labeled plastic bottle sealed with white color plastic screw cap, packed in a labeled outer hard carton.

<u>Identification</u>: Dextromethorphan HBr & Diphenhydramine HCl Identified.

<u>Assay</u>:

Dextromethorphan HBr

<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>6.25mg/5ml</td><td>5.84mg/5ml</td><td>93.46%</td><td>90-110%</td></tr>
</table>

(Complies)

Diphenhydramine HCl

<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>5.0mg/5ml</td><td>4.78/5ml</td><td>95.59%</td><td>90-110%</td></tr>
</table>

(Complies)

<u>PH:</u> Range: 3.5-5.5

Determined: 3.13 (Does Not Comply)

<u>Result:</u> The above sample is <u>Sub-Standard</u>, on the basis of PH test.</td>
</tr>
</table>

2. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (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 18-08-2023.

<u>Reply of firm to show cause notice vide letter no. Dexphen/Ludhran/1 dated 07-09-2023:</u>

Your letter no. PQCB/R-47/2023 dated 18 Aug 2023 refers.

1. It is submitted that our product Dexphen 60ml Syrup (Batch No. S-666) has been declared as Substandard on the basis of low pH by Drug Testing Laboratory Multan. In this regard following is submitted.

Substandard due to low PH. It is hereby clarified that our product is Liquid Syrup (range of pH 3.5 -5.5). Moreover, the above said Batch was manufactured in January 2022. 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 varied temperature. Although temperature is controlled inside the factory premises, but the product might have been exposed to high temperature during transportation, storage at distributor warehouse or medical store.

You know that weather in area of lower Punjab increases very high during summer. The product has faced one summer season. So, we think that this might be the cause of drop in pH. The assay of active ingredients (Dextromethorphan & Diphenhydramine) remained in the specified range, mentioned in U.S.P. So, this little drop in pH didn't affect the active ingredients' stability.

Hopefully, the patient will have received full medicine for his disease.

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 stability of pH in future, hence lenient view may be considered against Hisun Pharma as a special case.

4.Following documents/ Information are enclosed as desired: -

a. Attested copy of DML Annex A

b. Attested copy of registration of Dexphen Annex B

d. Name of Director Muhammad Nawaz CNIC NO (34601-9588618-1)

& Cell/Whatsapp NO. 0321-4900072 Muhammad

e. Shahid Inayat QCM CNIC NO (35201-1318639-3)

and Abdullah Abubakkar Production Manager CNIC (38201-1202500-1) & Cell No 0333-

6819533

5. Your sympathetic and favorable consideration in this case will highly be appreciated,

please.

4. Personal Hearing notice(s) issued to accused person(s) dated 07-11-2023.

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **272nd meeting** held on **22-11-2023** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department/Vice Chairperson PQCB. Mr. Misbah-Ud-Din Qamar Secretary DQCB, Lodhran attended the meeting online via zoom link and Mr. Mazhar Shabeer, Drug Inspector Tehsil Kahror Pacca District Lodhran was present along with original case record. No one among the nominated accused person was present. However, Sajjad Ali Khan (Quality Control Manager), representative on behalf of M/s Hisun Pharmaceutical Industries, 37-A, R-2 Industrial Estate Gadoon Pakistan was present.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case in the best interest of justice as the firm was not present at the time of hearing. The Board further decided to provide another opportunity of hearing to the accused.

5. Personal Hearing notice(s) issued to accused person(s) dated 11-12-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 01-2022**
- **Expiry Date: 01-2024**
- **Sampling Date (Form 4): 19-09-2022**
- **Sent to DTL (Form 6): 20-09-2022**
- **Date of receipt in DTL: 22-09-2022**
- **DTL Report Date (Form 7): 17-01-2023**
- **Time Extension: Granted in 254th meeting dated 13-12-2022**
- **1ST DI Communication with firm on dated: 03-04-2023**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: NA**
- **Investigation Report Dated: 09-05-2023**

CURRENTPROCEEDINGS & DECISION BY THE BOARD:

Case No. 20

PQCB/R-327, 328/2022

Tehsil Burewala, District Vehari

ATTENDANCE:

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. 121950 & 121948 dated 23-03-2022.
ii. Following drug sample, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:

<table>
<tr><th>Sr. No.</th><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>TRA No & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>1</td><td>Syrup Pizosun [Pizotifen (Hydrogen Maleate) 0.25mg/5ml, 120ml]

Mfg Date: 11-2021

Exp. Date: 11-2023

Regn. No: 056474</td><td>S-647</td><td>M/s Hisun Pharmaceutical industries, 37-A, R-2 Industrial Estate Gadoon-Pakistan.</td><td>No. 01-94002967

dated 26-05-2022</td><td><u>Results of test/analysis with specifications applied:</u> MS

<u>DESCRIPTION:</u> sunset yellow color syrup in labeled amber plastic bottle sealed with white plastic screw cap packed in a labeled outer hard carton.

<u>IDENTIFICATION:</u> Pizotifen as Hydrogen Maleate identified

<u>ASSAY:</u> UV- spectrophotometer

<table>
<tr><th>Assay</th><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td>Pizotifen</td><td>0.25mg/5ml</td><td>0.24mg/5ml</td><td>90-110%</td><td>95.02%</td></tr>
</table>
<u>pH:</u></td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td>Stated: 4.5-6.5

Determined: 4.21 Does not comply.

RESULT: The sample is Substandard on the basis of pH Test.</td></tr>
<tr><td>2</td><td>Syrup Pizosun 60ml [Pizotifen (Hydrogen Maleate) 0.25mg/5ml]

Mfg. Date: 01-2022

Exp. Date: 01-2024

Regn. No: 056474</td><td>S-663</td><td>M/s Hisun Pharmaceutical industries, 37-A, R-2 Industrial Estate Gadoon-Pakistan.</td><td>No. 01-94002969

dated 26-05-2022</td><td>Results of test/analysis with specifications applied: MS

DESCRIPTION: lemon yellow color syrup in labeled amber plastic bottle sealed with white plastic screw cap packed in a labeled outer hard carton.

IDENTIFICATION: Pizotifen as Hydrogen Maleate identified

ASSAY: UV- spectrophotometer

<table>
<tr><th>Assay</th><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td>Pizotifen</td><td>0.25mg/5ml</td><td>0.246mg/5ml</td><td>90-110%</td><td>98.42%</td></tr>
</table>
pH:

Stated: 4.5-6.5

Determined: 3.57 Does not comply

RESULT: The sample is Substandard on the basis of pH Test.</td></tr>
</table>

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 Portions of subject batches of the drug samples were sent to M/s Marva Trading 30 Khushal Colony near Molvi Ameer Shah Memorial Hospital GT Road Peshawar.
v. M/s Marva Trading 30 Khushal Colony near Molvi Ameer Shah Memorial Hospital GT Road Peshawar provided invoice/warranty no. 32 dated 08-01-2022 and invoice/warranty no. 212 dated 29-01-2022 respectively issued by M/s Hisun Pharmaceutical industries, 37-A, R-2 Industrial Estate Gadoon-Pakistan as a proof of its purchase.
vi. Copies of Test/ Analysis reports were 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. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: --

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

Summary: R-327/2022	**Summary: R-328/2022**

Manufacturing Date: 11-2021	**Manufacturing Date**: 01-2022
Expiry Date: 11-2023	**Expiry Date**: 01-2024
Sampling Date: 22-03-2022	**Sampling Date**: 22-03-2022
Sent to DTL (Form 6): 23-03-2022	**Sent to DTL (Form 6): 23**-03-2022
Date of receipt in DTL: 28-03-2022	**Date of receipt in DTL: 28**-03-2022
DTL Report Date: 26-05-2022	**DTL Report Date**: 26-05-2022
Time extension granted: N/A	**Time extension granted: N/A**
1ST DI Communication with firm on dated :23-12-2022	**1ST DI Communication with firm on dated** :23-12-2022
Date of Retesting Request of Firm: No	**Date of Retesting Request of Firm**: No
Fate of Retesting Request: N/A	**Fate of Retesting Request**: N/A
Investigation Report Dated: 21-01-2023	**Investigation Report Dated**: 21-01-2023

3 Show cause notice issued to the accused dated 13-02-2023

Firm submitted reply to show cause notice vide letter dated 08-03-2023

Your letter no. PQCB/R-327, 328/2022 dated 27 February 2023 refers.

1. It is submitted that Drug Testing Laboratory (DTL) Multan declared syrup Pizosun (Pizotefin Hydrogen Maleate) Batch no S-647 and S-663, substandard on the basis of low pH vide DTL report no 01-94002967 & 01-94002969/DTL Multan. As the content assay of Pizosun Syrup Batch no S-647 is within the limits i.e 95.02% (Limit 90----110%) whereas pH is 3.57 (Limit: 4.5--6.5) lower than the limit. The content assay of Pizosun Syrup Batch no S-663 is within the limits i.e 98.42 % Limit: 90-110% whereas pH is 4.21 (Limit 4.5-6.5) slightly lower than the limit. It is worth mentioning that temperature has inverse effect on pH and it might be possible that Chemist has not stored the product at specified storage condition resulting into drop of pH, while our retained stability samples of the said batches comply the pH limit.
2. We hereby verify the names of the Managing Director and Technical Staff nominated by Drug inspector.
3. Firm has verified names of managing director and technical staff by DI.
4. In view, it is requested that a sympathetic consideration may be accorded and issue of low pH is settled as a special case, please.

4 Personal Hearing Notice issued to accused person(s)

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **272nd meeting** held on **22-11-2023** under the chairmanship of Vice chairperson. Mr. Imran Rashid Secretary DQCB, Vehari vial zoom link attended meeting and Mr. Johnson Kamran Provincial Inspector of drugs Tehsil Burewala was present along with original case record. No one among the nominated accused person was present. However, Sajjad Ali Khan (Quality Control Manager),

representative on behalf of M/s Hisun Pharmaceutical Industries, 37-A, R-2 Industrial Estate Gadoon Pakistan was present.

6. The Board after due deliberation and discussion unanimously decided to **adjourn** the case in the best interest of justice as the firm was not present at the time of hearing. The Board further decided to provide another opportunity of hearing to the accused.

4 Personal Hearing Notice issued to accused person(s)

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 21

PQCB/R-701/2021

(Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Popular Chemical Works (Pvt.) Ltd., 9-Km Sheikhupura Road, Lahore, Pakistan** through its Director, Mian Khalid Rehman. 2. Mian Khalid Rehman Director 3. Nauman Aziz Production Incharge 4. Syed Sabir Hussain Bukhari Quality Control Incharge/ Warrantor **of M/S Popular Chemical Works (Pvt.) Ltd., 9-Km Sheikhupura Road, Lahore, Pakistan.**

BRIEF FACTS OF THE CASE

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

i. Her predecessor, on 23-11-2020, inspected the premises of M/s Mohsan Medical Store Ghousia Chowk Gamber Sabzi Mandi Road Sahiwal, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 78470 dated 24-11-2020.
ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Suspension Moxilium [Amoxycillin as Amoxycillin trihydrate 125mg/5ml, 45ml when reconstituted] **Mfg Date:** 07-2020 **Expiry Date:** 07-2022	MXS567	M/s Popular Chemical Works Pvt Ltd., 9km Sheikhupura Road, Lahore-Pakistan	01-25006264/DTL dated: 21-01-2021	**Analysis with specifications applied: BP 2020** **COMPOSITION:** Each 5ml contains: (When reconstituted) 125 mg Amoxycillin as Amoxicillin Trihydrate BP. **DESCRIPTION (MS):** White to off white color powder in amber color glass sealed bottle. Packed in unit carton. Upon reconstitution gives yellow color suspension (stated volume: 45 ml, when reconstituted) **pH (BP)** **Determined**: **7.504** **Limit**: **4.0 – 7.0 (Does not comply with specs.)** **IDENTIFICATION (USP):** Amoxicillin is identified. **ASSAY (BP) Amoxicillin**

Regn No. 006783				**Stated** 125mg/5ml **Determined 1**17.225mg/5ml **Percentage** 93.78% **LIMIT** NMT 120% **Amoxicilin (5th Day)** **Stated** 125mg/5ml **Determined:** 100.30mg/5ml **Percentage**: 80.24% **Limit**: NLT 80% **RESULT**: The sample is declared **SUB-STANDARD** on the basis of **pH Test.**

iii. Proprietor of M/s Mohsan Medical Store Ghousia Chowk Gamber Sabzi Mandi Road Sahiwal provided invoice/ warranty No. SOB-0049973 dated 19-11-2020 issued by M/s Lifeline Distributor, 12 Faisal Colony-1 Faisalabad Road, Okara as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Lifeline Distributor, 12 Faisal Colony-1 Faisalabad Road, Okara

v. M/s Lifeline Distributor, 12 Faisal Colony-1 Faisalabad Road, Okara provided invoice/warranty no. 156 dated 29-07-2020 issued by M/s Popular Chemical Works Pvt Ltd., 9km Sheikhupura Road, Lahore-Pakistan.

vi. A copy of test/analysis report was sent to M/s Popular Chemical Works Pvt Ltd., 9km Sheikhupura Road, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vii. Pursuant to firm's request, the Provincial Quality Control Board in its 236th meeting held on 15-12-2021, after due deliberation unanimously decided to allow the firm's request for retesting of the subject sample and the sample was sent to NIH, Islamabad for retest/analysis, from where subject drug sample also declared Substandard. The detail is as follow: -

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Moxilium (Amoxycillin 125mg/5ml) powder for oral Suspension	MXS567	M/s Popular Chemical Works Pvt Ltd., 9-km Sheikhupura Road, Lahore-Pakistan	No. 0297-P/2021 dated 31-01-2022	**Description:** White powder contained in amber colored labelled glass bottle along with measuring plastic cap packed in an outer carton, produces yellow colored suspension after reconstitution with distilled water. **pH:** Determined: 7.40±0.06 Limit: 4.0-7.0 **Does not comply with BP-2017**

				CONCLUSION: The sample is **Substandard** quality on the basis of tests performed.

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

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

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

REPLY OF SHOW CAUSE NOTICE BY FIRM:

1. Please refer to the subject cited above. We, M/s Popular Chemical Works (Pvt.) Ltd ("Popular Chemical Works (Pvt.) Ltd" or "we") are in receipt of the Show Cause Notice bearing reference No. PQCB / R - 701/2021 dated 13-02-2022 whereunder you have directed us to show cause as to why any legal action including but not limited to initiation of prosecution before the Honorable Drug Court and/or suspension/cancellation of the Drug Manufacturing License, Drug Sale and Drug Registration, may not be taken against us for allegedly contravening the provisions of the Drug Laws and the rules framed thereunder.

2. Firstly, please note that we had requested for the retesting of the product, namely, Suspension Moxilium Batch No. MXS567 ("Product") from the National Institute of Health Islamabad ("NIH") vide letter dated 18-06-2021. In this regard, the retesting request was allowed by the Board in its 20th committee meeting held on 15-12-2021, however, we have not been provided with any report issued by the NIH and remain completely unaware regarding whether the Product was tested by the NIH or not.

3. We would also like to highlight that the Show Cause Notice under reply contains an excerpt of the alleged report issued by the NIH on 31-01-2022. In this regard, it is essential to draw your attention towards the fact that a Bill No. 17 dated 16- 02-2022 was received by us from the NIH on 04-03-2022 wherein Popular Chemical Works (Pvt.) Ltd, was instructed to submit the requisite fee for the purpose of the retesting of the Product. In pursuance thereof, the requisite fee was deposited vide cheque No. 17499994 dated 22-03-2022 delivered to NIH on 23-06-2022. In view thereof, the retesting of the Product could only have been carried out once the requisite formalities had been completed. The aforementioned submission casts a serious doubt on the veracity of the alleged report issued by the NIH which has also not been delivered to us till date.

4. Even otherwise, it is affirmed that the pharmaceutical products manufactured by Popular Chemical Works (Pvt.) Ltd, are subjected to a rigorous testing regime prior to their release in the market. It is in this context that we had requested the sample of our Product to be tested from the NIH to enable us to refute the erroneous findings rendered by the Government Analyst Drug Testing Laboratory Bahawalpur vide TRA No. 01-25006264/DTL dated 21-01-2021. However, despite the foregoing, no information regarding the same has been provided to us till date.

5. Even otherwise, it is submitted that we have not contravened the provisions of the Drug Laws and the rules framed thereunder rather have shown strict compliance thereof. No complaint vis-à-vis the Product has been received from anywhere else which affirms it quality, safety and efficacy.

6. In view of the foregoing, it is essential to provide the NIH Report, if any, to Popular Chemical Works (Pvt.) Ltd, to enable it to review the same and make its submissions accordingly.

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 **272nd meeting** held on **22.11.2023** under the Chairpersonship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice Chairperson. Ahmad Awais, Secretary DQCB District Sahiwal attended the meeting online via Zoom Link along with original case record. No-one among nominated accused appeared before the Board. The firm submitted a written request for adjournment.

6. Keeping in view the request submitted by firm, the Board after due deliberation and discussion decided to **Adjourn** the case in best interest of justice and decided to provide another but final personal hearing to the firm.

Summary:

Manufacturing Date: 07.2020

Expiry Date: 07.2022

Sampling Date (Form 4): 23.11.2020

Sent to DTL (Form 6): 24.11.2020

Date of receipt in DTL: 27.11.2020

DTL Report Date (Form 7): 21.01.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 09.02.2021

Date of Retesting Request of Firm: 08.03.2021

Fate of Retesting Request: Allowed in 236th meeting dated 15.12.2021 (NIH Substandard)

Investigation Report Dated: 27.12.2022

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

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 22

PQCB/R-752/2019

(DHQ Teaching Hospital Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad through** its Managing Director Umar Farooq. 2. Umar Farooq — Managing Director 3. Arifullah Khan — Production Incharge/Warrantor 4. Noor Faraz — Quality Control Incharge **of M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad.**

BRIEF FACTS OF THE CASE

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

i. He, on 30-05-2019, inspected the premises of Medicine Store DHQ Teaching Hospital, Sahiwal and took subject drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Bahawalpur, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**	**DTL Test Report Result**
Injection. Tramaway [Tramadol HCl: 100mg/2ml]	9C206	M/S Caraway Pharmaceuticals, Plot No. 12, St.N-3, National Industrial Zone (RCCI), Rawat, Islamabad	01-25003902/DTL Dated. 31-07-2019	**Analysis with specifications applied: MS /BP 2018.** **Composition:** Each 2ml contains: Tramadol HCl……100mg **Description (MS):** Colorless solution, filled in transparent printed glass ampoule (stated volume: 2ml). **04 out of 20 ampoules containing undissolvable visible particulate matter (Does not comply with the parenteral specifications).** **Volume (MS):**

Limit	2.1±0.05ml
Determined	2.08ml

pH (MS):

Limit	4.5-8.5
Determined	6.15

Sterility (BP):

The product is sterile.

Identification (MS):

Tramadol HCl is identified

Assay (MS):

Tramadol HCl:

Stated	100mg/2ml
Determined	104.26mg/2ml
Percentage	104.26%
Limit	90-110%

Result:

The sample is declared **Substandard** on the basis of Physical Test.

iii. Store Keeper of Medicine Store DHQ Teaching Hospital, Sahiwal provided Invoice/warranty No CARA/DHQ/004, dated 28-04-2019 issued by M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad and they were asked to provide the requisite information in this regard. In Response the company challenge the Drug Testing Laboratory Report, Bahawalpur report, the request of retesting was placed in 230th meeting held on 20-02-2021 and the Board decided to turn down the said request of retesting. The firm also applied review petition which was upheld by the Board in its 249

th meeting dated 23.08.2022.

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

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

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board, under section 11 of Drugs Act 1976 in its **247th meeting** held on **21-07-2022** under the Chairmanship of Vice Chairperson Additional Secretary, Drugs Control Primary & Secondary Healthcare Department, Punjab in the presence of Board members as mentioned above. Mr. Ahmed Awais Secretary DQCB District Sahiwal was present along with original record of the case. Representative of the Firm Murad Alli (Current Quality Control Manager), Muhammad Javaid (Curent Production Manager) along with counsel of the firm Rana Maqsood Afzal (Advocate) appeared before the Board on the behalf of M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad. Counsel person of the firm submitted before the Board the orders of Honorable Lahore High Court, in the which the court directed the Provincial Quality Control Board to hear the Review Petition of the firm against the orders of retesting requests.
5. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case** with directions to address the Court Directions.

Summary:

Manufacturing Date: 03.2019

Expiry Date: 02.2021

Sampling Date (Form 4): 30.05.2019

Sent to DTL (Form 6): 30.05.2019

Date of receipt in DTL: 01.06.2019

DTL Report Date (Form 7): 31.07.2019

Time Extension: N/A

1ST DI Communication with firm on dated: 25.07.2020

Date of Retesting Request of Firm: 27.08.2020

Fate of Retesting Request: Turn Down (Review Petition upheld)

Investigation Report Dated: 02.06.2022

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

    Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-665/2020

(DHQ Teaching Hospital Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad through** its Managing Director Umar Farooq. 2. Umar Farooq Managing Director 3. Arifullah Khan Production Incharge/Warrantor 4. Noor Faraz Quality Control Incharge **of M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad.**

BRIEF FACTS OF THE CASE

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

i. He, on 06-11-2019, inspected the premises of Medicine Store DHQ Teaching Hospital, Sahiwal and took subject drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory **Bahawalpur**.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**	**DTL Test Report Result**
Injection. Tramaway [Tramadol HCl: 100mg/2ml]	9F357	M/S Caraway Pharmaceuticals, Plot No. 12, St.N-3, National Industrial Zone (RCCI), Rawat, Islamabad	01-25004650/DTL Dated. 14-02-2020	**Analysis with specifications applied: MS /USP 2018.** **Composition:** Each 2ml Ampoule contains: Tramadol HCl (BP)……100mg **Description (MS):** Colorless solution, filled in sealed transparent glass ampoule (stated volume:

2ml).

03 out of 20 ampoules containing undissolvable visible particulate matter (Does not comply with the parenteral specifications).

Volume (MS):

Limit	Not less than nominal (2ml)
Determined	2.00ml

pH (MS):

Limit	4.5-8.5
Determined	6.513

Sterility (BP):

The product is sterile.

Identification (MS):

Tramadol HCl is identified

Assay (MS):

Tramadol HCl:

Stated	100mg/2ml
Determined	94.17mg/2ml
Percentage	94.17%
Limit	90-110%

Result:

The sample is declared **Substandard** on the basis of Physical Test.

iii. Store Keeper of Medicine Store DHQ Teaching Hospital, Sahiwal provided Invoice/warranty No CARA/DHQ/005, dated 02-11-2019 issued by M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Caraway Pharmaceuticals, Plot No. 12, St. N-

3, National Industrial Zone (RCCI), Rawat, Islamabad and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad and they were asked to provide the requisite information in this regard. In Response the company challenge the Drug Testing Laboratory Report, Bahawalpur report, the request of retesting was placed in 230th meeting held on 20-02-2021 and the Board decided to turn down the said request of retesting. The firm also applied review petition which was upheld by the Board in its 249th meeting dated 23.08.2022.

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

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

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board, under section 11 of Drugs Act 1976 in its **247th meeting** held on **21-07-2022** under the Chairmanship of Vice Chairperson Additional Secretary, Drugs Control Primary & Secondary Healthcare Department, Punjab in the presence of Board members as mentioned above. Mr. Ahmed Awais Secretary DQCB District Sahiwal was present along with original record of the case. Representative of the Firm Murad Alli (Current Quality Control Manager), Muhammad Javaid (Curent Production Manager) along with counsel of the firm Rana Maqsood Afzal (Advocate) appeared before the Board on the behalf of M/S Caraway Pharmaceuticals, Plot No. 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad. Counsel person of the firm submitted before the Board the orders of Honorable Lahore High Court, in the which the court directed the Provincial Quality Control Board to hear the Review Petition of the firm against the orders of retesting requests.
5. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case** with directions to address the Court Directions.

Summary:

Manufacturing Date: 06.2019

Expiry Date: 05.2021

Sampling Date (Form 4): 06.11.2019

Sent to DTL (Form 6): 06.11.2019

Date of receipt in DTL: 09.11.2019

DTL Report Date (Form 7): 14.02.2020

Time Extension: Granted in 218-M

1ST DI Communication with firm on dated: 28.07.2020

Date of Retesting Request of Firm: 27.08.2020

Fate of Retesting Request: Turn Down (Review Petition upheld)

Investigation Report Dated: 02.06.2022

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

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 23

PQCB/R-772/2019

(Tehsil & District Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Caraway Pharmaceuticals, Plot No. 12, Stteet No. 3, National Industrial Zone, RCCI, Rawat, Islamabad** through its Managing Director Umar Farooq. 2. Umar Farooq — Managing Director 3. Arifullah — Production Incharge/Warrantor 4. Noor Faraz — Quality Control Incharge **of M/S Caraway Pharmaceuticals, Plot No. 12, Stteet No. 3, National Industrial Zone, RCCI, Rawat, Islamabad.**

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 08-10-2019, inspected the business premises of M/S Sadar Muhammad Agencies Medical Store, 13-Huma Colony Fateh Sher Road Tehsil and 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.0000050139, dated. 09-10-2019.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**	**DTL Test Report Result**
Tablet Carafenac-P [Diclofenac Potassium 75mg] **Mfg Date:** July-2019 **Exp Date:**	9G408	M/S Caraway Pharmaceuticals, Plot No. 12, Stteet No. 3, National Industrial Zone, RCCI, Rawat, Islamabad	01-25004571/DTL Dated. 28-11-2019	**Analysis with specifications applied:** **USP 2018.** **Composition:** Each Tablet contains: Diclofenac Potassium USP……75mg **Description (MS):** Light Blue Color, round, biconvex tablet which is plain on both sides and packed in an Alu-Alu Pack of 1 **Identification (USP):** Diclofenac Potassium is identified. **Assay (USP):**

June-2021

Registration No.

050019

Diclofenac Potassium:

Stated	75mg/tablet
Determined	80.16mg/tablet
Percentage	106.88%
Limit	90-110%

Dissolution Test (USP):

Does not Complies with the specifications of USP as detailed below.

Tolerance Limit: NLT 75% (Q) of the labelled amount of Diclofenac Potassium.

Stage	Number Tested	Acceptance Criteria	Aver
S1	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%	S1
Stage 1	Diclofeaac Potassium	Unit 1: 70.32%; Unit 2: 39.67%; Unit 3: 33.66%; Unit 4: 44.05%; Unit 5: 41.74%; Unit 6: 39.11%	44.09

Result:

The sample is declared **Substandard** on the basis of Dissolution Test..

iii. M/S Sadar Muhammad Agencies Medical Store, 13-Huma Colony Fateh Sher Road Tehsil and District Sahiwal provided Invoice/warranty No Inv-32808, dated 18-11-2019 issued by M/S Caraway Pharmaceuticals, Plot No. 12, Stteet No. 3, National Industrial Zone, RCCI, Rawat, Islamabad as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Caraway Pharmaceuticals, Plot No. 12, Stteet No. 3, National Industrial Zone, RCCI, Rawat, Islamabad and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Caraway Pharmaceuticals, Plot No. 12, Stteet No. 3, National Industrial Zone, RCCI, Rawat, 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 12th Committee Meeting of Retesting dated 25-08-2020 and Board after unanimous decision decided to turn down the said retesting request. The company again file review petition against the decision of PQCB Order dated 25-08-2020 on 17-11-2020 and the said Review Petition was placed in 15th Committee Meeting dated 10-04-2021 and the Board after unanimous decision

decided to uphold its previous decision.

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

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

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

Summary:

Manufacturing Date: 07.2019

Expiry Date: 06.2021

Sampling Date (Form 4): 08.10.2019

Sent to DTL (Form 6): 09.10.2019

Date of receipt in DTL: 11.10.2019

DTL Report Date (Form 7): 28.11.2019

Time Extension: N/A

1ST DI Communication with firm on dated: 24.12.2019

Date of Retesting Request of Firm: 13.01.2020

Fate of Retesting Request: Turn Down (Time Barred)

Investigation Report Dated: 14.09.2022

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

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 24

PQCB/R-502, 503/2022

Lady Willingdon Hospital, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan,** through its Managing Director Ch. Muhammad Israr Sharif. 2. Ch. Muhammad Israr Sharif Managing Director 3. Syed Faiz-ul-Haq Production Manager 4. Maqsood-ur-Rehman Quality Control Manager/Warrantor Of M/s Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Lady Willingdon Hospital, Lahore reported that:

i. The then drug inspector, on 24-06-2022, inspected the premises of medicine store of Lady Willingdon Hospital, Lahore, and took both drug samples on Form No.04 for the purpose of test/analysis and sent to DTL, Lahore vide memorandum no. 130541& 130540 dated 24-06-2022.
ii. Following drug samples after test/analysis were declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Sr. No	Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
1	Injection RBC Injection [Iron Sucrose eq to elemental iron 100mg/5ml] **Mfg date**: 04-2022 **Exp. Date**: 04-2024	0216I108	M/S Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi Pakistan	01-166004715/DTL Dated 03-09-2022	**Analysis with specifications applied:** USP 2021 **DESCRIPTION:** Blackish brown liquid in sealed amber glass ampoule having label printed on it. Claimed volume: 5ml **pH:** Determined: **10.23 at 20**.0°C Limit: 10.5-11.1 at 20°C **Does not comply** **EXTRACTABLE VOLUME:** Stated: NLT Nominal volume 5ml

<table>
<tr>
<td></td>
<td>Regn. No: 073465</td>
<td></td>
<td></td>
<td></td>
<td>Determined: 5.07ml

<u>STERILITY:</u> The product is sterile.

<u>ASSAY:</u> Elemental iron

<table>
<tr><td>Stated</td><td>100mg/5ml</td><td></td></tr>
<tr><td>Determined</td><td>98.76 mg/5ml</td><td></td></tr>
<tr><td>Percentage</td><td>98.76%</td><td></td></tr>
<tr><td>Limit</td><td>95-105%</td><td></td></tr>
</table>

RESULT: The sample is Substandard on the basis of pH performed as per USP.</td>
</tr>
<tr>
<td>2</td>
<td>Injection RBC Injection [Iron Sucrose eq to elemental iron 100mg/5ml]

Mfg date:

04-2022

Exp. Date:

04-2024

Regn. No: 073465</td>
<td>0215I108</td>
<td>M/S Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi Pakistan</td>
<td>01-166004714/DTL

Dated 03-09-2022</td>
<td>Analysis with specifications applied: USP 2021

<u>DESCRIPTION:</u> Blackish brown liquid in sealed amber glass ampoule having label printed on it, Claimed volume: 5ml

<u>pH:</u>

Determined: 10.24 at 20.0°C

Limit: 10.5-11.1 at 20C

Does not comply

<u>EXTRACTABLE VOLUME:</u>

Stated: NLT Nominal volume 5ml

Determined: 5.07ml

<u>STERILITY:</u> The product is sterile.

<u>ASSAY of</u> Elemental iron

<table>
<tr><td>Stated</td><td>100mg/5ml</td><td></td></tr>
<tr><td>Determined</td><td>99.65 mg/5ml</td><td></td></tr>
<tr><td>Percentage</td><td>99.65%</td><td></td></tr>
</table>
</td>
</tr>
</table>

					Limit	95-105%	
					RESULT: The sample is Substandard on the basis of pH performed as per USP.		

iii. Store keeper Lady Willingdon Hospital, Lahore provided Invoice/Warranty No. 6300000600 dated 31-05-2022 issued by M/S Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan as a proof of its purchase.
iv. Warrantor portion of both batches of drug sample was sent to M/S Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan.
v. Copies of test/analysis report was sent to M/S Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan with directions to explain their position and provide requisite information in this regard. In response, firm requested for retesting of both drug samples from NIH, Islamabad. The Board in its 253rd meeting requested withdrawal of retesting request of the firm.

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

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

3 Show cause notice issued to the accused dated 07-06-2023

The following submissions are made.

1. That the correspondence with Inspector and PQCB may please be taken as an integral part of this reply this Show Cause Notice.

2. That Genix Pharma (Private) Limited was founded in the year 2004 with the vision of helping and providing top quality and affordable medicine for all those in need. Since inception, Genix has grown from being relatively humble contender to being one of the fastest growing companies in the Pakistani Pharmaceutical Arena. Having the best human capital coupled with a state of the art manufacturing facility spanning over 175,000 sq. feet and the prime focus on quality, the company aims to become the benchmark in the pharmaceutical industry. The product line ranges from specialty products to OTC medicines, as we believe in providing a wide range of products to cater to the needs of all types of requirements. The company is making an ever-increasing contribution to the export exchequer of Pakistan by exporting medicines to more than 10 countries including Afghanistan, Sri Lanka, lvory Coast and African Countries. Genix is strongly committed to ts responsibility towards

community and patients. Genie's products bring a promise of QUALITY and ensure smooth and flawless operations at its facility with local manufacturing in compliance with global quality standards, which strictly maintained and followed meticulously at even level in the process of manufacturing.

3. That both the reports of the Government Analyst Drug Testing Laboratories Punjab, Lahore mentioned in the table of SCN are unlawful as **TIME BARRED because issued after STATUARY PRESCRIBED PERIOD OF SIXTY DAYS whic**h is an illegality because Mandatory Section 22 -2 of the drug Act 1976 has been violated. This single points makes the whole case misfit for any

prosecution under the Drug Act 1976 and rules framed thereunder.

4. That both the reports of the Government Analyst Drug Testing Laboratories Punjab, Lahore mentioned in the table of SCN are crystal clear that both the Batch of Injection RBC mentioned in the SCN Table are standard quality because all the test including assay are in compliance All the analytical parameters including Assay results are in compliance in both the sample detailed in SCN.The sample Injection is Substandard on the basis of pH performed as per USP. pH determined in both the samples are 10.23 at 20 O and 10.24 at 20 C respectively against Limit 10.5- 11.1 at 20 C . The pH has mainly two impact - On The stability of the Formulation and Clinical response after administration of the drug. The Elemental iron has been determined in both the sample which is within USP Limit 95-105% which indicates that there is no adverse impact on Stability of the drug due to slightly variability in pH. The Clinical impact of pH has not been evaluated in this case. The protocols are not given in

5. Response on Para 1 SCN - No response on 1.i1.i and 1.iii as proceedings were done without association of the company.

6. That Noncompliance to Section 19 (3) related to statutory requirement of sending warrantor's portion within seven days, is illegal. The **Warrantor's portion has not been sent to the manufacturer within statutory period of seven days** as prescribed under Section 193) (i) of the Drugs Act 1976. The non-observance to said procedure is reasonably doubtful and is illegal. The PQCB has unanimously dropped Case No. PQCB R-577-09/2016 related to Infusion Dorcip Batch No.Dc-075 declared as Adulterated and Substandard by Government Analyst Drug Testing Laboratory Rawalpindi vide DTL Report TRA. No. 1077/DTL Dated: 22-09-2016. The PQCB had observed that this case was FlT FOR PROSECUTIOW based on report. But this case was DROPPED as PQCB had observed that case would fail in Court because warrantor portion was not sent to the manufacturer within the statutory period as prescribed under Section 19 (3) f the Drug Act 1976.PQCB members may kindly compare the present case of misbranded drug with the IGNORED CASE of Infusion Dorcjp to ascertain level of potential and real clinical Risks / ADR. Both cases are similar for noncompliance to Section 19 (3) with the ignored case may differentiated as of more severity. It is added that the author of the SCW has not mentioned date of dispatch / recejpt of Warrantor's portion in Para-iv due to reason best known to him.

7. That the para 2 .It is vehemently contested as company has not contravened any provision of the Drug Act 1976 / DRAP Act 2012 as evident from the following facts and law

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

   Amendment 2017/ 2018.

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

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

8. That the Para 3 of the SCN is responded. The Section (1 1) of the Drugs Act, 1976 and Rules (5) of the Punjab Drug Rules 2007 (as amended) could not be invoked due following submission.

I. The company should not be prosecuted as has not committed any of the contravention(s] under the Drugs Act 1976.
II. The licensing Authority / Drug Registration Authority should not be Drug recomnended for cancellation suspension of your Manufacturing/ Sale License and Drug Registration as it would be against Section 11(5)/2) of the Drug Act 1976
III. The only appropriate and suitable legal action in this case is DROPPING without any adverse action.

9. "The company does not agree with all the names nominated by the Inspector who has acted mechanically while using long handle of Discretion in ascertaining name of Ch. Muhammad Israr Sharif, Managing Director as accused, in disrespect the section 11 & 34 of the Drugs Act 1976 and Rule 5 of the Punjab Drug Rules 2007. He is not directly related to the issues under consideration as all routine operations are done without his prior knowledge and consent. The specific persons are given full powers to ensure that all the operations and final finished products released for market are in accordance with prevailing regulatory requirements in accordance with Drugs Laws of Pakistan. No one including MD of the company ever has any advance Knowledge or Consent about their decision related to manufacture and sale within the legal framework of the section 34 of the Drugs Act 1976 or any rule framed thereunder. Additionally, the Honorable Supreme Court of Pakistan has settled the question of liability related to the company in a case reported as PLD 1978 Supreme Court 193 (Superintendent of Police, Federal Investigation Agency, Lahore and another---Appellants Versus Akhtar Hussain Bhutta-- -Respondent). Therefore, it would be difficult to presume that the respondent was guilty of the manufacture of the said substandard drug for and on behalf of the Company, just because he happened to be its Managing Director. This submission is given by keeping ín view the prevailing Drug law read with latest Policy Board guided DRAP-Guideline circulated by Drug Regulatory Authority of Pakistan - Government of Pakistan Ministry of National Health Services, Regulations & Coordination December 2022 Islamabad vide No. F11-13/2O22-LA Dated t 2nd reproduced below as ready reference.

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

The Pakistan Pharmaceutical Manufacturers' Association (PPMA) has approached the Drug Regulatory Authority of Pakistan (DRAP) regarding implementation of the DRAP Act 2012 and the Drugs Act 1976 in a just and judicious manner in accordance with the following "Whether Managing Director is liable. Managing Director being assisted by various executives and workers, it is difficult to presume that respondent is quality of manufacture of substandard drugs. Burden of proof lies on prosecution to prove offence having been committed within knowledge and consent of the

Director."

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

judgment of the Hon 'ble Supreme Court of Pakistan reported as PLD 1978 SC 193:

"13. [.] true that under the provisions of section 34 of Drugs Act 1976; if a person guilty of an offence under ibid Act is a company, corporation, or firm; then, every director, partner or officer of the said

company, corporation, or firm, with whose knowledge and consent the offence is committed, shall be guilty of the offence. Albeit the ibid provision has placed emphasis upon the knowledge and consent of the director, partner, or officer of the said company, corporation, or firm, qua the offence, which under the law shall be proved by the prosecution, [..]"

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

4, Noncompliance of the above referred provision with reference unnecessary involving the Directors)employee(s) wvho are not involved or who do not have knowledge or consent to the commission of the offence is adversely affecting the growth of the pharmaceutical industry.

Therefore DRAP Authority has directed to issue policy guidance under section 7) of the DRAP Act 2012 that the name(s) of only those director(s) partner(s) and employee(s) of the company corporation, firm or institution may be included in the prosecution whose knowledge or consent could be established through evidence under section 28 of the Drug Requlatory Authority of Pakistan Act, 2012 and section 34 of the Drugs Act, 1976. (Aamar Latif) - Additional Director (Legal Affairs)

10 That name of Mr. Maqsood Ur Rehman as Quality Control In-charge has been unlawfully included/ ascertained for prosecution by Drug Inspector for the offences of Manufacturing / Sale of Substandard and issuance False Warranty. Because manufacturing and Quality Control Department

are Distinct and Independent The definition of manufacture under section 3 of the Drugs Act 1976 is reproduced below as reference.

3(r) "manufacture" in relation to a drug, means all operations involved in the production of the drug, including processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labelling with a view to its storage, sale and distribution, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian and "to manufacture" shall be construed accordingly.

The rule 16 (e) of Drugs (Licensing, Registering and Advertising) Rules, 1976 dealing with Conditions for the grant or renewal of lience to manufacture drugs by way of formulation reproduced below.

16 (e) The Quality Control Department shall be independent of the manufacturing unit and its Incharge shall be whole time employee of the manufacturer and shall possess a degree in pharmacy, or a degree in sCience with chemistry or a degree in medicine or pharmacology (for pharmacological testing) or a degree in microbiology (for microbiological testing) and has sufficient experience in testing of drug.

In the light of above submissions, it is established doubts that there is no contravention of the Drug Act 1976, framed thereunder. This is an open and shut case due to unlawful TME BARRED because issued after STATUARY PRESCRIBED PERIOD OF SIXTY DAYS which is an illegality because Mandatory Section 22 -2 of the drug Act 1976. The case may please be dropped by the Provincial Quality Control Board. Punjab, Lahore. Every citizen of Pakistan is entitled to be dealt in accordance with law and Due Process, without any discrimination, as per requirement of 1973 beyond reasonable or any Rules Constitution of Islamic Republic of Pakistan.

Personal hearing notice issued to the accused dated 11-12-2023

Summary:

Manufacturing Date: 4-2022

Expiry Date: 4-2024

Sampling Date: 24-6-2022

Sent to DTL (Form 6): 24-06-2022

Date of receipt in DTL: 28-06-2022

DTL Report Date: 03-09-2022

Time extension granted: 250-M dated 22-9-2022

1ST DI Communication with firm on dated: 19-09-2022

Date of Retesting Request of Firm: 19-09-2022

Fate of Retesting Request: withdrawal 253-M dated 29-11-2022

Investigation Report Dated: 02-05-2023

Case is placed before the Board for the decision

PROCEEDING & DECISION BY THE BOARD:

Case No. 25

PQCB/R-825, 826/2021

Sheikh Zayed Hospital, Rahim yar Khan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan,** through its Managing Director Ch. Muhammad Israr Sharif. 2. Ch. Muhammad Israr Sharif Managing Director 3. Syed Faiz-ul-Haq Production Incharge 4. Maqsood-ur-Rehman Quality Control Incharge/warrantor Of M/s Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sheikh Zayed Medical College/Hospital, Rahim Yar Khan reported that:

i. He, on 06-05-2021, inspected the premises of Central Pharmacy (Main medicine store) of Sheikh Zayed Medical College/Hospital, Rahim Yar Khan and took drug sample of following drug on Form No.04 for the purpose of test/analysis vide memorandum No. 319 & 321/DI-SZH-RYK dated 06-05-2021.

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

Sr No	Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
1	INJECTION. WATER FOR INJECTION GENIX [STERILE 10ML WATER FOR INJECTION] **Mfg** Date:	134I019	Genix Pharma, Karachi 44,45, Korangi creek Road, Karachi-75190, Pakistan	01-77004025/DTL dated: 01-07-2021	**Specification Applied: BP 2020** **DESCRIPTION:** Clear, colorless liquid in sealed transparent glass ampoule. (Stated Volume: 10ml). **VOLUME:** Limit: ……. NLT Nominal volume (10ml) Determined: ……...10.2 ml **CONDUCTIVITY:** Limit: ……. NMT 25 µS/cm Determined: ……15 µS/cm **STERILITY:** The product is sterile. **ENDOTOXN TEST: Does not comply with specifications**

<table>
<tr>
<td></td>
<td>02-2021

Exp. Date:

02-2023

Regn No:

073671</td>
<td></td>
<td></td>
<td></td>
<td>
Technique: Gel-Clot Technique
<table>
<tr><th></th><th>Limit (EL)=NMT 0.25EU/ml</th><th colspan="2">Gel Formation</th><th>Remarks</th></tr>
<tr><th></th><th></th><th>Yes</th><th>No</th><th></th></tr>
<tr><td>1</td><td>Positive control λ</td><td>•</td><td></td><td rowspan="5">Does not comply with specs</td></tr>
<tr><td>2</td><td>Positive control 2λ</td><td>•</td><td></td></tr>
<tr><td>3</td><td>Negative control</td><td></td><td>•</td></tr>
<tr><td>4</td><td>Product Positive control</td><td>•</td><td></td></tr>
<tr><td>5</td><td>Sample</td><td>•</td><td></td></tr>
</table>
RESULT: The sample is declared <u>SUB-STANDARD</u> on the basis of <u>ENDOTOXIN TEST</u>.
</td>
</tr>
<tr>
<td>2</td>
<td>INJECTION. WATER FOR INJECTION GENIX [STERILE 10ML WATER FOR INJECTION]

Mfg Date:

04-2021

Exp. Date:

04-2023

Regn No:

073671</td>
<td>139I019</td>
<td>Genix Pharma, Karachi

44,45, Korangi creek Road, Karachi-75190, Pakistan</td>
<td>01-77004027/DTL BWP dated: 01-07-2021</td>
<td>
Specification Applied: BP 2020

<u>COMPOSITION</u>: Each Ampoule contains:

Water for injection BP…. 10ml

<u>DESCRIPTION</u>: Clear, colorless liquid in sealed transparent glass ampoule. (Stated Volume: 10ml). 08 out of 20 ampoules contain undissolvable particulate matter seen with naked eye.

Does not comply with parenteral specifications

<u>VOLUME:</u> Limit: ……. NLT Nominal volume (10ml)

Determined: ……...10 ml

<u>CONDUCTIVITY:</u>

Limit: ……. NMT 25 µS/cm

Determined: ……11 µS/cm

<u>STERILITY:</u> The product is sterile.
</td>
</tr>
</table>

ENDOTOXIN TEST: (Does not comply with the specifications).

Technique: Gel-Clot Technique

	Limit (EL)=NMT 0.25EU/ml	**Gel Formation**		**Remarks**
		Yes	**No**	
1	Positive control λ	•		**Does not comply with specs**
2	Positive control 2λ	•		
3	Negative control		•	
4	Product Positive control	•		
5	Sample	•		

RESULT:

The sample is declared SUB-STANDARD on the basis of **ENDOTOXIN TEST and PHYSICAL TEST**.

iii. Store keeper, Central Pharmacy (Main medicine store) of Sheikh Zayed Medical College/Hospital, Rahim Yar Khan provided Invoice/Warranty No. CIN-00096495 and CIN-00096502 dated 27-04-2021 issued by M/S Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan as a proof of its purchase.

iv. Warrantor portion of subject batches of drug samples were sent to M/S Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan.

v. Copies of test/analysis report were sent to M/S Genix Pharma Pvt Limited 44, 45-B Korangi Creek Road, Karachi-Pakistan with directions to explain their position and provide requisite information in this regard. Firm requested retesting of drug samples. The Board in its 239th meeting dated 24-02-2022 decided to turn down the retesting request of the firm. Then Board in its 259th meeting dated 18-4-2023 decided to turn down subject review petition.

Previous Proceeding regarding retesting request:

The Board in its **239th meeting dated 24-02-2022** decided to **turn down** the retesting request of the firm. Then Board in its **259th meeting dated 18-4-2023** decided to turn down subject review petition of the firm.

3 Show cause notice issued to the accused dated 30-08-2023

Firm submitted reply to show cause notice dated 11-09-2023

The Show cause Notice has been issued based upon the dishonest report of an inefficient Drug inspector who has not performed his duties within the framework of prevailing Drug Laws in Pakistan. The Drug inspector has himself relied upon unlawful test / analysis reports of Government Analyst as contained in the above SCN. Ihe company had submitted appropriate confrontation to the regulatory unlawful acts and omissions. Defence assertions & confrontations submitted by the company have been innocently + boorishly + malciously concealed in this Show Cause Notice. Ihe facts have been twisted and concealed I para I whereas misreading of law is crystal clear visible in Para 2 and 3 which making foundation for building structure of injustice. Prejudicial Proceeding plus against the fair-minded conduct, violation of due process of law and belligerent violation of Principle of Natural Justice (Procedural Fairness). The mechanical scrutiny and subsequent disputed unlawful unanimous PQCB decision /order related to turn down of Retesting Request (PQCB Meeting 24.2.2022) taken in the absence of the Company Authorized Representative without meaningful personal hearing is unlawful as well as unjust t is also reminded that PQCB is not a Government. So, using insignia and Name of Primary and Secondary Health care department at the top of SCN creates false impression that PQCB is Government

The following submissions are made.

1. That Genix Pharma (Private) Limited was founded in the year 2004 with the vision to hep and provide top quality and affordable medicine for all those in need. Since inception, Genix has grown from being a relatively humble contender to being one of the fastest growing companies in the Pakistani Pharmaceutical Arena. Having the best human capital coupled with a state-of-the-art manufacturing facility spanning over l75,000 sg, feet and the prime focus on quality the company aim to became the benchmark in the pharmaceutical industry, The product line ranges from specialty products to OTC medicines, as we believe in providing a wide range of products to cater to the needs of all types of requirements. The company is making an ever-increasing contribution to the export exchequer of Pakistan by exporting medicines to more than 20 countries including Afghanistan, Srilanka, lvory Coast and African Countries. Genix is strongly committed to its responsibility towards community and patients. Genix's products bring a promise of QUALITY and ensure smooth and lawless operations at its facility with local manufacturing in compliance with global quality standards that are strictly maintained and tallowed meticulously at every level in the process of manufacturing.

2. That as per Right provided under the Principle of Natural Justice and drug law company needs fallowing information and attested copies documents for appropriate and rational preparation of written defense in response to Show Cause Notice No. POCB/R825, 826/2021 Dated 5D. D8. 2023.

a. The report of the Inspector submitted to PQCB- Punjab, Lahore under section 19 (6) of the Drug Act 1976.

b. The letter Na. DI-SZH-RYK/BIG Dated/B.072IZ3 of the Drug inspector, Sheikh Zayed Hospital, Rahin Yar Khan.

E. The copy the record to be presented before PLCB by the concerned Government Analyst because his report is usually silent about the pratocol of tests etc. He is a party to this case and is usually associated in PQCB decision making in the absence of person aggrieved by his report.

d The copies of form No.4 and Form No. 6.

e. The date of receipt of the Warranty from the person from whom samples were taken and Date of

Dispatch of Warrantor 's Portion to the company Genix.

f The decision of PQCB related to examination of the case under Rule 5(3) of the Punjab Drug Rules 2007 (Amended 201 2018) Rule 5(3) is reproduced below.

5(3) The Provincial or the District Board shall examine a case referred to it by an Inspector and shall, if an action is proposed to be taken against a person under the Act or the rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person recommending suspension or cancellation of his license to the licensing authority.

This may please be taken as an INTERIM REPLY to SCN The FINAL SELF-CONTAINED REPLY WRITTEN DEFENCE to SCN No. PQCB/R- 825, 826/2021 Dated 30-08-2023 would be submitted within four days after receipt of above documents and information.

At the end it is requested that meaningful personal hearing may kindly be provided whenever this Case is presented before the PQCB for any Interim or Final

4 Personal hearing notice issued to the accused dated 11-12-2023

Summary:

Manufacturing Date: 08-2021

Expiry Date: 02-2023

Sampling Date: 06-05-2021

Sent to DTL (Form 6): 06-05-2021

Date of receipt in DTL: 06-05-2021

DTL Report Date: 01-07-2021

1ST DI Communication with firm on dated: 26-07-2021

Date of Retesting Request of Firm to DI: 02-08-2021

Fate of Retesting Request: Turn down (239-M dated 24-02-2022), turn down the review petition. (259-M dated 18-04-2023)

Investigation Report Dated: 13-07-2023

Case is placed before the Board for the decision

PROCEEDING & DECISION BY THE BOARD:

Case No. 26

PQCB/ R-668/2021

Sir Ganga Ram Hospital, Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/s Genix Pharma (Pvt.) Limited 44, 45-B, Korangi Creek Road, Karachi-Pakistan** through its Managing Director/Chief Executive Officer Chaudhary Muhammad Israr Sharif. 2. Chaudhary Muhammad Israr Sharif Managing Director/Chief Executive Officer 3. Maqsood ur Rahman Quality Control Incharge/Warrantor 4. Syed Faiz ul Haq Production Incharge Of M/s Genix Pharma (Pvt.) Limited 44, 45-B, Korangi Creek Road, Karachi-Pakistan.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 07-10-2021 inspected the premises of Medicine Store, Sir Ganga Ram Hospital, Lahore, took sample of Water for Injection, Batch No. 148I019, manufactured by M/s Genix Pharma (Pvt.) Limited 44, 45-B, Korangi Creek Road, Karachi on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No. 0000108685 Dated 07-10-2021.
ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Lahore as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Injection Water for Injection BP Sterile 10ml [Water for Injection BP 10ml (Genix Pharma)] **Mfg. Date**: 07-2021 **Exp. Date**: 07-2023 **Reg** # 073671	148I019	M/s Genix Pharma (Pvt.) Limited 44, 45-B, Korangi Creek Road, Karachi	01-73010297/ DTL dated: 06 Dec 2021	**Result of test/ analysis with specifications applied:** BP 2021 **PHYSICAL DESCRIPTION:** Colourless liquid in colourless sealed glass ampoule with label printed on it. Claimed volume 10ml. **EXTRACTABLE VOLUME:** Determined: 11.0ml Limits: NLT Nominal volume; i.e. 10.0ml **CONDUCTIVITY:**

				Determined: 29.09 uS/CM AT 25.4C Limits: NMT 25 uS/CM AT 25C ± 1 **(Not Complies)** **TEST FOR ACIDITY/ALKALINITY**: Complies **CALCIUM & MAGNESIUM**: Complies **SULPHATES**: Complies **OXIDIZABLE SUBSTANCES**: Complies **STERILITY**: Sample is sterile **RESULT:** **The above sample is SUB-STANDARD on the basis of Conductivity test as per BP.**

iii. The Store keeper, Medicine Store, Sir Ganga Ram Hospital provided warranty/invoice bearing No. CIN-00107849 dated 25-09-2021 issued by M/s Genix Pharma (Pvt.) Limited 44, 45-B, Korangi Creek Road, Karachi.
iv. Warrantor Portion was sent to M/s Genix Pharma (Pvt.) Limited 44, 45-B, Korangi Creek Road, Karachi.
v. A copy of Test/ Analysis reports was sent to M/s Genix Pharma (Pvt.) Limited 44, 45-B, Korangi Creek Road, Karachi and they were directed to provide requisite information in this regard.
vi. The firm's request for re-testing by Appellate Laboratory was forwarded to Secretary, provincial Quality Control Board, and Punjab on 01-03-2022.
vii. Re-testing request was turned down by Provincial Quality Control Board in its 244th meeting dated 31-05-2022.

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

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

3. Showcause was issued to accused person(s) vide dated10-07-2023.

REPLY OF SHOW CAUSE NOTICE

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

The company had supplied Water for Injection BP 10 ml B No. 148I0I3 to Sir ganga Ram Hospital, Lahore The samples was taken by the inspector from the medicine store of the aforesaid Hospital for the purpose of test / analysis on bI7-10-202LHe had sent the sample to government Analyst Drug Testing Laboratory. Lahore far test /analysis who submitted lest /analysis reports TRA No. DTL 73010297/DTL Dated 6 Dec 2022 under Section 22 of the Drugs Act 1976the name of government Analyst is not mentioned on the reports which raises doubts regarding appointment of Gazette Notified Government Analyst as per requirement of section l of the Drug Act 1976 The perusal of the aforesaid report related to Sterile Water for injection BP 10ml B no. 1481019 purported to be manufactured by M/s Genix Pharma Pvt. limited 4, 45-8 Korangi Creek Road Karachi: Pakistan. Samples the Volume Sterility and Endotoxin Last as per Pharmacopoeial limits/ approved standard

conductivity Test Non-Complaint. Genix Pharma (Private) limited was founded in the year 2004 with the vision of helping and providing top quality and

Affordable medicine for those in need Since inception Genix has grown firm being a relatively humble contender to being one of the fastest growing companies in the Pakistani Pharmaceutical Arena. Having the best human capital coupled with a state-of-the-art manufacturing facility spanning giver l7500D sq. feet and the prime focus on quality.

The company aims to become the benchmark in the pharmaceutical industry The product line ranges from specialty products to OTC medicines as we believe in providing a wide range of products to cater to the needs of all types at requirements The company is making an ever-increasing contribution to the export exchequer of Pakistan by exporting medicines to more than 20 countries including Afghanistan Shi lanka, vary Coast and African countries. Being is Strongly committed to its responsibility towards community and patients. Genix's products bring a promise of QUALITY and ensure smooth and lawless operations at its facility with local manufacturing in compliance with global quality standards that are strictly maintained and followed meticulously at every level in the process of manufacturing.

2 That reference sample of the same batch has been tested by high tech Particles Measuring System employed at the Quality Control Department of the Company. Report is in compliance with Pharmacopoeial specification. Report

attached

3 That above report mentioned in SCN under reply is related to Sterile Water for injection BP l0ml B. No. 481019 purported to be manufactured by M/S Genix Pharma Pvt. Limited 44 45-B Korangi Creek Road Karachi-Pakistanis non-conclusive unlawful as full protocols the test aphid to reach the conclusion and Result of disputed drug as substandard have not been given in the Test Report The single bench of Lahore High Court has held that Reports of Analyst must be Conclusive and must disclose the tests applied to formulate opinion of government Analyst There is always likelihood of errors in tests/analysis report that would be of adverse consequence and definitely affects substantial rights of a person Therefore the description of the experiment including method evaluating standards/results must be Crystal clear whenever report would be disputed Reliance on PLD 2003 Lahore the honorable Single Judge relied on these judgments in the reported cases- by Gyanendra Nath Mittal v. State AlR 1359 AM. E34: S. Dutta and another. the D8 Judgments of Peshawar High Court and Quetta High Court had also held that report without protocol were fatally Defective and unlawful. Reliance on 1359G P CrL JI83 (Peshawar). 15, PLI 2012 Cr. C. (Duetta) 546 (D8). The

honorable Supreme Court has held in case reported as 2019 SCM 330 Report of the Government Analyst must contain Protocol The term protocol" has not been detained in the Rules lts dictionary meaning is A plan of scientific experiment are other procedure It is also referred to as the precise method for carrying out or reproducing a given experiment (Chambers 2ist Century Dictionary. 2007 Edition, page

(htps//wikidiftcam/protocol/method) These definitions are in line with the elaboration of the term protocol given in case of lmam Bakhsh wherein the Court stated the expression protocol' to mean an explicit plan of an experiment procedure. Or test It is clarified that protocol' is. Therefore, a recognized standard method or plan for carrying out the test applied to ascertain the nature of the substance under examination. No test can take place without protocol the Report of the government Analyst must stow that the test applied was in accordance with a recognized standard Protocol Any test conducted without protocol lases 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

(iii) The Result of the Test(s)

The Government Analyst has failed to give complete stepwise detail of Official Conductivity Test which raises reasonable Doubt related to Conclusions Authenticity and credibility of the testing and subsequent result. The official testing procedure

Is pasted below as ready reference.

4. That the manufacturer is not liable for any contravention if something goes wrong due to inadequate storage condition outside prescribed labelled direction. The section 32(3) of the Drugs Act 1976 require that it must be ascertained that Drug while in possession of purchaser. Was properly 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. The drugs must be stored, throughout the shelf life including "prior to test- Storage Condition during sampling. Transit Storage and storage at the concerned DTLs. Nobody know that whether storage conditions were compliant to section 32 of the Drugs Act 1976 during the process of sampling. Transport and storage. 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 1985 P Cr. I. J 281.

1984 P Cr. LJ 1580.

5. That Noncompliance to Section 19 (3) related to statutory requirement of sending warrantor's portion within seven days, is illegal. The Warrantor's portion has not been sent to the manufacturer within statutory period of seven days as prescribed under Section 19(3) (iv) of the Drugs Act 1976. The non-observance to said procedure is reasonably doubtful and is illegal. The POCB has unanimously dropped Case No. POCB R-577-09/2016 related to Infusion Dorcip, Batch No. Dc-075 declared as Adulterated and Substandard by Government Analyst Drug Testing Laboratory Rawalpindi vide DTL Report. TRA No. 1077/DTL Dated: 22-09-2016. The PQCB had observed that this case was FIT FOR PROSECUTION based on report. But this case was DROPPED as PQCB had observed that case would fail in court because warrantor portion was not sent to the manufacturer within statutory period as prescribed under Section 19 (3) of the Drug Act 1976.POCB members may kindly compare the present case with the IGNORED CASE of Infusion Dorcip

To ascertain level of potential and real clinical Risks/ADR. Both cases are similar to the ignored case and may be Differentiated as of mare severity. It is added that the author of the SCN has not mentioned date of dispatch/receipt he charge of issuance of false warranty is based uyon misreading of relevant law. The warranty was used after release of standard quality report by Quality Control Department of the company The offence of issuance of false warranty is added to enhance punishment with malafide intention. The implication of the Section 27(2) dealing with false warranty is malice in law as well Be malice in fact

Because good and sufficient reason Were available as warranty was given after release of medicines By quality control Department of the company. The section 27, (2) (b) is reproduced below 27 (2) whoever himself or by any other person on his b (a) Ur (6) 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 2B 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

E That the para 3 of the SCN is responded- "The company does not agree with all the names nominated by the inspector who has acted mechanically while using long handle of Discretion in ascertaining name of Muhammad lsrar Sharif, Managing Director as accused in disrespect the section Il & 34 of the Drugs Act 1976 and Punjab drug rules 2007 He is not directly related to the issues under consideration as al routine operations are done without his prior knowledge and consent The Honorable Supreme Court of Pakistan has settled the question of liability reeve to the company in a case reported as PLD I978 Supreme Court 193 (Superintendent of Police Federal resignation Agency, Lahore, and another---Appellants Versus Akhtar Hussain Bhutta-Respondent Therefore, be difficult to presume that the respondent was quality of the manufacture of the said substandard drug tor and

n behalf of the company, just because he happened to be its Managing Director:

many, the name of Mr. Maqsood Ur Rehan as Duality Controller-charge has been unlawfully included ascertained prosecution by Drug inspector or the offences of Manufacturing/ Sale of Substandard and issuance of false Warranty . because manufacturing and quality Control Department are Distinct and independent the definition of manufacture under section 3 of the Drugs Act 197G is reproduced below as reference SG manufacture" in relation to a drug, Means all operations involved the production of the drug, including processing, compounding, formulating, packing, repacking, ornamenting. finishing and labeling with a view to its storage sale and distribution but does not include the compounding and dispensing or the packing of any Drug in the ordinary course of retail business or on D prescription after registered medical practitioner are dentist or of veterinarian and to manufacture shall be construed accordingly

me rule l6 (e) of Drugs (licensing Renicterina and Advertising) Rules 1376 dealing with Lenitions tor the grant or

renewal of license to manufacture drugs by way of formulation reproduced below 16 (e) The Quality Control Department shall be independent of the manufacturing unit and its Incharge shall be whale time employee of the manufacturer and shall possess degree in pharmacy Dr. a degree in science with chemistry or a degree in medicine or pharmacology (for

pharmacological testing) or a degree in microbiology (or microbiological testing) and has

sufficient experience in testing of drug

8 The PARA 3of SCN is reproduced or there are required under Section (W of the Drugs Act 1976 and Rules (5) of the Punjab Drug Rules 2007 (as amended) ta show cause as to why, should not be prosecuted far committing the above said contraventions] in the Drug Court.

6. That no Pre-Show Cause Notice (SCN) scrutiny done and SCN issued in violation of rule 5. (3) The Punjab Drugs Rules 2007 is illegal. This mandatory scrutiny would have done Justice with the applicant who has been dragged in the process Of malicious prosecution. The rule reproduced as The POCB shall examine a case referred to it by an Inspector and shall, if an action is proposed to be taken against a person under the Act or the rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension

Or cancellation of his license to the licensing authority.

7. That the para 2 of the SCN is vehemently denied as company has not contravened any provision of the Drug Act 1976/DRAP Act 2012 as evident from the following facts and law

i. The company has neither contravened section 23/27 of the Drug Act 1976 (as amended) nor the DRAP Act 2012 and Rules framed thereunder. The case is based upon the Non-Conclusive Report of Government Analyst, as sufficient evidence in contraversion to this report is available as per the requirement of section 22(4) of the Drug Act 1976 23/27 of the Drug Act 1976 is maliciously applied By admitting the specific sections. 23(1) (a-l-x b-h 10i-i and (27-1). (27-2). (27-3) and (27-4). The Punjab Amendment in the Drug Act 1976 and DRAP Act 2012 are not applicable simultaneously in this case because the Drug Act 1976 which is the part of Schedule VI of DRAP Act 2012 is different from the Drug Act 1976 with Punjab Amendment 2017/2018.

he licensing Authority/Drug Registration Authority should not be recommended for cancellation

Suspension of your Drug Manufacturing/Sale License and Drug Registration. bar suitable legal action [s] should not be taken against you. The prosecution would be unlawful because it would be based upon a Non-Conclusive Report that cannot

Be used as evidence in any criminal trial. Furthermore, mandatory provisions of Drug Act 196 have

been violated which would adversely affect the prosecution culminating into a futile exercise which

Would ultimately lead to acquittal of the accused. It is respectfully repeated/reminded that report of

Government Analyst which form basis of this SCN is neither legal nor conclusive. The quality of sample

must be ascertained by Retesting from the NIH Islamabad which is appellate lab under the Drug Act

1976. Please read with the comments + explanation of Para 2 of the SCN. The POCB cannot give recommendation of the licensing Authority/Drug Registration Authority either for cancellation/suspension of your Drug Manufacturing or/and Drug Registration because the POCB has not conducted any inspection as per requirement of Section II(5)(a) of the Drug Act 1976 (Punjab

Drug Amendment Act 2017/2018) is reproduced below. II (5) The following shall be the powers and functions of the Provincial Quality Control Board, namely:

(a) To inspect any premises where any drug is being, or is to be. manufactured or sold and to recommend to the appropriate authority the cancellation or suspension of the license to manufacture or sell drugs

Granted to any person who is found to be contravening. Or to have contravened, any of the provisions of this Act, or the rules.

The only legal action would be dropping of the case under the Drug Act 1976 because any other action would be equivalent to out of good faith- unlawful act outside the legal boundaries of the applicable

Prevailing Drug laws in Punjab/Pakistan.AT the end it is requested Kindly ignore the case, as there would be no likelihood of success of this case in any Court of law. The PQCB is requested to pass speaking order by giving annulated confrontation to the defense of the company. It is now well

settled that non-speaking order is to be discouraged and authority is required to give reasons while passing

Administrative as well as judicial orders. It must supply adequate reasons for the conclusion arrived at and should reflect application of judicious mind by the Judge/authority and not to be mechanical or non-speaking. Reliance, in this regard, can be placed upon Province of Sindh through Secretary Education Government of Sindh Karachi and 3 others vs Miss Salma Bano and others (2003 SCMR 1126). Muhammad Farooq Shah v Shakirullah (2006 SCMR 1657). Abdul Majeed Zafar and others v. Governor of the Punjab through Chief Secretary and others (2007 SCHR 330), Umar

Din through L Rs. V. Mst. Shakeela Bibi and others (2009 SC4R 29). Secretary Ministry of Health Government of Pakistan, Islamabad, and another v. Dr. Rehana Hameed and others (2010 SCMR 511). Government of Pakistan through Director General, Ministry of Interior Islamabad, and others v. Farheen Rashid (2011 SCMR I) and others vs. Messrs MFM Industries Ltd. In addition, others v. Federation of Pakistan through Ministry of Commerce and others (2015 SCMR 1550).

Personnel hearing notice(s) issued to accused person(s) vide dated 11-12-2023.

Case is placed before the Board.

Summary:

Manufacturing Date: 07-2021

Expiry Date: 07-2023

PROCEEDINGS AND DECISION BY THE BOARD:

Sampling Date: 07-10-2021

Sent to DTL (Form 6): 07-10-2021

Date of receipt in DTL: 11-10-2021

DTL Report Date: 06-12-2021

Time Extension: N/A

1ST DI Communication with firm on dated: 31-01-2022

Date of Retesting Request of Firm: 01-03-2021

Fate of Retesting Request: -T.D in 244th meeting (time Barred case)

Investigation Report Dated: 07-12-2022

Case No. 27

PQCB/R-596/2018

Tehsil & District Vehari

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Harrison Pharmaceuticals, 10km Lahore Road Sargodha Pakistan** through its CEO/warrantor Abdul Ghafir 2. Abdul Ghafir — Chief Executive Officer/warrantor 3. Sadiqa Ishtiaq — Quality Control Manager 4. Khawar Abbas — Production Manager of M/s Harrison Pharmaceuticals, 10km Lahore Road Sargodha -Pakistan

BRIEF FACTS OF THE CASE

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

i. The then Drug inspector, on 17-03-2018 inspected the business premises of M/s Al Fareed Medicine Company Club Road Vehari and took subject drug sample on Form No. 4 for the purpose of test/analysis vide memorandum no. 7390 dated 17-03-2018.
ii. Following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below: -

Name of drug	Batch no.	Name of manufacturer	TRA No & Date	DTL Test Report Results
Tablet H-Fan [Diclofenac (K):50mg] **Mfg. Date**: 07-2017 **Exp. Date**: 07-2019 **Regn. No**: 060371	HN-56	M/s Harrison Pharma, 10km Lahore Road Sargodha	No. 01-60001405/DTL dated 22-05-2018	**Results of test/analysis with specifications applied: USP** **DISSOLUTION TEST: Does not comply with specs as described below:** **Tolerance limit**: NLT 75% (Q) of the labelled amount of diclofenac dissolved in 60 minu

Level	Units	Acceptance criteria
S1	**6**	No unit is less than **Q+5%
S2	6	Average of 12 unit (S1+S2) is equal to or greater than Q, and no unit is less than Q-15%
S3	12	Average of 24 unit (S1+S2+S3) is equal to or greater than Q, and NMT 2 u are less than Q-15% and no unit is less than Q-25%
Level	**Units**	**% release**

S1	6	U #1	U #2	U #3	U #4	U #5	U #6	**Does no comply**	Pr ac th cri of S1
determined		10.03%	9.25%	9.50%	9.70%	6.90%	7.45%		

*According to USP the dosage unit (U) is specified as one tablet.

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

ASSAY: Diclofenac

Stated: 50mg/tab

Determined: 45.20mg/tab

Percentage: 90.40%

Limit: 90-110%

iii. M/s Al-Fareed Medicine Company Club Road, Vehari provided Invoice/ warranty No. SOB-0004696 dated 14-03-2018 issued by M/s Asif Traders Masjid wali F/Block Vehari.
iv. Warrantor Portion was sent to M/s Asif Traders Masjid wali F/Block Vehari.
v. M/s Asif traders Masjid Wali F/Block Vehari provided invoice/warranty no. 17 dated 09-09-2017 issued by M/s TG pharma H # 105 Shah Mir Villas Bank Road Lahore who in turn provided invoice/warranty no. HP71 dated 17-07-2017 Harrison Pharmaceuticals, 10km Lahore Road Sargodha Pakistan as a proof of its purchase.
vi. A copy of Test/ Analysis report was sent to M/s Harrison Pharmaceuticals, 10km Lahore Road Sargodha Pakistan and they were directed to provide requisite information in this regard. In response, Firm requested retesting of the sample from NIH, Islamabad. Pursuant to Firm's request, sample was sent to NIH, Islamabad. That Chief, Appellate Laboratory/NIH Islamabad also declared the sample drug in question as **Substandard**. The detail is as follow: -

Name of drug	**Batch no.**	**Name of manufacturer**	**NIH Test Report No. & Date**	**NIH Test Report Results**
H-Fan Tablet 50mg	HN.56	M/s Harrison Pharmaceuticals, 10km Lahore Road Sargodha	No. 0136-P/2019 dated 19-06-2019	**Reference:** USP-39 **DESCRIPTION:** **B**rown colored circular, biconvex coated tablets packed in blister packing further contained in an outer carton. **IDENTIFICATION:** Diclofenac potassium identified **DISSOLUTION TEST:** **Determined**: **14.27%** of labelled amount. All six tablets deviated from limit (Q) within 60mins.

				LIMT: NLT 75% (Q) of the labelled amount dissolved in 60 minutes. **Does not** comply with USP-39 **ASSAY:** **Assay** | **Stated** | **Found** | **Limit** | **Percentage** Diclofenac Potassium | 50mg/tab | 47.302mg/tab | 90-110% | 94.605% **Complies with USP-39** **CONCLUSION:** The sample is **Sub-standard** quality on the basis of tests performed.

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

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

3 Show cause notice issued to the accused dated 14-11-2023

4 Personal hearing notice issued to the accused dated 11-12-2023

Summary:

Manufacturing Date: 07-2017

Expiry Date: 07-2019

Sampling Date: 17-03-2018

Sent to DTL (Form 6): 17-03-2018

Date of receipt in DTL: 24-03-2018

DTL Report Date: 22-05-2018

1ST DI Communication with firm on dated: 19-01-2019

Date of Retesting Request of Firm: 25-02-2019

Fate of Retesting Request: allow (8-CM dated 08-05-2019)

Sample received in NIH: 17-05-2019

NIH report date: 19-06-2019

Investigation Report Dated: 19-09-2023

Case is placed before the Board for the decision

PROCEEDING & DECISION BY THE BOARD:

Case No. 28

PQCB/R-584/2018

(Tehsil & District Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Star Laboratories, 23-Km Multan Road, Lahore,** through its Chief Executive Officer, Muhammad Israr H. Malik, 2. Muhammad Israr H. Malik Chief Executive Officer/ Warrantor 3. Ubaid Mahmood Khan Production Incharge 4. Mohsin Gull Aziz Quality Control Manager 5. Sameer Ashfaq Warrantor **of M/S Star Laboratories, 23-Km Multan Road, Lahore.**

BRIEF FACTS OF THE CASE

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

i. Her Predecessor, on 12.05.2018, inspected the premises, Store of Directorate Live Stock, Jogi Chowk, Tehsil & District Sahiwal and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo. No. 13215, dated 12.05.2018.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur,** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Injection Pred CPM (Prednisolone: 10mg, Chlorpheniramine Maleate: 4mg) **Mfg Date:** 04.2018 **Exp Date:** 04.2020	VD 255	M/S Star Laboratories, 23-Km Multan Road, Lahore	01-25001392/DTL Dated. 27.08.2018	**Analysis with specifications applied: MS** **Composition: Each ml contains:** Prednisolone: 10mg, Chlorpheniramine Maleate: 4mg **Description:** A white to off white color suspension filled in amber glass vial of 50ml, sealed with rubber stopper and flips off seal. **Avg. Filled Volume:** limit: 50.0-51.0 ml, Determined: 51ml **pH:** Limit: 5.0-7.5, Determined: 5.051 **Sterility:** The product is sterile **Identification:** prednisolone and Chlorpheniramine Maleate identified.

Registration No. 031449				**Assay (USP):** **Result:** The Sample is **Sub-Standard** on the basis of Assay Test.

Ingredient	**Stated**	**Determined**	**Percentage**
Prednisolone	10mg/ml	2.189mg/ml	**21.89%** Limit: 90-110%
Chlorpheniramine Maleate	4mg/ml	4.36mg/ml	109.11% Limit: 90-110%

iii. Store keeper of Store of Directorate Live Stock, Jogi Chowk, Tehsil & District Sahiwal provided delivery challan/ Invoice/warranty No. 94 dated 10.04.2018 issued by M/S Star Laboratories, 23-Km Multan Road, Lahore as a proof of its purchase.
iv. Warrantor portion of drug sample was sent to M/S Star Laboratories, 23-Km Multan Road, Lahore.
v. A copy of test/analysis report was sent to M/S Star Laboratories, 23-Km Multan Road, Lahore and they were directed to explain their position and to provide the requisite information in this regard.

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

    a. **Manufacture/ Selling / Stock of Substandard drug.**
    b. **Issuance of false warranty**

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

Reply of Show Cause Notice:

1. Pred-CPM Injectable Suspension Batch No, VD-255 was allegedly declared Substandard by DTL Bahawalpur on the basis of Assay for Prednisolone vide DTL Bahawalpur report TRA No. 01-25001392/DTL dated 27.08.2018.

2. As per the DTL report, the results are as below:

Description: A white to off white color suspension filled in amber glass vial of 50ml, sealed with rubber stopper and flips off seal.

Avg. Filled volume: 50ml Limit: (50 - 51ml)

pH: 5.051 Limit: (5 - 7.5)

Sterility: The Product is Sterile.

Assay:

Prednisolone: 21.89% (Does Not Comply) Limit: (90 - 110%)

Chlorpheniramine Maleate: 109.11% (Complies) Limit: (90 - 110%)

[Important to note that the "Description" given in the report does not match with the assay result of Prednisolone. If the suspension is described as white to off white, then the assay for Prednisolone cannot be 21.89%. Prednisone is the only suspended material responsible for the white appearance of the product, and a low percentage of Prednisolone would undoubtedly affect the product's appearance. It is crucial to determine whether the "Description" or the "Reported assay for Prednisolone" is incorrect or vice versa.]

3. In response to the Show Cause Notice following in submitted:-

i The sample received by DTL Bahawalpur was on 18.05.2018, and the report was generated on 27.08.2018, which is invalid because same has been generated after lapse of 40 days instead of stipulated time of 60 days as per provision in Drug Act 1976. (Copy of DTL report attached Flag A)

ii .The Drug Inspector informed the company on 25.09.2018, almost one month after receipt of the report, and the letter was received on 09.10.2018 (Copy of Letter attached Flag B).

iii. The company promptly requested for re-test on 09.10.2018 (Copy of Letter attached Flag C).

iv. The "PERSONAL HEARING NOTICE" for Re-Test was received on 06.07.2021, which was well after the EXPIRY of the product (Copy of Letter attached Flag D). Company representatives attended the 17th Retesting committee meeting on 13.07.2021 and apprised the Board accordingly.

v. Till to date, NO intimation has been received from the Punjab Quality Control Board whether our request for retesting was entertained or otherwise.

vi. The same batch has also been declared as of Standard quality by DTL Multan vide their report TRA No. 01-56000652 dated 14.06.2018 (Copy of Letter attached Flag E).

vii. The DTL report is time-barred, with a delay of one month in informing us by the Drug Inspector, the product has already expired, and there has been no intimation from the Board regarding the request for a Retest for more than two years. The firm has been deprived of its legal right for a Retest, resulting in a significant financial loss of the expired batch.

4. Keeping in view the above, we, M/s Star Laboratories (Private) Limited, humbly request the board to drop the case in the best interests of justice, equity, and fair play. We believe that the circumstances surrounding this case warrant a thorough reevaluation, and we trust that the Board will consider the facts presented in our response.

We remain committed to upholding the highest standards of quality and compliance in our operations and look forward to a fair resolution of this matter.

Summary:

Manufacturing Date: 04.2018

Expiry Date: 04.2020

Sampling Date (Form 4): 12.05.2018

Sent to DTL (Form 6): 12.05.2018

Date of receipt in DTL: 18.05.2018

DTL Report Date (Form 7): 27.08.2018

Time Extension: Granted in 190-M

1ST DI Communication with firm on dated: 25.09.2018

Date of Retesting Request of Firm: 09.10.2018

Fate of Retesting Request: Not Entertained

Investigation Report Dated: 13.04.2023

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

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 29

PQCB/R-665/2020

(Tehsil and District Sahiwal)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi** through its Managing Director Mr Jawad Amin Khan 2. Mr. Jawad Amin Khan — Managing Director 3. Mrs. Bina Riaz — Production In-charge 4. Mr. Sayed Shakeel Ahmed — Quality Control In-charge 5. Mr. Shehzad Ahmed Khan — Warrantor **Of M/S Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi.**

BRIEF FACTS OF THE CASE

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

i. She, on 23-07-2022, inspected the premises of Medicine Store, o/o CEO (DHA) Sahiwal and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo. No. 134134, dated 23-07-2022.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Bahawalpur, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Nebulizer Solution Zaftolin [Salbutamol 5mg/ml (as Salbutamol Sulphate)] **Mfg Date:** June-2022 **Exp Date:** June-2025	94	M/S Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi	01-10094000311/DTL Dated. 30-09-2022	**Specification applied: BP 2022** **COMPOSITION** Each ml Contains: Salbutamol 5mg (As Salbutamol Sulphate BP) **DESCRIPTION** Colorless liquid in white sealed white plastic bottle. Packed in outer carton. (Stated volume: 20 ml) **pH (BP)** Determined: **6.782** Limit: 3.0 – 5.0 **(DOES NOT COMPLY WITH SPECS.)** **IDENTIFICATION (BP)** Salbutamol is identified.

Registration No. 039618				**ASSAY (BP) Stated Determined Percentage** Salbutamol 5mg/ml 5.065mg/ml 101.31% **LIMIT: 95.0 – 105.0%** **RESULT**: The sample is declared **SUB-STANDARD** on the basis of **pH TEST**.

iii. Store keeper of Main Medicine Store o/o CEO (DHA) Sahiwal provided delivery challan/ Invoice/warranty No. 307525, dated 07-07-2022 issued by M/S Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi as a proof of its purchase.
iv. Warrantor portion of drug sample was sent to M/S Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi**.**
v. A copy of test/analysis report was sent to M/S Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard. In response, the firm requested for re-test/ analysis of the drug sample.
vi. Pursuant to the request of manufacturer, the PQCB portion of the drug sample was sent to Appellate Laboratory. The drug was declared substandard from Appellate Laboratory, National Institute of Health Sciences, Islamabad as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Report No. & Date**	**NIH Test Report Result**
Nebulizer Solution Zaftolin [Salbutamol 5mg/ml (as Salbutamol Sulphate)]	94	M/S Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi	0338-P/2022 dated 04-01-2023	**Analysis with specifications applied: MS** **pH Test** **Determined:** 6.8± 0.06 **Limit: 3.0-5.0** **Does not comply with manufacturer specification** **Result:** The sample is of **Sub-standard** quality on the basis of tests performed.

vii. A copy of NIH Report was sent to M/S Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi with directions to explain their position and provide requisite information in this regard.

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

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

3. Show-cause notice(s) issued to accused person(s).
4. Firm Submitted Reply of Show Cause Notice

Summary:

Manufacturing Date: 06.2022

Expiry Date: 06.2025

Sampling Date (Form 4): 23.07.2022

Sent to DTL (Form 6): 23.07.2022

Date of receipt in DTL: 27.07.2022

DTL Report Date (Form 7): 30.09.2022

Time Extension: Granted in 251-M

1ST DI Communication with firm on dated: 18.10.2022

Date of Retesting Request of Firm: 24.10.2022

Fate of Retesting Request: Substandard by NIH

Investigation Report Dated: 28.02.2023

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

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 30

PQCB R-333/2022

Bosan Town, District Multan

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Leads Pharma (Pvt) Ltd., (Vet Div), Plot No. 8-A, Street No. 6, 1-10/3, Industrial Area, Islamabad-Pakistan,** through its Managing Director, Shoaib Amjad 2. Shoaib Amjad — Managing Director 3. Asim Sultan — Production Incharge 4. Muhammad Zubair — Quality Control Incharge 5. Muhammad Naveed Aslam — Warrantor of M/S Leads Pharma (Pvt) Ltd., (Vet Div), Plot No. 8-A, Street No. 6, 1-10/3, Industrial Area, Islamabad-Pakistan.

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 08-04-2022, inspected the premises of Main Medicine Store, O/o Director Live Stock, Gulshan-e-Mehar Colony, Multan and took 14 different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.
ii. The subject drug sample, sent vide memo no. 123267 dated:08-04-2022, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, Multan, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Toldivet (Toldimfos Sodium 200mg/mL) Injection 100 mL **Mfg. dated: 02-2022** **Exp. date: 02-2024** **Reg# 043557**	4484	M/S Leads Pharma (Pvt.) Ltd, (Vet Div.) Plot # 81-A, St. No 6, I-10/3. Industrial Area, Islamabad - Pakistan.	01-94003192 /DTL, Dated: 09-06-2022

Specification applied: MS

Description: A clear lemon to yellow color solution in a labeled amber glass vial closed with a rubber stopper, seal with aluminum and white flip off lid packed in a labeled outer hard carton.

Identification Toldimfos Sodium Identified.

Assay: UV-Spectrophotometer

Toldimfos Sodium

Stated: 200 mg/ mL

Determined: 183.48 mg/ mL

Percentage: 91.74 %

Limit: 90-110% (Complies)

Extractable Volume

Limit: NLT stated

Determined: 105 mL (Complies)

pH

Limit: 9.50-12.50

Determined: **9.16** **(Does Not Comply)**

Sterility: It conforms to sterility test (Complies)

Result: The above sample is **Sub-Standard** on the basis of **pH Test**

iii. Store Keeper, Main Medicine Store, O/o Director Live Stock, Gulshan-e-Mehar Colony, Multan, provided invoice/ warranty No.523 dated 19-03-2022 issued by M/s Leads Pharma (Pvt.) Ltd, (Vet Div.) Plot # 81-A, St. No 6, I-10/3. Industrial Area, Islamabad - Pakistan., as a proof of its purchase

iv. Warrantor portion of drug sample was sent to M/s Leads Pharma (Pvt.) Ltd, (Vet Div.) Plot # 81-A, St. No 6, I-10/3. Industrial Area, Islamabad - Pakistan.

v. A copy of test/analysis report was sent to M/S Leads Pharma (Pvt.) Ltd, (Vet Div.) Plot # 81-A, St. No 6, I-10/3. Industrial Area, Islamabad - Pakistan. and they were asked to explain their position and provide the requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.

vii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Toldivet (Toldimfos Sodium 200mg/mL) Injection 100 mL	4484	M/S Leads Pharma (Pvt.) Ltd, (Vet Div.) Plot # 81-A, St. No 6, I-10/3. Industrial Area, Islamabad -	0260-P/2022 dated: 03-11-2022	**Analysis with specifications applied: MS** **pH:** **Determined**: 6.0 ±0.06

		Pakistan		**Limit:** 9.50-12.50 (Does not comply with manufacturer specifications) **Result:** The sample is of **Substandard** quality on the basis of tests performed.

viii. Copy of NIH report was sent to M/S Leads Pharma (Pvt.) Ltd, (Vet Div.) Plot # 81-A, St. No 6, I-10/3. Industrial Area, Islamabad - Pakistan.

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

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

b. **Issuance of false warranty**

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

Reply to Show Cause Notice:

Reference to your office letter no. PQCB/R-333/2022 dated 05-05-2023 received on 11-05-2023, it is to be stated as follows.

1- We have Pass reports for same batch from 2 DTLS (Bahawalpur and Faisalabad).

2- Limit of the pH is 9.5-12.5, while DTL report is 9.16, which in not very significant variance.

3- Such difference is also possible if the equipment is not properly calibrated.

4- Our Warrantor and Retained samples are also as per specifications.

5- Also, such a small variation in pH does not affect the efficacy of the product as evident by the analysis of the product and other tests performed.

6- Required information is also attached herewith.

It is therefore requested to show leniency towards us & dismiss the case with warning. We will be very much thankful to you.

Personal hearing notice(s) issued to accused person(s) on 11-12-2023.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:02-2022**
- **Exp. Date: 02-2024**
- **Sampling date (Form 4): 08-04-2022**
- **Sent to DTL (Form 6): 08-04-2022**
- **Date of receipt in DTL: 12-04-2022**

- **DTL Report Date (Form 7): 09-06-2022**
- **DI 1st intimation to firm: 09-06-2022**
- **Retesting request if any: Yes, allowed in 250th meeting, dated: 22-09-2022**
- **Fate of Retesting Request: NIH Substandard**
- **Investigation report Dated: 21-01-2023**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 31

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.

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

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.

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 **260th meeting** held on **04-05-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. M. Asif Abbas, Secretary DQCB, District Dera Ghazi Khan & Mr. Faisal Mahmood Khan, Drug Inspector, Tehsil Dera Ghazi Khan (Urban), District Dera Ghazi Khan were present along with the original case record. Among the nominated accused persons, Muhammad Rafiq, Production Incharge of **M/s Z-Jans Pharmaceuticals (Pvt.) Ltd. 148-A, Industrial Estate, Hayatabad, Peshawar Pakistan** appeared before the Board and reiterated the arguments already submitted in response to show cause notice. He further submitted that they have changed the PH range of the product i.e. 3.5-5.5 according to which the PH of the subject drug sample is well within the limit. The firm requested to take lenient view from the Board.

6. The Board on scrutiny of the case record observed that the product was declared Misbranded on the basis that 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. The Board observed that the firm has submitted rectified label in this regard. The Board further observed that product was declared Substandard on the basis of pH that was determined to be 4.103 at 25^{o}C while the range is 4.5-5.5. The Board after due deliberation and discussion unanimously decided to **pend** the case with directions to the firm to submit evidence regarding stability profile of the subject drug sample on the pH 4.5-5.5 according to manufacturer’s specifications.

7. Firm provided accelerated stability data, received in the office of Provincial Quality Control Board dated 04-12-2023.

Z-JANS PHARMACEUTICALS (PVT) LTD

Quality Control Department

(Accelerated Stability Data)

Product ; *ALBENZA (ALBENDAZOLE) 100 mg/5ml suspension* Storage condition

Batch No ; *Trill 001* Temperature; 40 ± 2° C

Data started ; 13-01-2023 Humidity ; 75 ± 5%

Batch Size ; 1000bottles *Mfg* 01/2023 EXP 1/2025

Packing ; Glass bottle with sealed Aluminum cap

TEST PARAMETER	Specification	INITIAL 13-01-2023	1 MONTH 13-02-2023	2 MONTH 13-03-2023	3 MONTH 13-04-2023	6 MONTH 13-07-2023
Description	White suspension	White suspension	White suspension	White suspension	White suspension	White suspension
Identification	Positive for albendazole	Complies	Complies	Complies	Complies	Complies
Taste	Sweet	Complies	Complies	Complies	Complies	Complies
Flavor	Tutee fruity	Complies	Complies	Complies	Complies	Complies
Ph	3.5————5.5	5.01	4.99	4.90	4.84	4.80
Assay,(ALBENDAZOLE	90.00% to 110.0%	105.76%	104.01%	103.98%	103.97%	102.01%

Date of report; 13-07-2023

Conclusion ; Albendazole100 mg/5ml suspension Trill No 001 meets the requirement at the end of 6 months after keeping at 40º C, 75% RH

ANALYST **Quality Control Manager**

Z-JANS PHARMACEUTICALS (PVT) LTD

Quality Control Department

(Accelerated Stability Data)

Product ; *ALBENZA (ALBENDAZOLE) 100 mg/5ml suspension* Storage condition

Batch No ; *Trill 02* Temperature; 40 ± 2° C

Data started ; 17-01-2023 Humidity ; 75 ± 5%

Batch Size ; 1000 bottles *Mfg* 01/2023 EXP 1/2025

Packing ; Glass bottle with sealed Aluminum cap

TEST PARAMETER	Specification	INITIAL 17-01-2023	1 MONTH 17-02-2023	2 MONTH 17-03-2023	3 MONTH 17-04-2023	6 MONTH 17-07-2023
Description	White suspension	White suspension	White suspension	White suspension	White suspension	White suspension
Identification	Positive for albendazole	Complies	Complies	Complies	Complies	Complies
Taste	Sweet	Complies	Complies	Complies	Complies	Complies
Flavor	Tutee fruity	Complies	Complies	Complies	Complies	Complies
Ph	3.5————5.5	4.99	4.73	4.70	4.68	4.66
Assay,(ALBENDAZOLE	90.00% to 110.0%	104.26%	103.99%	103.17%	102.55%	101.91%

Date of report; 17-07-2023

Conclusion ; Albendazole100 mg/5ml suspension Trill No 002 meets the requirement at the end of 6 months after keeping at 40º C, 75% RH

ANALYST **Quality Control Manager**

Z-JANS PHARMACEUTICALS (PVT) LTD

Quality Control Department

(Accelerated Stability Data)

Product ; ALBENZA (ALBENDAZOLE) 100 mg/5ml suspension Storage condition

Batch No ; Trill 003 Temperature; 40 ± 2° C

Data started ; 20-01-2023 Humidity ; 75 ± 5%

Batch Size ; 1000bottles Mfg 01/2023 EXP 1/2025

Packing ; Glass bottle with sealed Aluminum cap

TEST PARAMETER	Specification	INITIAL 20-01-2023	1 MONTH 20-02-2023	2 MONTH 20-03-2023	3 MONTH 20-04-2023	6 MONTH 20-07-2023
Description	White suspension	White suspension	White suspension	White suspension	White suspension	White suspension
Identification	Positive for albendazole	Complies	Complies	Complies	Complies	Complies
Taste	Sweet	Complies	Complies	Complies	Complies	Complies
Flavor	Tutee fruity	Complies	Complies	Complies	Complies	Complies
Ph	3.5----------5.5	5.01	4.95	4.91	4.91	4.83
Assay,(ALBENDAZOLE	90.00% to 110.0%	104.87%	103.11%	102.02%	101.55%	101.01%

Date of report; 20-07-2023

Conclusion ; Albendazole100 mg/5ml suspension Trill No 003 meets the requirement at the end of 6 months after keeping at 40° C, 75% RH

ANALYST

Quality Control Manager

Z-JANS PHARMACEUTICALS (PVT) LTD

Quality Control Department

(Long term Stability Data)

Product ; ALBENZA (ALBENDAZOLE) 100 mg/5ml suspension Storage condition

Batch No ; Trill 001 Temperature; 25 ± 2° C

Data started ; 13-01-2023 Humidity ; 60 ± 5%

Batch Size ; 1000bottles Mfg 01/2023 EXP 01/2025

Packing ; Glass bottle with sealed Aluminum cap

TEST PARAMETER	Specification	INITIAL 13-01-2023	1 MONTH 13-02-2023	3 MONTH 13-04-2023	6 MONTH 13-07-2023	12 MONTH	18 MONT	24 MONTH
Description	White suspension	White suspension	White suspension	White suspension	White suspension			
Identification	Positive for albendazole	Complies	Complies	Complies	Complies			
Taste	sweets	Complies	Complies	Complies	Complies			
Flavor	Tutee fruity	Complies	Complies	Complies	Complies			
pH	3.5----------5.5	5.01	4.99	4.84	4.80			
Assay albendazole	90.00% to 110.0%	105.76%	104.1%	103.97%	102..01%			

ANALYST

Quality Control Manager

Z-JANS PHARMACEUTICALS (PVT) LTD
Quality Control Department
(Long term Stability Data)

Product ; ALBENZA (ALBENDAZOLE) 100 mg/5ml suspension Storage condition
Batch No ; Trill 002 Temperature; 25 ± 2° C
Data started ; 17-01-2023 Humidity ; 60 ± 5%
Batch Size ; 1000bottles Mfg 01/2023 EXP 01/2025
Packing ; Glass bottle with sealed Aluminum cap

TEST PARAMETER	Specification	INITIAL 13-01-2023	1 MONTH 13-02-2023	3 MONTH 13-04-2023	6 MONTH 13-07-2023	12 MONTH	18 MONT	24 MONTH
Description	White suspension	White suspension	White suspension	White suspension	White suspension			
Identification	Positive for albendazole	Complies	Complies	Complies	Complies			
Taste	sweets	Complies	Complies	Complies	Complies			
Flavor	Tutee fruity	Complies	Complies	Complies	Complies			
pH	3.5----------5.5	4.99	4.73	4.68	4.66			
Assay albendazole	90.00% to 110.0%	104.26%	1103.99%	102.55%	101.91%			

ANALYST Quality Control Manager

Z-JANS PHARMACEUTICALS (PVT) LTD
Quality Control Department
(Long term Stability Data)

Product ; ALBENZA (ALBENDAZOLE) 100 mg/5ml suspension Storage condition
Batch No ; Trill 003 Temperature; 25 ± 2° C
Data started ; 20-01-2023 Humidity ; 60 ± 5%
Batch Size ; 1000bottles Mfg 01/2023 EXP 01/2025
Packing ; Glass bottle with sealed Aluminum cap

TEST PARAMETER	Specification	INITIAL 20-01-2023	1 MONTH 20-02-2023	3 MONTH 20-04-2023	6 MONTH 20-07-2023	12 MONTH	18 MONT	24 MONTH
Description	White suspension	White suspension	White suspension	White suspension	White suspension			
Identification	Positive for albendazole	Complies	Complies	Complies	Complies			
Taste	sweets	Complies	Complies	Complies	Complies			
Flavor	Tutee fruity	Complies	Complies	Complies	Complies			
pH	3.5----------5.5	5.01	4.95	4.91	4.83			
Assay albendazole	90.00% to 110.0%	104.87%	103.11%	101.55%	101.01%			

ANALYST Quality Control Manager

Case is placed before the Board for Decision

Summary:

- **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:

Case No. 32

PQCB R-261/2023

Tehsil Choubara, District Layyah

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Obsons Pharmaceuticals 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore-, Pakistan,** through its Managing Partner, Noor Hussain Gondal 2. Noor Hussain Gondal — Managing Partner 3. Muhammad Nadeem — Production Manager 4. Abid Shabbir — Quality Control Manager 5. Waqas Idrees — Warrantor of **M/S Obsons Pharmaceuticals 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore-, Pakistan**

BRIEF FACTS OF THE CASE

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

i. He, on 30-11-2022, inspected the business premises of M/s Madina Medical Store, Tehsil Choubara, District Layyah, and took 02 different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.
ii. The subject drug sample, sent vide memo no.150215, dated:01-12-2022, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, Multan, as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date
Suspension Vomson 60ml [Each ml contains: Domperidone…1mg] **Mfg. Date: Sep-2022** **Exp. Date: Sep-2024** **Reg. # 113042**	22I168	M/s Obsons Pharmaceuticals 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore-, Pakistan.	01-94007237 /DTL, Dated:01-04-2023

Specification applied: MS

Description:

Off-white color suspension, contained in amber colored labeled plastic bottle sealed with white screw cap, packed in a labeled outer hard carton.

Identification: Domperidone Identified.

Assay: by HPLC

Domperidone	
Stated	1mg/ml
Determined	0.0401mg/ml
Percentage	4.01% **(Does not Comply)**
Limit:	90-110%

Result: The above sample is **Sub-Standard**, on the basis of **Assay test.**

iii. M/s Madina Medical Store, Tehsil Choubara, District Layyah, provided invoice/ warranty No. 60412, dated 12-11-2022, issued by M/s Al-Haseeb Medicine Company, Opp. Marjan Hotel, Near Lodhran Hospital, Layyah as a proof of its purchase.
iv. Warrantor portion of drug sample was sent to M/s Al-Haseeb Medicine Company, Opp. Marjan Hotel, Near Lodhran Hospital, Layyah.
v. Al-Haseeb Medicine Company, Opp. Marjan Hotel, Near Lodhran Hospital, Layyah, in turn provided invoice/warranty no.220900481, dated: 10-10-2022 issued by M/s Obsons Pharmaceuticals 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore-, Pakistan as a proof of purchase.
vi. A copy of test/analysis report was sent to by M/s Obsons Pharmaceuticals 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, 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 06-11-2023.

Reply to Show Cause Notice: Ref: OB/786/23-237, dated: 28-11-2023

With reference to your letter No. PQCB/R-261/2023 on dated: 06-11-2023, received on 21-11-2023, that our product Vomson Suspension. 60ml (Domperidone) Batch No. 221168 has been declared Substandard by Drug Testing Laboratory Multan on the basis of Assay test.

It is stated that, our product Vomson Suspension 60ml is a stable product. We have investigated the complete batch of Vomson Suspension and found no observations. We have tested our keeping sample and found it of standard quality. That's why we are confident about stability of our product.

It is observed that degradation of product has been noted in the warrantor portion of product.

We need to conduct product formulation study of the above-mentioned batch. We need 6 months of formulation study to identify the degradation causing agent. It is requested; kindly give us six-month time for our final report.

We have already updated the formulation of this product.

However, we have already recalled all our stock of Vomson Suspension from all distributors who purchased this product. Copy of Recall form and recall letters to all distributors are attached.

Personal hearing notice(s) issued to accused person(s) on 11-12-2023.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:09-2022**
- **Exp. Date: 09-2024**
- **Sampling date (Form 4): 30-11-2022**
- **Sent to DTL (Form 6): 01-12-2022**
- **Date of receipt in DTL: 05-12-2022**
- **DTL Report Date (Form 7): 01-04-2023**
- **DI 1st intimation to firm: 15-04-2023**
- **Retesting request if any: No**
- **Investigation report Dated: 15-05-2023**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 33

PQCB/R-389/2022

(B.V. Hospital Bahawalpur)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Karim Industries, ½ Km- Lahore Raiwind-Road, Lahore-Pakistan** through its Managing Director/ Warrantor, Hamid Bukhtiar 2. Hamid Bukhtiar Managing Director / Warrantor 3. M. Hayat Hussain Production Incharge 4. Amar Mureed Quality Control Manager of M/s Karim Industries, ½ Km- Lahore Raiwind-Road, Lahore-Pakistan.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Central Pharmacy, Bahawal Victoria Hospital, District Bahawalpur reported that: -

i. She, on 21-02-2022 inspected the premises of Central Pharmacy, Bahawal Victoria Hospital, District Bahawalpur, took three different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the drug sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 119183 dated 21-02-2022.
ii. The subject drug sample, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report No. & Date**	**DTL Test Report Result**
Gauze. Soft Gauze [10CM X 10 CM (8ply) (Gauze Swab)] **Mfg Date:** Jan 2022 **Expiry Date:** Jan 2024	1014	M/s Karim Industries, ½ Km- Lahore Raiwind-Road, Lahore-Pakistan.	01-86001078/ DTL Dated 09-04-2022	**Analysis with specifications applied:** BPC 1973/ BP 2022 **DESCRIPTION:** Cotton cloth of plain weave, bleached to good white, Clean and reasonably free from weaving defects, leaf and shell. **WARP (BPC 1973):** Limit: Avg 73/10cm (SD: 1.33) Determined: 74.4/10cm **WEFT (BPC 1973):** Limit: Avg 57/10cm (SD: 1.33) Determined: 55.2/10cm

Regn No. 050293				**WEIGHT/UNIT AREA (BPC 1973):** Limit: Avg 15 gm/m^2 (SD: 0.33) Determined: **20.056 gm/m^2 (Does not comply with the specifications)** **SINKING TIME (BPC 1973):** Limit**:** Not more than 10 seconds. Determined: 2.65 seconds **ACIDITY/ALKALINITY (BPC 1973):** Limit**:** Phenolphthalein= No pink color Methyl orange= Yellow color Determined: No pink color with Phenolphthalein and yellow color with Methyl Orange **STERILITY (BP 2022):** The product is Sterile. **RESULT:** The sample is declared **SUB-STANDARD** on the basis of Weight/m^2 Test**.**

iii. Additional Medical Superintendent, Bahawal Victoria Hospital, District Bahawalpur provided Invoice/Warranty No. 1206 dated 19-02-2022 issued by M/s M/s Karim Industries, ½ Km- Lahore Raiwind-Road, Lahore-Pakistan as a proof of its purchase of the subject drug.
iv. Warrantor portion of drug sample was sent to M/s Karim Industries, ½ Km- Lahore Raiwind-Road, Lahore-Pakistan.
v. A copy of test/analysis report was sent to M/S Karim Industries, ½ Km- Lahore Raiwind-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 above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

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

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

4. Personal hearing Notice issued to the accused person(s)

Summary:

Manufacturing Date: 01.2022

Expiry Date: 01.2024

Sampling Date (Form 4): 21.02.2022

Sent to DTL (Form 6): 21.02.2022

Date of receipt in DTL: 24.02.2022

DTL Report Date: 09.04.2022

Time Extension: N/A

1st DI Communication with firm on dated: 26.01.2023

Date of Retesting Request of Firm: N/A

Fate of retesting Request: N/A

Investigation Report Dated: 10.02.2023

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 34

PQCB/ R-640/2020

PRODUCT SPECIFIC INSPECTION REPORT OF

M/S LEGACY PHARMACEUTICALS, 111-A INDUSTRIAL ESTATE, HAYATABAD PESHAWAR

Members of Inspection Committee:

1	**Prof. Dr. Mahmood Ahmad** (Member PQCB)	**Convener**
2	**Prof. Dr. Muhammad Uzair** (Member PQCB)	Member
3	**Mr. Rana Abdul Mateen** (DDC PQCB)	Member

DATE OF INSPECTION:

Inspection was conducted on 13-10-2023 with reference to PQCB Order No. **PQCB/ R-640/2020** dated 04-10-2023 by Prof. Dr. Mahmood Ahmad (Convener) and Mr. Rana Abdul Mateen (Member) while Prof. Dr. Muhammad Uzair (Member) did not join the inspection due to the Health Issue. Sample of drug was taken by Provincial Inspector of drugs, Tehsil Choubara, District Layyah from the premises of M/S Usman Medical Store, Chak No. 479/TDA Adda Hayyatwala Tehsil Choubara District Layyah

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Syrup Ribena-F 60ml [Iron (lll) Hydroxide Polymaltose Complex eq. to Elemental Iron: 50mg/5ml: Folic Acid: 0.35mg/5ml]	LS-132	M/s Legacy Pharmaceuticals, 111-A Hayatabad Peshawar-Pakistan	01-87001818/DTL Dated 05-09-2020	**Result of Test/Analysis with specifications applied: MS** **Description**: Dark brown color syrup with chocolate flavor, filled in amber glass bottle capped, labelled in a unit carton. **Identification:** Iron (lll) hydroxide polymaltose complex & folic acid identified. **Assay Analysis Technique Titration** **(**Iron (lll hydroxide, Polymaltose complex eq. Elemental Iron**)**

Mfd#05-2020 Exp#05-2022				

Stated	50mg/5ml
Determined	43.42mg/5ml
Percentage	**86.84% (Does not comply)**
Limit	90-110%

Analysis Technique HPLC (Folic Acid**)**

Stated	0.35mg/5ml
Determined	0**.1998mg/5ml**
Percentage	**57.115% (Does not comply)**
Limit	90-110%

Result: The above sample is **Substandard** on the basis of tests performed.

BRIEF ABOUT MANUFACTURING UNIT:

A National pharmaceutical company duly certified with **ISO 9001, 14001 and 45001:2018** Certified company and also complied with the latest **cGMP** Standards.

Manufacturing Unit	M/s Legacy Pharmaceuticals (Pvt) Ltd
Location/Address	111-A Hayatabad Industrial Estate Peshawar
DML No. and Validity (Date of DML renewal)	000632 01.06.2023
Approved Sections	Oral Syrup Liquid, Tablet, Capsule, ointment/Cream, Sachet and Dry Suspension sections
Management	1. **Mr. Amin Ullah** **Director Operation/MD**

Firm's Representatives	1. **Mst. Robina Shaheen** Quality Control Manger 2. **Mr. Muhammad Inam Jan** Production Manger 3. **Mr. Umar Farooq** Plant Manger

Batch Processing Record of Specific Product

1. Batch Number: LS-132
2. BMR Record: Available.
3. Retention Sample Analysis record: Available
4. Ambient Stability Study Data: Available
5. list of Equipment: Available
6. Vendor Qualification of Raw Material: Available
7. QC Equipment list & its Calibration Certificates: Available

OBSERVATIONS:

1. Active and In-active materials were placed at the same place in the quarantine area without distinguishing the label of Active & In-Active.
2. Single Weighing Balance was used in the Sampling Booth and Dispensing Area in In-Active Materials General Store
3. No Bottle Blowing area in the Oral Syrup Liquid section.
4. Currently, Product Syrup Ribena-F 60ml was not manufactured due the API/Raw Material price fluctuation in the market.
5. Firm provided the ambient stability study Data (3^{rd} month, 6^{th} month, 9^{th} month & 12^{th} month) of Ribena-F 60ml, Batch No. LS-132 along with chromatograms which showed the assay of Folic Acid and Iron (lll hydroxide, Polymaltose complex eq. Elemental Iron within the Pharmacopoeial Limit (90-110%).
6. Firm used the working standards for the test/analysis of Products.

RECOMMENDATIONS

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

- Firm has to distinguish the area for Active and In-Active materials separately in the Quarantine Area.
- Firm has to purchase more weighing balance for sampling booth.
- Firm has to establish a separate Bottle Blowing Area in the oral syrup liquid Section.
- The firm has to purchase Primary Standards of APIs.
- Data loggers should be available for temperature and humidity control records at all critical areas.
- Root cause analysis for fail batches and market complaints should be conducted by the firm.

CONCLUSION

After careful evaluation of record and physical verification of the plant and equipment involved at the time of production, the panel is of the opinion that the drug in question declared as substandard due to use of working standards at the stage of QC analysis of the product. The firm is advised to follow strictly the Good Manufacturing Processes with letter and spirit. Moreover, the quality control department should be improved and instruments should be routinely validated and validation record be maintained.

M/s Legacy Pharmaceuticals, 111-A Industrial Estate Hayatabad Peshawar submitted following response in terms of Corrective & Preventive Actions taken with respect to the PSI report vide letter no. WKR/LPL/RAM/PQCB-0112/2023-24 dated 01-12-2023:

After receiving substandard report of Ribena-F Syrup, LS-132 from DTL Multan, through no. TRA 01-87001818 dated: 5th Sep,2020, we performed the following corrective & preventive actions.

- Immediately stop the supply to the market
- Extensive testing is done at our end the details of which are mentioned below:

Sr	Activity	Analysis Result							Result
1	**Retention sample Analysis**	Iron (III) Hydroxide Polymaltose Complex eq. to Elemental iron	**By AAS 102.31%**			Folic Acid		**104.26%**	**OK**
			By Titration 103.8%						
	Assay	**Limit: 90-110%**				**Limit: 90-110%**			
2	**Ambient Stability Study Data**	Initial	3rd	6th	9th	12th	18th	24th	
	Iron (III) Hydroxide Polymaltose Complex eq. to Elemental iron	**103.8%**	101.63%	99.41%	100.535	99.41%	98.30%	97.18%	**OK**
	Folic Acid	**109.0%**	102.24%	105.01%	106.37%	102.52%	100.02%	99.28%	**OK**
	Assay	**Limit: 90-110%**				**Limit: 90-110%**			
3	**Microbiological Analysis**	Total Microbial Aerobic Count (TAMC) Total Combined Yeast/Mold Count (TYMC) Bile Tolerant Gram-Negative Bacteria Pseudomonas Aeruginosa Staphylococcus Aureus E.Coli Salmonella sp Clostridia				Comply Comply Comply Comply Comply Comply Comply			**OK**

		Candida Albicans		Comply Comply Comply		
4	**Expired Retention sample Analysis**	Iron (III) Hydroxide Polymaltose Complex eq. to Elemental iron	**By AAS 108.61%** **By Titration 108.99%**	Folic Acid	**101.4%**	**OK**
	Assay	**Limit: 90-110%**		**Limit: 90-110%**		
5	**Review of Batch Documents**	**Checked by production Manager**		**Audited by QC Manager**		**OK**
6	**Review of other batches of Ribena-F Syrup (Accelerated Stability data** **Batch # LS-180**	**1st**	**2nd**	**3rd**		
	Iron (III) Hydroxide Polymaltose Complex eq. to Elemental iron	107.23%	106.11%	103.88%		**OK**
	Folic Acid	104.09%	100.13%	100.63%		
	Assay	**Limit: 90-110%**		**Limit: 90-110%**		

Conclusion:

As from the findings mentioned-above, the product is ok in all respects & results are well within the limits even after the expiry.

As far as the formulation of our product concerns, the same product Ribena-F syrup batch no. LS-57 was picked up by FID & declared of standard quality by CDL through memorandum no. F.10-174-176/2019-Legacy-Drap-851.

As the results are below limit y DTL Multan, we assume that this may happen due to non-breakage of Iron (III) hydroxide Polymaltose Complex.

Tehsil Choubara, District Layyah

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Legacy Pharmaceuticals, 111-A Industrial Estate, Hayatabad Peshawar** through its Owner Aminullah 2. Aminullah Owner/Director Operation/Warrantor 3. Hidayat Ullah Production Manager 4. Robina Shaheen Quality Control Incharge of **M/s Legacy Pharmaceuticals, 111-A Industrial Estate Hayatabad Peshawar**

BRIEF FACTS OF THE CASE

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

i. His predecessor, on 27-06-2020, inspected the business premises of M/s Usman Medical Store, Chak No. 479/TDA Adda Hayyatwala Tehsil Choubara District Layyah and took two different types of following drug samples on Form No.04 for the purpose of test/analysis and sent to Drugs testing laboratory Multan.
ii. Following drug sample was declared as **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 Result</th></tr>
<tr><td>Syrup Ribena-F 60ml [Iron (lll) Hydroxide Polymaltose Complex eq. to Elemental Iron: 50mg/5ml: Folic Acid: 0.35mg/5ml]</td><td>LS-132</td><td>M/s Legacy Pharmaceuticals, 111-A Hayatabad Peshawar-Pakistan</td><td>01-87001818/DTL

Dated 05-09-2020</td><td>Result of Test/Analysis with specifications applied: MS

<u>Description</u>: Dark brown color syrup with chocolate flavor, filled in amber glass bottle capped, labelled in a unit carton.

<u>Identification:</u> Iron (lll) hydroxide polymaltose complex & folic acid identified.

<u>Assay Analysis Technique Titration</u>

(Iron (lll hydroxide, Polymaltose complex eq. Elemental Iron)

<table>
<tr><td>Stated</td><td>50mg/5ml</td></tr>
<tr><td>Determined</td><td>43.42mg/5ml</td></tr>
<tr><td>Percentage</td><td>86.84% (Does not comply)</td></tr>
</table>
</td></tr>
</table>

				Limit: 90-110% **Analysis Technique HPLC (**Folic Acid**)** Stated: 0.35mg/5ml Determined: 0**.1998mg/5ml** **Percentage: 57.115% (Does not comply)** Limit: 90-110% **Result:** The above sample is **Substandard** on the basis of tests performed.

iii. M/s Usman Medical Store, Chak No. 479/TDA Adda Hayyatwala Tehsil Chaubara District Layyah provided Invoice/warranty No C 20421 dated 20-06-2020 issued by M/s Al Ghani Enterprises Housing Colony No. 03, Block-A, House # 302-E, Layyah who in turn provided invoice/warranty No. 1214 Dated 07-05-2020 issued by M/s Legacy Pharmaceuticals, 111-A Hayatabad Peshawar as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Al Ghani Enterprises Housing Colony No. 03, Block-A, House # 302-E, Layyah and they were asked to provide requisite information in this regard

v. A copy of test/analysis report was sent to Legacy Pharmaceuticals, 111-A Hayatabad Peshawar 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. Subject request for retesting were turn down by the committee of PQCB in its 16th Meeting held on 16-06-2021.

Note:

The firm filed a **Review Petition** vide letter no. WKR/LPL/PQCB-1001/2021-22, dated: 10-01-2022, against the PQCB order dated: 16-06-2021, wherein the Request for Retesting of the product Syrup Ribena-F 60ml, Batch #LS-132 was turned down by the Board.

The subject Review Petition was referred back by the Secretary PQCB vide letter dated: 21-01-2022, as the Honorable Drug Court, Lahore had restrained the Board from taking up the review petitions against any orders issued by the Board itself.

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 28-06-2022.

Reply to Show cause notice:

Reference your letter no. PQCB/R-640/2020 Dated 28th June 2022,

Attached please find the details as required by your good self. Sir, these details were also provided to the board previously through letter no. WKR/LPL/PQCB-1001/2021-22 dated the Peshawar 10th January 2022. (Copy of the letter is attached for your ready reference)

Sir, the product Rebina F Syrup Batch No. LS-132, expired on May - 2022, but sir, at the end of expiry we test our product again placed under ambient condition on **HPLC & Atomic Absorption Spectrophotometer.** The result was found well within the finished product specification limit (the last tested data is attached as ready reference)

Sir, in the light of above test results we requested the honourable board to consider our request.

4. Personal hearing notice(s) issued to accused person(s) on 12-09-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 268th meeting held on 21-09-2023:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **268th meeting** held on **21-09-2023** under the Chairmanship of Special Secretary (Operations) (Vice Chairperson, PQCB), Primary & Secondary Healthcare Department Punjab. Mr. Amir Shakeel, Secretary DQCB, District Layyah attended the meeting via Zoom Link and Mr. Awais Qamar, Drug Inspector, Tehsil Choubara, District Layyah was present. Aminullah (MD) among the nominated accused of **M/s Legacy Pharmaceuticals, 111-A Hayatabad Peshawar-Pakistan** was present along with Umar Farooq (Plant Manager) of the firm. The technical representative of the firm pleaded that at the end of expiry we tested our product again placed under ambient condition on **HPLC & Atomic Absorption Spectrophotometer** and the result was found well within the specification limit.
6. The Board after careful perusal of the case record observed that the subject drug sample **Syrup Ribena-F 60ml** has been declared substandard from Drug Testing Laboratory, Multan on the basis of assay of Iron and Folic acid, i.e. **86.84% and 57.115%,** respectively, whereas, the prescribed limit in official monograph is 90-110%. On query regarding the analytical technique used for assay of Iron and folic acid, the representative of the firm apprised the Board that they use HPLC for folic acid and Titration for assay of Iron, however, they also have Atomic Absorption Spectrophotometer for iron analysis. The Board, in consideration of the product portfolio and repute of the firm and detailed scrutiny of the case, was of the opinion that in order to dig out the root cause of this lesser assay percentage of Iron and Folic Acid, Production and Quality Control & Assurance for subject drug is needed to be evaluated. Therefore, the Board decided to **Pend the case** and to constitute a committee comprising of the followings to conduct **Product Specific Inspection (PSI)** of **M/s Legacy Pharmaceuticals, 111-A Hayatabad Peshawar-Pakistan** and submit report for consideration by the Board:
7. The Board further directed the committee to submit report within 90 days otherwise, secretary PQCB would be authorized to change the committee members.

Prof. Dr. Mehmood Ahmad	**Convener**
Prof. Dr. Muhammad Uzair	**Member**

Mr. Rana Abdul Mateen Khan (DDC, PQCB)	**Member**

Personnel Hearing notice(s) issued to accused person(s) on 11-12-2023.

Case is placed before the Board for Decision.

Summary of the case:

- **Mfg. date: 05-2020**
- **Exp. Date: 05-2022**
- **Sampling date (Form 4): 27-06-2020**
- **Sent to DTL (Form 6): 29-06-2020**
- **Date of receipt in DTL: 07-07-2020**
- **DTL Report Date (Form 7): 05-09-2020**
- **Time Extension: Yes, in 226th meeting dated: 15-09-2020**
- **DI 1st intimation to firm: 21-10-2020**
- **Retesting request if any: Yes**
- **Fate of retesting: Turned down in 16th committee meeting**
- **Review Petition against Retesting order: 17-01-2022**
- **Referral back of review petition: 21-01-2022**
- **Investigation report Dated: 14-02-2022**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 35

PQCB/R-537/2022

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

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Berlex Lab. International 10-km Nagshah Chowk, Karachi Road, Multan** through its Chief Executive Iftikhar Ahmad Khan 2. Iftikhar Ahmad Khan — Chief Executive Officer 3. Salman-Ul-Muazzam — Production Manager 4. Sajid Manzoor — Quality Control Manager/ Warrantor 5. M. Amir Sajjad — Quality Assurance Manager Of **M/s Berlex Lab. International 10-km Nagshah Chowk, Karachi Road, Multan.** 6. Muhammad Waqas Ahmad — Proprietor Of **M/s Al-Raheem Medicine Agency situated at Block No. 8 Jamia Masjid road Dera Ghazi Khan.**

BRIEF FACTS OF THE CASE

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

i. He, on 13-09-2022 inspected the business premises of M/s Al-Raheem Medicine Agency situated at Block No. 8 Jamia Masjid road Dera Ghazi Khan, took sample of five different types of drugs on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide Memorandum No. 140094 dated 14-09-2022.

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

Name of drug	Batch no.	Name of manufacturer	DTL Test Report No. & Date	DTL Test Report Results
Para (Paracetamol 1g/100 ml) Infusion 100 ml **Mfg. date:** Jan-2022 **Exp. Date:**	2242	M/s Berlex Lab. International 10-km Nagshah Chowk, Karachi Road, Multan	TRA No. 01-94005955/DTL dated: 30-12-2022	**Result of Test/Analysis with Specifications applied:** MS **Description:** Colorless, clear liquid filled in a sealed, labeled, transparent glass vial closed with a grey color rubber stopper, sealed with aluminium and red color flip off lid in a labeled outer hard carton.

Dec-2023 **Reg.No.** 099611				**The product claims USP Finished Drug Product Specifications and in USP the monograph of Paracetamol Infusion is not given, so the claim is false & misleading.** **Mis-Branded (Does not comply)** **Identification:** Paracetamol identified. **Assay: Complies** **Sterility: Complies** **Extractable volume: Complies** **PH: Complies** **RESULT:** The above mentioned sample is **Misbranded** as defined under Section 3 (s) (iv) of The Drugs Act 1976.

iii. M/s Al-Raheem Medicine Agency situated at Block No. 8 Jamia Masjid road Dera Ghazi Khan provided invoice/ Warranty No. 0 dated 05-07-2022 issued by M/s Berlex Lab. International 10-km Nagshah Chowk, Karachi Road, Multan as proof of their purchase.
iv. Warrantor Portion was sent to M/s Berlex Lab. International 10-km Nagshah Chowk, Karachi Road, Multan and they were asked to provide requisite information in this regard.
v. A copy of Test/ Analysis report was sent to M/s Berlex Lab. International 10-km Nagshah Chowk, Karachi Road, Multan and they were asked to provide requisite information in this regard.
vi. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:-

Name of accused persons	**Offences**
1. **M/s Berlex Lab. International 10-km Nagshah Chowk, Karachi Road, Multan** through its Chief Executive Iftikhar Ahmad Khan 2. Iftikhar Ahmad Khan Chief Executive Officer 3. Salman-Ul-Muazzam Production Manager 4. Sajid Manzoor Quality Control Manager/ Warrantor 5. M. Amir Sajjad Quality Assurance Manager Of **M/s Berlex Lab. International 10-km Nagshah**	a. **Manufacture for Sale/ Sale of Misbranded Drug.** b. **Issuance of false warranty.**

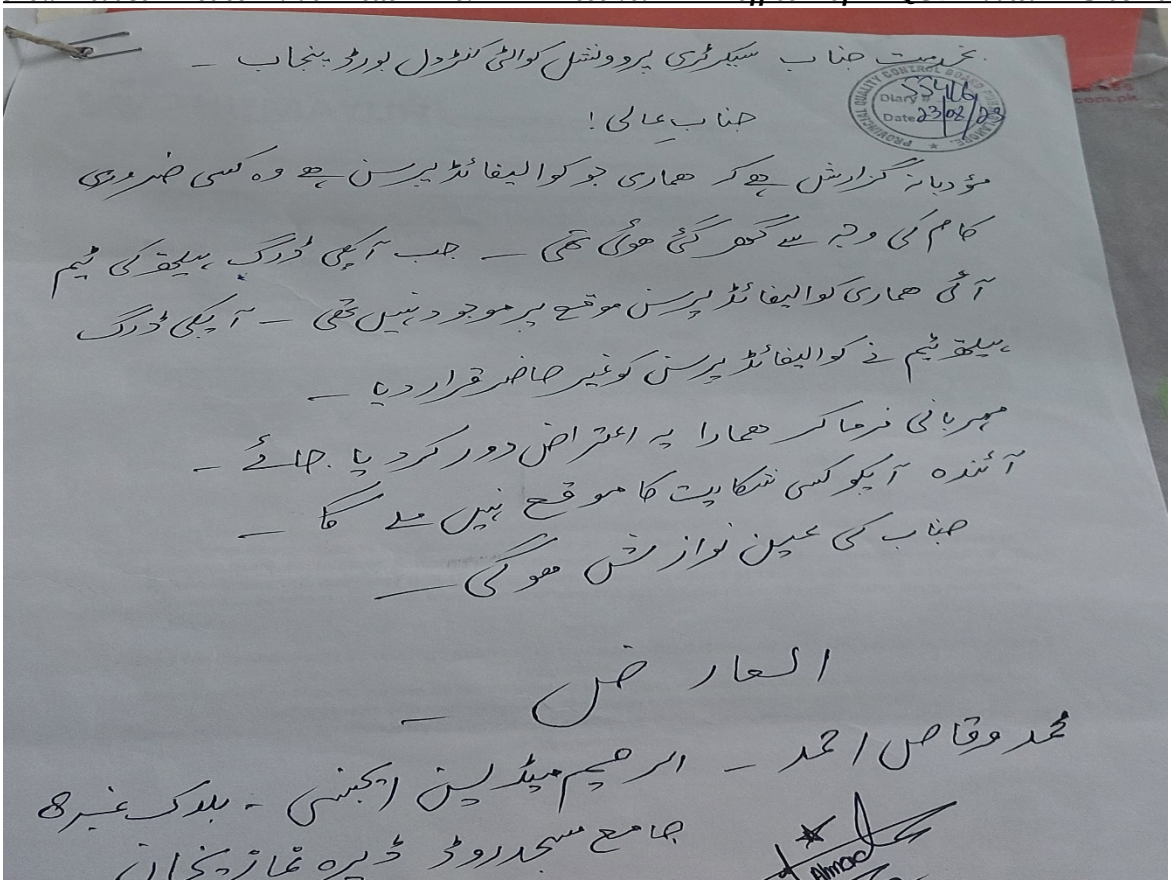
Chowk, Karachi Road, Multan.	
6. Muhammad Waqas Ahmad Proprietor Of **M/s Al-Raheem Medicine Agency situated at Block No. 8 Jamia Masjid road Dera Ghazi Khan.**	a. **Sale of drug in absence of Qualified Person.** b. **Sale of drug without invoice/ warranty (as he failed to provide the correct/ valid invoice/ warranty as a proof of his purchase of Inj. Surolex 100mg Btach no. SL-617 Mfg. by M/s Hamayun International Faisalabad despite receipt of letter dated 28-09-2022)**

3. Show cause notice(s) issued to accused person(s) dated 11-08-2023.

Reply of firm to show cause notice vide letter no. Ref. No. BLI/115-08/23 dated 22-08-2023:

With reference to your letter No. POCB/R-537/2022 dated 11th August,2023 issued from your kind office, We M/s Berlex Lab International are sending our reply documents via courier & email as mentioned in your letter.

Reply of M/s Al-Raheem Medicine Agency situated at Block No. 8 Jamia Masjid road Dera Ghazi Khan to show cause notice vide letter no. nil received in office of PQCB dated 23-08-2023:



خدمت جناب سیکرٹری پروونشل کوالٹی کنٹرول بورڈ پنجاب ۔

جناب عالی !

مؤدبانہ گزارش ہے کہ ہماری جو کوالیفائڈ پرسن ہے وہ کسی ضروری کام کی وجہ سے گھر گئی ہوئی تھی ۔ جب آپکی ڈرگ ہیلتھ کی ٹیم آئی ہماری کوالیفائڈ پرسن موقع پر موجود نہیں تھی ۔ آپکی ڈرگ ہیلتھ ٹیم نے کوالیفائڈ پرسن کو غیر حاضر قرار دیا ۔

مہربانی فرما کر ہمارا یہ اعتراض دور کر دیا جائے ۔

آئندہ آپکو کسی شکایت کا موقع نہیں ملے گا ۔

جناب کی عین نوازش ہوگی ۔

العارض ۔

محمد وقاص احمد ۔ الرحیم میڈیسن ایجنسی ۔ بلاک نمبر 8 جامع مسجد روڈ ڈیرہ غازیخان

4. Personal Hearing notice(s) issued to accused person(s) dated 11-12-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 01-2022**
- **Expiry Date: 12-2023**
- **Sampling Date (Form 4): 13-09-2022**
- **Sent to DTL (Form 6): 14-09-2022**
- **Date of receipt in DTL: 17-09-2022**
- **DTL Report Date (Form 7): 30-12-2022**
- **Time Extension: Granted in 253rd meeting dated 29-11-2022**
- **1ST DI Communication with firm on dated: 09-01-2023**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: NA**
- **Investigation Report Dated: 27-04-2023**
- **Total warnings to firm for misbranded cases (2020-2023): Nil**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 36

PQCB/R-867/2019

Aziz Bhatti Town, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Sami Pharmaceuticals (Pvt) Ltd. F-95, S.I.T.E Karachi Pakistan** through its Managing Director Abdul Salam 2. Abdul Salam — Managing Director 3. Shamim Ahmed — Managing Director 4. Ghazala Dil Afroz — Production Manager 5. Shamim Akhtar — Quality Control Manager 6. Shahid Ayub — Warrantor/Deputy Director Marketing Of **M/s Sami Pharmaceuticals (Pvt) Ltd. F-95, S.I.T.E Karachi Pakistan**.

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Aziz Bhatti Town, Lahore reported that:-

i. The then Drug Inspector on 18-01-2019, inspected the business premises of White plus Pharmacy (franchise of New Mehmood Pharmacy) at SE-6R-164/3+4 Allama Iqbal Road, Dharampura took subject drug sample on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Lahore vide memorandum no. 249 dated 19-01-2019.

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

iii. Proprietor M/s White plus Pharmacy (Franchise of New Mehmood Pharmacy) at Se-6R-164/3+4 Allama Iqbal Road, Dharampura submitted Invoice/warranty No. 2018IL0543676 dated 10-11-2018 issued by M/s Farhat Ali Pharmalink 7 Fane Road Lahore

iv. Warrantor Portion of the drug sample was sent to M/s Farhat Link Pharmalink 7 Fane Road Lahore

v. M/s Farhat Ali Pharmalink 7 Fane Road Lahore provided invoice/warranty no. 81101108456 dated 17-10-2018 issued by M/s Sami Pharmaceuticals (Pvt) Ltd. F-95, S.I.T.E Karachi Pakistan as a proof of its purchase of the said drug

vi. A copy of test report of the subject drug sample was sent M/s Sami Pharmaceuticals (Pvt) Ltd. F-95, S.I.T.E Karachi Pakistan 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**
Film coated tablet Tonoflex-P [tramadol HCl 37.5mg paracetamol 325mg]	065D	M/s Sami Pharmaceuticals (Pvt) Ltd. F-95, S.I.T.E Karachi Pakistan	TRA No. 01-132003641/DTL Dated: 13-05-2019	**Result of Test/ Analysis with specifications applied:** USP 2018 **Physical Description:** light brown oblong biconvex film coated tablet with "Sami" engraved on both sides in an Alu-Alu blister packing of 10units.

Mfg.date:

08-2018

Exp. date:

07-2020

Regn No.

067163

Identification: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (Tramadol HCl identified).

Assay of Tramadol HCl:

Stated	**Determined**	**Percentage**	**Limit**
37.5mg/tab	**33.04mg/tab**	**88.11% (DOES NOT COMPLY)**	**90.0-110.0**% of the label claim

Identification: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (Paracetamol identified).

Assay of Paracetamol:

Stated	**Determined**	**Percentage**	**Limit**
325mg/tab	316.88mg/tab	97.5%	90.0-110.0% of the label claim

Result: The above sample is **Substandard**, on the basis ASSAY of Tramadol HCl performed as per USP.

Note:

- DI, Aziz Bhatti Town, Lahore vide letter no. 111-10/2020/DI(ABT) dated 28-07-2020 intimated about retesting request of the firm received in office of PQCB dated 26-08-2020.
- A letter of submission of evidence sent to the firm on 20-11-2020.
- Firm submitted evidence vide letter dated 02-12-2020 received in office of PQCB dated 8-12-2020. (date of expiry of sample 07-2020).
- Sample got expired in July, 2020. Retesting request was placed in 248-M dated 04-08-2022,can’t be entertained and DI was directed to submit complete investigation report vide letter dated 21-12-2022

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

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

Summary:

Manufacturing Date: 08-2018

Expiry Date: 07-2020

Sampling Date: 18-01-2019

Sent to DTL (Form 6): 19-01-2019

Date of receipt in DTL: 29-01-2019

DTL Report Date: 13-05-2019

Time extension granted: 203-M dated 29-03-2019

1ST DI Communication with firm on dated: 21-07-2019

Date of Retesting Request of Firm To DI: 25-02-2020

Fate of Retesting Request: 248-M (cannot entertained)

Investigation Report Dated: 30-09-2023

3 Show cause/personal hearing notice issued to the accused dated 11-12-2023

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

Case No. 37

PQCB R-69/2023

Children's Hospital, Lahore

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan** through its Managing Director Ch. Zahid Yousaf 2. Ch. Zahid Yousaf — Managing Director 3. Shakil Ahmed — Production Manager 4. Muhammad Asif Chattha — Quality Control Manager 5. Aqsa Shaukat — Warrantor Of **M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, The Children's Hospital & The University of Child Health Sciences, Lahore reported that: -

i. He, on 13-02-2023, inspected the premises of Medicine Store, Central Pharmacy, Children's Hospital and The Institute of Child Health, Lahore and took 06 drug samples on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Lahore.
ii. Following drug sample, sent vide memo no. 157242 dated 03-02-2023, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing laboratory **Lahore** as detailed below: -

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Injection Vit-K1 (Phytomenadione (vitamin K1) 2mg/ml) **Mfg.date:** July-2022 **Exp. date:** July-2024	VKI004	M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan	TRA No. 01-177004743/DTL Dated: 10-04-2023	**Result of Test/ Analysis with specifications applied:** BP 2022 **Physical Description: Y**ellow colored liquid in amber glass ampoule with label printed on it, packed in individual blister packing further packed in unit carton. Claimed Volume=1ml **Extractable Volume**: Determined: 1 ml Limit: NLT nominal volume i.e., 1ml **(Complies)** **Identification:** The retention time of major peak in the

Reg# 077088				sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Phytomenadione Identified). **Assay:** Phytomenadione **(Complies)** **PH:** Limit: 5.0-7.5 **Determined: 4.07 at 24.7ºC (Does not Comply)** **Sterility:** The sample is sterile. **(Complies)** **Bacterial Endotoxin Test:** The sample complies the Endotoxin limit of Not more than 0.2EU/MG **(Complies)** **RESULT:** The above sample is **Substandard**, on the basis of pH test performed as per BP.

Stated	Determined	Percentage	Limit
2mg/ml	2mg/ml	99.77%	90-115% of the stated amount

iii. The Medical Director, Children's Hospital provided warranted delivery challan No. 000102 dated 20-01-2023 issued by M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan, as a proof of purchase.
iv. Warrantor Portion was sent to M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan.
v. Copy of test/analysis report was sent to M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan, with directions to explain their position and provision of 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 drugs**
b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) vide 30-08-2023.

Reply to Show Cause Notice:

With reference to your letter no. PQCB / R-69/2023 dated 30-08-2023, received on 12-09-2023 about substandard declaration of our product Vit- K1, Batch No. VKI0034, by Government Analyst Drug Testing Laboratory Lahore on the basis of pH test. Rest of the test results are well within the specified limits.

It is stated that different samples of this particular batch VK1004 is analyzed by the different drug testing laboratories of the Government Punjab and most of the samples are declared of standard quality, Copy of DTL reports are attached.

Above reports indicates that we are manufacturing standard quality products, change in the pH of some samples is may be due to improper storage of the stock or transportation under bad conditions.

Furthermore, we have also taken corrective measures to minimize such types of issues in future by installing online pH meter for continuous monitoring of the pH of the product during manufacturing and filling process. Also, we have get changed the product specification of this product from "BP " to "USP". USP has wider range of pH for this product i.e. 3.5 to 7.0.

In view of above it is humbly requested that kindly wave off this show cause notice, we assure you that in future we will be more careful during manufacturing process.

Personal hearing notice(s) issued to accused person(s) on 11-12-2023

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:07-2022**
- **Exp. Date: 07-2024**
- **Sampling date (Form 4): 13-02-2023**
- **Sent to DTL (Form 6): 13-02-2023**
- **Date of receipt in DTL: 15-02-2023**
- **DTL Report Date (Form 7): 10-04-2023**
- **DI 1st intimation to firm: 29-04-2023**
- **Retesting request if any: No**
- **Investigation report Dated: 01-06-2023**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 38

PQCB/R-131/2023

Tehsil & District Lodhran

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan** through its Managing Director Ch. Muhammad Zahid Yousaf 2. Ch. Muhammad Zahid Yousaf — Managing Director 3. Shakil Ahmed — Production Incharge 4. Muhammad Asif Chattha — Quality Control Incharge 5. Aqsa Shoukat — Warrantor Of **M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He, on 26-09-2022, inspected Main Medicine Store o/o Chief Executive Officer DHA Lodhran, took sample of sixteen 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. 0000141743 dated 26-09-2022.
ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:

iii. Store Keeper, Main Medicine Store o/o Chief Executive Officer DHA Lodhran submitted Invoice/warranty No. 000670 dated 08-06-2022 issued by M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan as a proof of its purchase of the said drug.
iv. Warrantor Portion of the drug sample was sent to M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan and they were asked to provide requisite information in this regard.
v. A copy of test report was sent to M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-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 Committee of Provincial Quality Control Board in its 20th Committee meeting held on 17-05-2023, after due deliberation and discussion unanimously decided to **accept firm's request for withdrawal of retesting request** of the subject drug sample and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

Name of drug	Batch	Name of	DTL Report	DTL Test Report Results

<table>
<tr><th></th><th>No.</th><th>manufacturer</th><th>TRA No. & Date</th><th></th></tr>
<tr><td>Vit-K1 (Phytomenadione (vitamin K1) 2mg/ml) Injection

Mfg.date:

Mar-2022

Exp. date:

Mar-2024

Regn No.

077088</td><td>VKI002</td><td>M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan</td><td>TRA No. 01-94006332/DTL

Dated:-14-01-2023</td><td><u>Result of Test/ Analysis with specifications applied:</u> MS

<u>Description</u>: Light yellow color liquid filled in sealed & amber color glass ampoule with white printed label blistered in ALU-PVC blister packed in labeled outer hard carton. Each outer hard carton contains 01 ampoule i.e. 1*1 ml ampoule).

<u>Extractable Volume</u>: Limit: NLT stated

Determined: 1.06 ml (Complies)

<u>PH:</u> Range: 5.0-7.5

Determined: 4.62 (Does not Comply)

<u>Identification:</u> Vitamin K1 identified.

<u>Assay:</u> Vitamin K1

<table><tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr><tr><td>2mg/ml</td><td>1.94mg/ml</td><td>97.16%</td><td>90-115%</td></tr></table>
(Complies)

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

<u>RESULT:</u> The above sample is <u>Substandard</u>, on the basis of PH test.</td></tr>
</table>

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

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

3. Show cause notice(s) issued to accused person(s) dated 11-08-2023.
4. Personal Hearing notice(s) issued to accused person(s) dated 11-12-2023.

Case is placed before the Board for Decision

<u>Summary:</u>

- **Manufacturing Date: 03-2022**
- **Expiry Date: 03-2024**

- **Sampling Date (Form 4): 26-09-2022**
- **Sent to DTL (Form 6): 26-09-2022**
- **Date of receipt in DTL: 27-09-2022**
- **DTL Report Date (Form 7): 14-01-2023**
- **Time Extension: Granted in 254th meeting dated 13-12-2022**
- **1ST DI Communication with firm on dated: 01-02-2023**
- **Date of Retesting Request of Firm: 01-03-2023**
- **Fate of Retesting: Committee of the Board decided to accept firm's appeal for withdrawal of retesting request in 20th Committee meeting dated 17-05-2023.**
- **Investigation Report Dated: 17-06-2023**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 39

PQCB/R-283/2023

Jinnah Hospital Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan** through its Managing Director Ch. Muhammad Zahid Yousaf 2. Ch. Muhammad Zahid Yousaf — Managing Director 3. Shakil Ahmed — Production Incharge 4. Muhammad Asif Chattha — Quality Control Incharge 5. Aqsa Shoukat — Warrantor Of **M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan.**

BRIEF FACTS OF THE CASE

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

i. She, on 06-03-2023, inspected Main Medicine Store-A of Jinnah Hospital Lahore, took sample of four different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Lahore vide memorandum No. 0000159553 dated 06-03-2023.
ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below:

iii. Drug Inspector directed the Store Keeper, Main Medicine Store-A of Jinnah Hospital Lahore not to dispose off stock of the said sample vide Form 3 dated 23-05-2023.
iv. Store Keeper, Main Medicine Store-A of Jinnah Hospital Lahore submitted DC/warranty No. 00135 dated 28-02-2023 issued by M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan as a proof of its purchase of the said drug.
v. Warrantor Portion of the drug sample was sent to M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan and they were asked to provide requisite information in this regard.
vi. A copy of test report was sent to M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan 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**
Vit-K1 (Phytomenadione (vitamin K1)B.P... 2mg/ml) Injection	VKI004	M/s English Pharmaceutical Industries Link Kattar Bund	TRA No. 01-177005179/DTL Dated:-16-05-2023	**Result of Test/ Analysis with specifications applied:** BP 2022 **Description:** Yellow colored liquid in amber glass ampoule

Mfg.date: Jul-2022 **Exp. date:** Jul-2024 **Regn No.** 077083		Road, Thokar Niaz Baig, Multan Road, Lahore-Pakistan		with label printed on it packed in individual blister packing further packed in unit carton. Claimed volume= 1ml. **PH:** Determined: **4.22 at 24^{o}C** Limit: 5.0-7.5 **(Does not Comply)** **Extractable Volume**: Determined: 1.0 ml Limit: Not less than nominal **Identification:** The retention time of the major peak in sample chromatogram corresponds to the retention time of the major peak in the standard chromatogram (Phytomenadione identified). **Assay of Phytomenadione** **Stated** | **Determined** | **Percentage** | **Limit** 2mg/ml | 2.23mg/ml | 111.47% | 90.0-115.0% of the stated amount **(Complies)** **Sterility Test:** The sample is sterile. **RESULT:** The above sample is **SUB-STANDARD**, on the basis of PH test performed as per BP-2022.

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

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

3. Show cause notice(s) issued to accused person(s) dated 23-11-2023.

Reply of the firm to show cause notice vide letter no. EP No. 0745-23 dated 05-12-2023:

With reference to your letter no. PQCB/R-283/2023 dated 23-11-2023, received on 01-12-2023 about substandard declaration of our product Vit-K1, Batch No. VK1004, by Government Analyst Drug Testing Laboratory Lahore on the basis of pH test vide TRA No. 01-177005179/DTL, dated 16-05-2023. Rest of the test results are well within the specified limits.

It is stated that different samples of this particular batch VK1004 is analysed by the different drug testing laboratories of the Government Punjab and most of the samples are declared of standard quality, detail of samples declared as standard quality is listed below;

S/N	Name of DTL	Number of samples declared as of standard quality
1	DTL Lahore	04
2	DTL Faisalabad	03
3	DTL Rawalpindi	01
4	DTL Bahawalpur	01

Total samples 09

Copy of DTL reports are attached as Annexure "A"

Above reports indicates that we are manufacturing standard quality products, change in the pH of some samples is may be due to improper storage of the stock or transportation under bad conditions.

Furthermore we have also taken corrective measures to minimise such types of issues in future by installing online pH meter for continuous monitoring of the pH of the product during manufacturing and filling process. Also we have get changed the product specification of this product from "BP" to "USP". USP has wider range of pH for this product i.e. **3.5 to 7.0.**

The names nominated by the Drug Inspector are hereby verified.

The requisite documents are attached.

In view of above it is humbly requested that kindly wave off this show cause notice, we assure you that in future we will be more careful during manufacturing process.

Please feel free to contact for any further information required.

4. Personal Hearing notice(s) issued to accused person(s) dated 11-12-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 06-2022**
- **Expiry Date: 06-2024**
- **Sampling Date (Form 4): 06-03-2022**
- **Sent to DTL (Form 6): 06-03-2023**
- **Date of receipt in DTL: 07-03-2023**

- **DTL Report Date (Form 7): 16-05-2023**
- **Time Extension: Granted in 260th meeting dated 04-05-2023**
- **1ST DI Communication with firm on dated: 23-05-2023**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Nil**
- **Investigation Report Dated: 07-09-2023**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 40

PQCB/ R-642/2022

Rawal Town, and District Rawalpindi

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore** through its Managing Director, Ch. Zahid Yousaf 2. Ch. Zahid Yousaf Managing Director 3. Shakil Ahmad Production Manager 4. Muhammad Asif Chattha Quality Control Manager 5. Ms. Aqsa Warrantor Of M/S English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Rawal Town, and District Rawalpindi reported that:-

i. His predecessor, on 30-06-2022 inspected the office of CEO (DHA), Rawalpindi and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo No.0000132157 Dated 01-07-2022.
ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Rawalpindi as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
INJECTION VIT-K1, 1ML (PHYTOMENADIONE (VITAMIN K1): 2MG/ML) **Mfg. Date**:04-2022 **Exp. Date**: 04-2024 **Reg** # 077088	VK1003	M/S English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore	01-74004911 / DTL dated:11-10-2022	**Result of test/ analysis with specifications applied:** BP 2022 **PHYSICAL DESCRIPTION** Light yellow coloured Visibly clear solution, filled in labelled ambered glass ampoule with plastic cover on head, packed in plastic tray sealed with an aluminium labelled sheet, further packed in outer labelled unit carton. **Extractable Volume:** Determined volume: 1.0 ml Limit: Not less than nominal pH: Observed: 4.49 at 25.0 oC (DOES NOT COMPLY)

				Limit: 5.0-7.5 **ASSAY:** Stated: 2 mg/ml Determined: 2.203 mg/ml Percentage: 110.15 % Limit: 90-115 % **STERILITY TEST:** No visible microbial growth observed **RESULT:** The above sample is "Substandard" on the basis of the pH test performed

iii. The District Health Officer (Medical Services) DHA, Rawalpindi provided warranty/invoice No.00001 dated 08-06-2022 issued by M/S English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore.
iv. The drug Inspector issued Form-3 to dispose of stock dated 20-10-2022.
v. Warrantor Portion was sent to M/S English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore .
vi. A copy of Test/ Analysis reports was sent to M/**S** English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. In response, the firm challenged the report and requested for re-testing of the sample from Appellate Laboratory.
vii. Pursuant to the retesting request of the firm, the retesting request of the Firm placed in 255th Board meeting dated 29-12-2022 but Firm requested to withdraw their retesting request. The Board after due deliberation and discussion unanimously decided to accept the Firm's request for withdrawal of subject drug sample.

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

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

3. Showcause was issued to accused person(s) vide dated 31-10-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no.EP No. 0652-23 dated 08-11-2023 stating that:

With reference to your letter no. PQCB/R-642/2022 dated 31-10-2023, received on 07-11-2023

About substandard declaration of our product Vit- K1, Batch No. VKI003, by Government Analyst

Drug Testing Laboratory Rawalpindi on the basis of pH test. Rest of the test results are well

within

The specified limits.

It is stated that different samples of this particular batch VK1003 is analyzed by the different drug

testing laboratories of the Government Punjab and most of the samples are declared of standard

quality, Copy of DTL reports are attached as Annexure "A"

Above reports indicates that we are manufacturing standard quality products, change in the pH

of some samples is may be due to improper storage of the stock or transportation under bad

Conditions.

Furthermore we have also taken corrective measures to minimize such types of issues in future

by installing online pH meter for continuous monitoring of the pH of the product during

Manufacturing and filling process. Also we have get changed the product specification of this

Product from "BP" to "USP" USP has wider range of pH for this product i.e. 3.5 to 7.0.

The requisite documents are attached as under;

S/N

Documents Detail

1.Copy of Drug manufacturing License

2. Copy of registration letter of Vit-K1 Injection

3. CNIC copies of Managing Director (Ch, Zahid Yousaf), Production

Manager (Mr. Shakil Ahmad), Quality Control Manager (Mr. M. Asif

Chattha) & Warrantor (Ms. Aqsa).

Copy of batch record of the Vit-K1 injection VK1003

Certificate of analysis of Vit-K1 injection VK1003

Attachment

Annexure B

Annexure C

Annexure D

Annexure E

Annexure F

In view of above it is humbly requested that kindly wave off this show cause notice, we assure

You that in future we will be more careful during manufacturing process.

Please feel free to contact for any further information required.

Personnel hearing notice(s) issued to accused person(s) vide dated 11-12-.

Case is placed before the Board.

Summary:

Manufacturing Date: 04-2022

Expiry Date: 04-2024

Sampling Date: 30-06-2022

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

Date of receipt in DTL: 04-07-2022

DTL Report Date: 11-10-2022

Time Extension: 250 Meeting

1ST DI Communication with firm on dated: 20-10-2022

Date of Retesting Request of Firm: 29-10-2022

Fate of Retesting Request: -Firm Withdraw their retesting request

Investigation Report Dated: 03-08-2023

PROCEEDINGS AND DECISION OF THE BOARD:

Case No. 41

PQCB/ R-701/2022

Said Mitha Hospital Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	1. **M/S English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore** through its Managing Director, Ch. Zahid Yousaf 2. Ch. Zahid Yousaf Managing Director 3. Shakeel Ahmed Production Incharge 4. Muhammad Asif Chattha Quality Control Incharge/Warrantor Of M/S English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore.

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Said Mitha Hospital Lahore reported that:-

i. He on 22-09-2022 inspected the premises of medicine store of Govt. Said Mitha Teaching Hospital Lahore took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Lahore vide memo No. 0000141451 Dated 23-09-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
VIT-K1 (Phytomenadione .....2mg/mL) INJECTION **Mfg. Date**: 03-2022 **Exp. Date**: 03-2024 **Reg** # 077088	VKI002	M/S English Pharmaceuticals Industries, Link Kattar Bund Road Thokar Niaz Baig Multan Road Lahore Pakistan.	01- 183001402 / DTL dated: 17 NOV 2022	**Result of test/ analysis with specifications applied: MS** **PHYSICAL DESCRIPTION:** Yellow colored liquid in amber glass ampoule with label printed on it packed in individual blister packing further packed in unit carton. Claimed volume = 1mL. **pH:** Determined: 4.66 at 23.2° C Limit: 5.0-7.5 (DOES NOT COMPLY) **EXTRACTABLE VOLUME:**

				Determined: 1.0mL Limit: 1.00-1.10mL **IDENTIFICATION OF PHYTOMENADIONE:** The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in the standard chromatogram (Phytomenadione identified). **ASSAY OF PHYTOMENADIONE:** Stated = 2 mg/mL Determined = 2.08 mg/mL Percentage = 103.93% Limit = 90.0-115.0% of the stated amount **STERILITY TEST:** The sample is sterile. **BACTERIAL ENDOTOXIN TEST:** The sample complies the limit of NMT 0.2 EU/mg. **RESULT: The above sample is SUB-STANDARD, on the basis of pH performed as per Manufacturer provided method of analysis.**

iii. The store keeper supplied invoice bill/warranty no. INV00072/Mer dated 03-09-2022 issued by M/S Merlin International. In response Merlin International provided warranty/invoice No. June-00747 Dated 15-06-2022 issued by M/S English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore

iv. Warrantor Portion was sent to M/**S** Merlin International .

v. A copy of Test/ Analysis reports was sent to M/**S** English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, and Multan Road Lahore.

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

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

3. Showcause/Cum Personal Hearing date was issued to accused person(s) vide dated 11-12-2023

Case is placed before the Board.

Summary:

Manufacturing Date: 03-2022

PROCEEDINGS AND DECISI

Expiry Date: 03-2024

Sampling Date:22-09-2022

Sent to DTL (Form 6): 23-09-2022

Date of receipt in DTL: 23-09-2022

DTL Report Date: 17-11-2022

Time Extension: N/A

1ST DI Communication with firm on dated: 03-10-2023

Date of Retesting Request of Firm: N/A

Investigation Report Dated: 17-10-2023

ON OF THE BOARD:

Case No. 42

SM-86-06/2018

(Tehsil and District Layyah)

ATTENDANCE

BRIEF FACTS OF THE CASE:

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

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

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

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

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

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

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

PREVIOUS PROCEEDINGS AND DECISION BY THE COMMITTEE:

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

PERVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

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

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

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

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

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

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

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

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

said to be same offences.

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

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

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

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

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

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

The case is placed before the Board.

Case No. 43

PQCB/R-329/2023

(Tehsil Yazman District Bahawalpur)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan** through its Chief Executive M. Anwar Bajwa. 2. M. Anwar Bajwa — Chief Executive 3. M Ahsan Aslam — Production Manager 4. Muhammad Ali — Quality Control Manager 5. Abdul Raheem — Warrantor of **M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He, on 09.05.2023, inspected the premises of Medicine Store Situated at Chapu Farm Live Stock Cholistan Tehsil Yazman 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 Faisalabad vide memorandum no. 166192 dated 10.05.2023.
ii. Following Drug samples 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	DTL Test Report Result
Injection Oxycon-50, 50ml (Oxytetracyclin: 50mg/ml) **Mfg Date:** 03.2023 **Expiry Date:** 03.2025	OX027	M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan	01-10097003444/ DTL dated: 14.06.2023	**Specifications applied: USP 2022** **Composition:** Oxytetracylcin HCl:50mg/ml (U.S.P) **Description:** Light green to yellow color liquid filled in amber glass bottle, sealed with grey rubber stopper and aluminium. Stated volume: 50ml **NOTE:** The label on the vial contains USP Finished Drug Product Specifications, However Oxytetracycline Injection USP monograph states "It contains the equivalent of NLT 90.0% and NMT 120.0% of the labelled amount of oxytetracycline". Whereas product label claims Oxytetracycline HCl which is in contradiction to USP monograph. The label of "Injection OXYCON-50" does not bear the Registered name of drug and Dosage in urdu while the Rule "(3)" Clause "(h)" sub clause "(i and ii)" of The Drugs (Labelling and Packing) Rules, 1986 clearly states that Registered name of drug and Dosage should be mentioned in urdu on label. **(The product is**

Regn No. 012343				**misbranded).** **pH:** Limit: 8.0-90. Determined: 7.853 **(Does not Comply)** **Sterility:** The product is sterile **Identification:** Oxytetracyline HCl is identified. **Assay (USP):** Complies **Result:** The sample is declared **SUB-STANDARD** on the basis of pH TEST and **MISBRANDED** according to Rule "3" Clause "(h)" sub clause "(i and ii)" of The Drugs (Labelling and Packing) Rules, 1986 and as defined under sub- section (s) of section 3 of the Drug Act 1976.

iii. Medicine Store Situated at Chapu Farm Live Stock Cholistan Tehsil Yazman District Bahawalpur provided Invoice/warranty No 1375, Dated. 02.05.2023 issued by M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan and they were asked to provide the requisite information in this regard.

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

a. **Manufacture and selling of Substandard & Misbranded drug**
b. **Issuance of false warranty**

2. Show-cause/Personal Hearing notice(s) issued to accused person(s).

Summary:

Manufacturing Date: 03.2023

Expiry Date: 03.2025

Sampling Date (Form 4): 09.05.2023

Sent to DTL (Form 6): 10.05.2023

Date of receipt in DTL: 10.05.2023

DTL Report Date (Form 7): 14.06.2023

Time Extension: N/A

1ST DI Communication with firm on dated: 03.07.2023

Date of Retesting Request of Firm: 19.06.2023

Fate of Retesting Request: Withdrawn

Investigation Report Dated: 13.10.2023

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 44

PQCB/R-330/2023

(Tehsil Yazman District Bahawalpur)

ATTENDENCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan** through its Chief Executive Officer (CEO) Abdul Majeed Bajwa. 2. Abdul Majeed Bajwa — Chief Executive Officer (CEO) 3. Muhammad Anwar — Production Manager 4. Muhammad Ali — Quality Control Manager 5. Abdul Raheem — Warrantor of **M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Bahawalpur City reported that: -

i. He, on 11.05.2023, inspected the premises of Main Medicine Store, Director Livestock at Habib Colony, Street No. 2 Bahawalpur and took different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide memorandum no. 166413 dated 12.05.2023.
ii. Following Drug samples 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	DTL Test Report Result
Injection Oxycon-50, 50ml (Oxytetracyclin: 50mg/ml) **Mfg Date:** 04.2023 **Expiry Date:** 04.2025	OX035	M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan	01-10097003505/ DTL dated: 14.06.2023	**Specifications applied: USP 2022** **Composition:** Oxytetracylcin HCl:50mg/ml (U.S.P) **Description:** Light green to yellow color liquid filled in amber glass bottle, sealed with grey rubber stopper and aluminium. Stated volume: 50ml **NOTE:** The label on the vial contains USP Finished Drug Product Specifications, However Oxytetracycline Injection USP monograph states "It contains the equivalent of NLT 90.0% and NMT 120.0% of the labelled amount of oxytetracycline". Whereas product label claims Oxytetracycline HCl which is in contradiction to USP monograph. The label of "Injection OXYCON-50" does not bear the Registered name of drug and Dosage in urdu while the Rule "(3)" Clause "(h)" sub clause "(i and ii)" of The Drugs (Labelling and Packing) Rules, 1986 clearly states that Registered name of drug and Dosage should be mentioned in urdu on label. **(The product is**

Regn No. 012343				**misbranded).** **pH:** Limit: 8.0-90. Determined: 7.839 **(Does not Comply)** **Sterility:** The product is sterile **Identification:** Oxytetracyline HCl is identified. **Assay (USP):** Complies **Result:** The sample is declared **SUB-STANDARD** on the basis of pH TEST and **MISBRANDED** according to Rule "3" Clause "(h)" sub clause "(i and ii)" of The Drugs (Labelling and Packing) Rules, 1986 and as defined under sub- section (s) of section 3 of the Drug Act 1976.

iii. The Director Livestock, Bahawalpur Division, Bahawalpur provided Invoice/warranty No 1374, Dated. 18.04.2023 issued by M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No. 7-10B, Industrial Estate Bhimber, AJK, Pakistan and they were asked to provide the requisite information in this regard.

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

a. **Manufacture and selling of Substandard & Misbranded drug**
b. **Issuance of false warranty**

2. Show-cause/Personal Hearing notice(s) issued to accused person(s).

Summary:

Manufacturing Date: 04.2023

Expiry Date: 04.2025

Sampling Date (Form 4): 11.05.2023

Sent to DTL (Form 6): 12.05.2023

Date of receipt in DTL: 13.05.2023

DTL Report Date (Form 7): 14.06.2023

Time Extension: N/A

1ST DI Communication with firm on dated: 03.07.2023

Date of Retesting Request of Firm: 27.06.2023

Fate of Retesting Request: Withdrawn

Investigation Report Dated: 01.08.2023

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 45

PQCB R-22/2021

Tehsil Liaqatpur & District Rahim Yar Khan

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Indusrtrial Area Karachi-Pakistan** through its Managing Partner Muhammad Saleem. 2. Muhammad Saleem Managing Partner 3. Farhat Begum Production Incharge 4. Zeenat Quality Control Incharge/Warrantor of **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Indusrtrial Area Karachi-Pakistan.** 5. Salman Warrantor Of **M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi.** 6. Muhammad Tahir Nadeem Proprietor/Warrantor Of **M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan.** 7. Ghulam Abbas S/O Muhammad Ismail Proprietor **Of M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur.**

BRIEF FACTS OF THE CASE:

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

i. He, on 30-09-2020, inspected the business premises of M/S Abbas Medical Store Madni Bazar Feroza, Tehsil Liaqatpur, District Rahim Yar Khan and took two drug samples on Form No.04 for the purpose of test/analysis.
ii. Following Drug sample after test/analysis was declared as **Spurious** 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

<table>
<tr>
<td>Injection Cintox [Oxytocin 10-I.U/ml</td>
<td>041</td>
<td>M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan</td>
<td>01-77002408/DTL

Dated. 04-02-2021</td>
<td>
<u>Analysis with specifications applied:</u> USP 2020.

<u>Composition:</u>

Each ml contains:

Oxytocin U.S.P…….10 I.U

<u>Description:</u>

Colorless liquid in amber glass sealed vial with grey stopper and silver metallic seal, packed in outer carton. (Stated volume 50ml).

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

<table>
<tr><td>Limit</td><td>NLT nominal volume</td></tr>
<tr><td>Determined</td><td>51ml</td></tr>
</table>

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

The product is sterile.

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

Oxytocin is not identified.

(Does not comply with the specifications.)

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

<table>
<tr><td>Stated</td><td>10IU/ml</td></tr>
<tr><td>Determined</td><td>0.00 IU/ml</td></tr>
<tr><td>Percentage</td><td>0.00%</td></tr>
<tr><td>Limit</td><td>90.0-110.0%</td></tr>
</table>

<u>Result:</u>

The sample is declared <u>Spurious</u> as defined under section 3 (zb)(i) of the drugs act 1976.
</td>
</tr>
</table>

iii. M/s Abbas Medical Store Madni Bazar Feroza, Tehsil Liaqatpur, District Rahim Yar Khan provided Invoice/warranty No 12197 dated 25-07-2020 issued by M/s Ruman Medicine House

No. 7, Malik Street, West Street, 111/P West Rahim Yar Khan who in turn provide invoice/warranty No. 074, dated 18-07-2020 issued by M/S Osman & Company Jamlana Mansion Katchi Gali # 2, Marriot Road, Karachi who in turn provide invoice/warranty No.538, dated 14-05-2020 issued by M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Ruman Medicine House No. 7, Malik Street, West Street, 111/P West Rahim Yar Khan and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan and they were asked to provide the requisite information in this regard.

2. Drug Inspector requested for grant of Registration for FIR 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 Persons	**Offences**
1. Ghulam Abbas S/O Muhammad Ismail Proprietor **Of M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur**	a. **Stocking/Selling for sale of Spurious drug**
1. Muhammad Tahir Nadeem Proprietor/Warrantor Of **M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan.**	a. **Selling/Stocking for sale of Spurious drug** b. **Issuance of false warranty**
2. Salman Warrantor Of **M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi.**	a. **Selling/Stocking for sale of Spurious drug** b. **Issuance of false warranty**
1. **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Indusrtrial Area Karachi-Pakistan** through its Managing Partner Muhammad Saleem. 2. Muhammad Saleem Managing Partner 3. Farhat Begum Production Incharge 4. Zeenat Quality Control Incharge/Warrantor of **M/s Epoch Pharmaceuticals. 83-**	a. **Manufacturing/selling/Stocking for sale of Spurious drug** b. **Issuance of false warranty**

85, Sector, 15 Korangi Indusrtrial Area Karachi-Pakistan.	

3. Show cause notice issued to accused person(s) vide dated 05-11-2021

Reply of the firm:

1- In this regard your kind attention is invited to your earlier show cause notice no. POCB/R-22/2021 dated 31-03-2021 (received on 05-04-2021) on the said subject and we responded vide our letter no. nil dated 07-04-2021

2- That on the receipt of personal hearing letter no. PQCB/R-22/2021 dated 15-062021, we appear in the 232 meeting of PQCB Lahore held on 24-06-2021 through our council Mr. Rana M. Maqsood Afzal khan and defended the said case by way of oral discussion as well as submitted our written arguments vide letter no. nil dated 24-06-2021. After arguing the case, we were told that the decision will be conveyed later on. But so far no such decision has been conveyed to us till date. (At agenda of the meeting the serial no. of the case was 70 of item-2 regular cases.)

3- That instead of receiving the decision of the Board, we received a letter from the Drug Inspector vide no. DI-LQP/2036 dated 03-07-2021, asking for some in formations, which we responded the same under intimation to PQCB vide our letter no. nil dated 12-07-2021, wherein in lieu of 232 meeting of PQCB dated 24-06-2021, we requested the Drug Inspector to inform us about the decision of the Board for further correspondence in the matter. 4- That again we received a letter from the Drug Inspector vide no. DI-LQP/2085 dated 17-07-2021 (received on 24-07-2021) and again this letter was silent regarding the decision of the meeting of the PQCB dated 24-06-2021. A comprehensive reply to this letter was sent to DI vide our letter no. nil dated 27-07-2021 and Drug Inspector was asked that since the case has been heard by the Board after the completion of your investigation and you requested for prosecution against the accused persons, then under what authority who authorized you to initiate further correspondence with us before decision of the Board. Our request for the provision of decision of 232 meeting of Board dated 24-06-2021 was repeated for further correspondence.

5- That surprisingly your fresh revised show cause notice is also silent on previous proceedings of the case and still we are un-aware about the decision taken by the Board in its 232d meeting held on 24-06-2021.

6- That after completion of the investigation of the case and subsequently hearing of the case in 232 meeting of the Board held on 24-06-2021, then under what law & grounds fresh and revised show cause notice has been issued to us.

7-That in view of above submissions your good offices are requested to provide us the copy of decision taken by the Board on the subject case in its 232n meeting held on 24-06-2021.

Reply of the Osman & Company

Purchased invoice by M/s Epoch bill # 538 dated 14th May 2020 along with Drug Sale license. It is reiterated that the purchase and sale of drug was as per law and I have not done anything against the provision of the Drugs Act 1976 and rues framed there under. Hence it is requested that I may please be acquitted of the case.

Reply of Ruman Medicine

Ruman medicine authorized Distributor of Pharmaceutical products under the license No. 03-313-0156-049150D. We have purchased Inj Cintox from M/s Osman & Company Jamlana Mansion Katchi. We have provided warranty to the chemist with warranty No. 074 dated 18-7-2020. Mr. Salman is warrantor of Osman & Company who is the sole agent of the M/s Epoch Pharmaceutical Karachi who in turn provided invoice/warranty of Epoch and the firm own the said product. It is requested that we have purchased above aid product from authorized sole agent and also provided warranty chain. So, please take sympathetic view.

Reply of Abbas Medical Store:

I (Ghulam Abbas) took medicine Inj. Cintox from M/s Ruman Medicine and provided warranty/invoice No. 12197 issued by Ruman medicine who in turn provided warranty issued from Osman & Company to Drug Inspector Liaqatpur. So, please exclude my name from this case.

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 **232rd meeting held on 24-06-2021**. Mr. Mazhar Shabeer Provincial Inspector of Drugs, Tehsil Liaqatpur, district Rahim Yar Khan was present along with original case record. No one among nominated accused persons of **M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan** was present**.** However, Rana Maqsood Afzal Khan, (Advocate) appeared on behalf of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan.

6. During proceedings of the meeting of the Board, the Drug inspector requested for reinvestigation and resubmission of complete investigation report. The Board after keen perusal of the case record, allowed to Drug Inspector to submit reinvestigation Report.

7. Revised Showcause notice issued to accused person (s)

8. Personal Hearing Notice issued to accused persons

PQCB 236th meeting held on 15-12-2021:

9. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **236th meeting held on 15-12-2021** under the chairmanship of Mr. Imran Sikandar Baloch Secretary Primary & secondary Healthcare Department Punjab, in the presence of Board members as mentioned above. Mr. Amjad Farooq Secretary District Quality Control Board, Rahim Yar Khan and Mr. Arfan Ali Provincial Inspector of Drugs, Tehsil Liaqatpur, District Rahim Yar Khan were present along with original case record. No one among nominated accused persons of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan was present. However, Muhammad Salman S/O Muhammad Saleem along with counsel, Rana Maqsood Afzal Khan, (Advocate) appeared before the Board on behalf of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan. M. Salman CNIC 42000-9472060-1, warrantor of M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi was present. Muhammad Tahir Nadeem (Proprietor) of M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan and Ghulam Abbas (Proprietor) of M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur appeared before the Board along with their counsel Sh. Irfan Saeed.

10. Ghulam Abbas (Proprietor) of M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur submitted that he took medicine Inj. Cintox from M/s Ruman Medicine and provided warranty/invoice No. 12197 dated 25-7-2020 issued by M/s Ruman Medicine to the drug inspector which was verified. He requested a lenient view.

11. Counsel of M/s Ruman Medicine House no. 7, Malik Street, west Street, 111/P West Rahim Yar Khan submitted that he is an authorized Distributor of Pharmaceutical products under the license No. 03-313-0156-049150D. He has purchased Inj. Cintox Batch No. 041 from M/s Osman & Company Jamlana Mansion Katchi and also provided warranty to the chemist with invoice/warranty No. 074 dated 18-7-2020. Mr. Salman was warrantor of M/s Osman & Company who is the sole agent of the M/s Epoch Pharmaceutical Karachi who in turn provided invoice/warranty of Epoch and the firm owned the said product. He requested that they have purchased above said product from authorized sole agent and also provided warranty which is linked up to the manufacturer chain, which was also verified. So, he requested for sympathetic view from the Board.

12. Counsel of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan submitted that they appeared in the 232nd meeting of PQCB Lahore held on 24-06-2021 through their counsel Mr. Rana Maqsood Afzal khan and defended the case in detail discussion as well as submitted their written arguments vide letter no. nil dated 24-06-2021. After detailed argument of the case, they were told that the decision of the Board will be conveyed later on. So far, no such decision of the Board has been conveyed to them till date. He further argued that as the case has been submitted in the Board by the concerned Drug Inspector then under what authority and whose authorization the Drug Inspector concerned, initiated further correspondence with the firm before the decision of the Board. Moreover, they received fresh revised show cause notice which was also silent on previous proceedings of the case and still they are un-aware about the decision taken by the Board in its 232nd meeting held on 24-06-2021. He further added that after completion of the investigation of the case and subsequent hearing of the case in 232nd meeting of the Board held on 24-06-2021, under which law & grounds fresh and revised show cause notice has been issued to them. He further submitted that a licensed manufacturer cannot take risk of making spurious drugs when he has invested millions of rupees in making manufacturing unit. So, it is requested to retest the sample in the best interest of justice as the expiry of Inj. Cintox Batch No. 041 is April 2022.

13. The Board, thoroughly scrutinized complete case record and observed that the stance of the firm regarding revised showcause notice without any authority is invalid as the Drug Inspector in compliance of the orders of PQCB dated 25-06-2021, reinvestigated the case and submitted detailed investigation report vide letter no DI-LQP/2014. In the light of investigation report, PQCB issued revised showcause of even no. dated 05-11-2021. The Board after thorough screening of the documents provided by M/s Osman & Company, Karachi observed that two different authority letters dated 01-01-2020 and 01-07-2020 have been provided by them. The authority letter dated 01-01-2020 states that:

> *"We, M/s Epoch Pharmaceuticals, Karachi has authorized M/s Osman & Company, Jamlana Mansion, Katchi Gali No. 02, Marriot Road, Karachi as our appointed sole agent them to supply offer our registered products all over the Pakistan. The authorized sole agent M/s Osman 7 Company, Karachi are further authorized to issue their invoice & warranty onward to their dealer M/s Ruman Medicine 111/P west House # 7 Malik Street Rahim Yar Khan"*.

While the authority letters issued on dated 01-07-2020 states that:

> *"This is to certify that M/s Osman & Company,* Jamlana Mansion Katchi gali # 2, Marriot Road, *Karachi is our authorized distributor. This authorization letter is valid till 30-06-202. However, company reserves right to amend change the validity at any time by giving one-month notice.*

14. The Board observed that the authority letters dated 01-01-2020 and 01-07-2020 are contradictory with two different statements, format and signatures of the firm. The Board asked Salman warrantor of M/S Osman & Company to explain his position in this regard. However, he refused to give any statement and submitted that he is presenting M/S Epoch at the moment and he cannot answer any question as warrantor of M/s Osman & Company. The Board showed serious concern that Salman bearing CNIC 42000-9472060-1 despite of his presence and appearance before the Board refused to clarify and explain this matter and submitted a copy *Drug Sale License by way of Wholesale* No. DHSKDK(Drug)/-254 Licence No. 3193 dated 19-2-2020 of M/s Osman & Company being authorized agent of M/s Epoch Pharmaceuticals issued by Government of Sindh.

15. Drug Inspector briefed about the facts of the case and requested for permission of registration of FIR against all the nominated accused persons. The Board after detailed scrutiny of the case record, statement of the accused and Drug Inspector was of the view that the two authority letters issued by the firm M/s Epoch Pharmaceuticals, Karachi in favour of M/s Osman & Company, Karachi shows that both the distributors *i.e.,* M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi and M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan are beneficiaries,

involved in selling/stocking for sale of spurious drug. Furthermore, the firm has the right to apply for retesting of the sample in writing, to Drug Inspector or the Provincial Quality Control Board, Punjab within 10 days after the intimation of DTL Report. The firm did not show any such intention. However, during hearing of the case, the firm requested the Provincial Quality Control Board, Punjab for retesting of its product therefore, violating the time limit of ten days as prescribed in the Drug Acts 1976 (as amended). The Board was of the unanimous view that a detailed police investigation is required in subject case regarding statements and contradictory documents provided by the accused and such elements must be dealt with iron hands to curb the menace of spurious drugs which is a cognizable offence under Drugs Act 1976/DRAP Act 2012 and rules framed there under. Keeping in view the facts of the case, the Board after due deliberation and discussion at length unanimously decided to **grant permission of registration of FIR** at the concerned police station**,** against the following below mentioned accused persons under Section 11 (5) (b) & (e) of Drug Act 1976 for the offences of:

1. **M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan** through its Managing Partner Muhammad Saleem. 2. Muhammad Saleem Managing Partner 3. Farhat Begum Production Incharge 4. Zeenat Quality Control Incharge/Warrantor of **M/s Epoch Pharmaceuticals, 83-85, Sector, 15** **Korangi Industrial area Karachi- Pakistan.**	a. **Manufacturing/selling/Stocking for sale of Spurious drug** b. **Issuance of false warranty**
5. Salman Warrantor Of **M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi.**	a. **Selling/Stocking for sale of Spurious drug** b. **Issuance of false warranty**
6. Muhammad Tahir Nadeem Proprietor/Warrantor Of **M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan.**	a. **Selling/Stocking for sale of Spurious drug** b. **Issuance of false warranty**

9. The Board further decided to exonerate the name Ghulam Abbas (Proprietor) of M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur under section 32 (3) of Drug act 1976 as the warranty provided by him was verified and owned by M/s Ruman Medicine House Rahim Yar Khan.

10. Review petition submitted by M/s Epoch Pharmaceuticals, Karachi vide letter no. nil dated 24-01-2022 received in the office of PQCB dated 27-01-2022. In the light of Honorable Drug Court, Lahore Orders dated 25.08.2021 the review petition submitted by M/s Epoch Pharmaceuticals dated 24-01-2022 against PQCB Order dated 15-12-2021, cannot be entertained vide letter No. PQCB/R-22/2021 dated 31-01-2022. The operative part of the order is;

11. *"There is no provision or section which empowers the Board to review or revision so that illegal practice which was started since 2002 till date has no legal cover rather the same is based on unlawful Orders passed by the Board under the shadow of notification dated 03.05.2002 is without legal authority in these cases and the same is declared illegal and un*

lawful..."

12. ***Firm vide letter no. Ref: 67 dated 08-02-2022 received in office of PQCB dated 10-02-2022***
13. *It is requested that as the order has been passed by the honorable court in W.P No. 895/2022 dated 04-02-2022 for not to take any further action against the petitioner till pending decision of review petition of petitioner.*

Form No. HCJD/C-121

ORDER SHEET

IN THE LAHORE HIGH COURT,

BAHAWALPUR BENCH, BAHAWALPUR

JUDICIAL DEPARTMENTT

Writ Petition No.895 of 2022

Date of Order: 04-02-2022

Farhat Begum Vs Chairman Provincial Quality Control Board, Lahore etc.

Learned counsel for the petitioners contends that review petition against order dated 15.12.2021 filed by the present petitioner is pending before respondent/Chairman Provincial Quality Control Board (Health Department) Punjab Lahore which is still pending without any meaningful hearing and remedy i.e., provided in law will become infructuous if the order impugned in the said review petition is implemented.

2. It is contended by learned counsel that no heed is being paid in the matter despite repeated visits and requests to review the application and also contends that he will be satisfied if a direction is given to respondent No.1 to decide the review application, expeditiously.

3 Learned Law Officer has not opposed this request.

4. The instant petition is **disposed** of with the direction to respondent No. 1 to decide the review application, if still pending, strictly in accordance with law, after providing an opportunity of hearing to the concerned parties**, preferably within two weeks from the date of receip**t of certified copy of this order. The Respondent-Department is expected not to take any further adverse action against the petitioner, before deciding the aforementioned review application.

PQCB 239th meeting held on 24-02-2022

14. In compliance to Lahore High court order, the issue was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **239th** meeting held on **24-02-2022** under the chairmanship of Secretary Health Primary & Secondary Healthcare Department, Punjab, in the presence of Board members as mentioned above. Mr. Amjad Farooq, Secretary DQCB, Rahim Yar Khan and Mr. Arfan Ali, Provincial Inspector of Drugs, Tehsil Liaqatpur, District Rahim Yar Khan was present along with the original case record. Muhammad Saleem (Managing Partner) along with counsel, Ch. Mahmood Ali (Advocate) of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan appeared before the Board. Counsel for the firm raised the argument as stated in the writ petition and requested to accept the same. He further added that report is time barred and requested for retesting of the sample of the subject drug and submitted that the warrantor portion was not sent to the company till now.

15. The Board after careful scrutiny of the case record observed that argument of the petitioner regarding warrantor portion is not correct as the warrantor portion was sent to M/s Ruman Medicine company vide letter no. DI/LQP/459 dated 10-10-2020 and time extension as required under section 22(2) of the Drugs act 1976 was granted by the Board. Provincial Inspector of Drug apprised the Board that FIR has been registered against the accused persons vide F.I.R No. 17/22 dated 14-01-2022 in concerned police station.
16. In the light of the above forgoing facts, as the Board does not have any **application of Review Petition of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan pending before Provincial Quality Control Board.**
17. **Lahore High Court Bahawalpur Bench, Bahawalpur Crl. Rev.No. 62 of 2022 order dated 06-06-2022 Operative part is**

…….. *The learned counsel for the petitioner has failed to point out any illegality or irregularity in impugned order, as the same is well-reasoned and calls for no interference by this Court, consequently the instant petition having no substance* **is dismissed.**

18. Drug Inspector submitted Investigation report vide letter no. 810 dated 16-06-2022 for grant permission for prosecution against the accused
19. SCN issued to the accused dated 29-07-2022
20. ***Firm filed writ petition No. 30570/Writ dated 27-06-2023*** **Lahore High Court, Bahawalpur Bench, Bahawalpur Crl. Org. No. 389-W/2022 in W.P No. 895/2022** Order dated 13-06-2023

ORDER SHEET

IN THE LAHORE HIGH COURT,

BAHAWALPUR BENCH, BAHAWALPUR

JUDICIAL DEPARTMENT

Crl.Org. No. 389-W of 2022 BWP.

Muhammad Saleem Vs Imran Sikandar Baloch etc

Date of Order: 13-06-2023

It is apprised by learned Law Officer that pursuant to direction passed by this Court, speaking order dated 11-03-2022 on review petition of petitioner has been passed copy of which is annexed with reply submitted by respondents.

2. When confronted, learned counsel for petitioner submits that order passed by this Court in previous round of litigation has not been complied with in letter and spirit and the matter has been disposed of with observation that no review petition was pending.

3. In this view of the matter, petitioner is directed to file review petition before respondent No. 1 and if it is filed, the same shall be dealt with and decided on merits strictly in accordance with law, after hearing petitioner and all concerned, through speaking order **within a period of seven days**, failing which petitioner shall be at liberty to move an appropriate application for revival of this contempt petition.

4. The instant petition is *disposed of accordingly.*

PQCB 24th Committee Meeting held on **10-08-2023**

21. The issue was considered by the Committee of the Board in **24th Committee Meeting** held on **10-08-2023** under the Convenorship of Director General, Drugs Control. Issue was considered by the Committee of Provincial Quality Control Board, as empowered by Board under section 11 (6) & (7) of the Drugs Act 1976 in its 258th meeting. Secretary PQCB apprised the Committee about the details of the case. The Committee after due deliberation and discussion unanimously decided to place the case on direction of Lahore High Court orders in upcoming Board meeting.

22. Personal Hearing Notice issued to accused persons vide dated 11-08-2023.

23. Case is placed before the Board for Decision.

PQCB 266th meeting held on 24-08-2023

24. The subject review petition was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **266th meeting held on 24-08-2023** under the Chairmanship of Vice-Chairperson. Mr. Rafaqat Ali Secretary DQCB District Rahim Yar Khan and Mr. Arfan Ali Drug Inspector Tehsil Liaqatpur were present along with original record of the case. Among the nominated accused persons Muhammad Saleem (Managing Partner) was present of **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Indusrtrial Area Karachi-Pakistan** along with Representative of the firm Khan Muhammad (Current Quality Control Manager) and counsel person Hafiz Ahsan (Advocate) and Noor Mehar (Advocate).

25. Hafiz Ahsan (Advocate) appeared on the behalf of **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Indusrtrial Area Karachi-Pakistan** and stated that the technical persons was engaged with the petition on 23-08-2023, therefore due to lack of time, proper consultation cannot be made with my client. Serious legal question is involved in the present case i.e to continue with the petition or to withdraw the same, Therefore, it is in the best intrest of justice that give time to the technical persons for detailed discussion. Therefore it is requested to kindly adjourn the case in the next meeting of PQCB in the best interest of justice.

26. 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

27. Personal Hearing Notice issued to accused persons vide dated 12-09-2023.

PQCB 268th meeting held on 21-09-2023:

28. The subject review petition was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **268th meeting held on 21-09-2023** under the Chairmanship of Vice-Chairperson. Mr. Rafaqat Ali Secretary DQCB District Rahim Yar Khan appeared via zoom link and Mr. Arfan Ali Drug Inspector Tehsil Liaqatpur was present along with case record. Counsel person of the firm Asim Malik (Advocate) and Hafiz Ahsan Naseer Aslam (Advocate) appeared before the Board on the behalf of **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Indusrtrial Area Karachi-Pakistan** and submitted that the said titled review petition is filed before the Honourable Board on 21-09-2023 in compliance of directions of Hounarable High Court Bahawalpur Bench passed in writ petition No. 29737/2023. In addition, the said time being is not intended to file review petition and submit before the honorable Board that we would defend our case on merit at the time of arguments in the main case. However, it is requested to decide the application of the firm dated. 31-08-2023 for providing the protocol of tests according to its merit.

29. Keeping in view the facts of the case, the Board, thoroughly scrutinized complete case record and decided that the stance of the firm regarding **withdrwal of its review petition is hereby accepted** and further directed to place the said case as regular case in Board meeting.

30. Personal Hearing Notice issued to accused persons vide dated 11-12-2023.

31. Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 04-2020

Expiry Date: 04-2022

Sampling Date (Form 4): 30-09-2020

Sent to DTL (Form 6): 03-10-2020

Date of receipt in DTL: 08-10-2020

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

Time Extension: Not Time Barred (Extension granted in 232M)

1ST DI Communication with firm on dated: 26-02-2021

Retesting Request of Firm: NO

Fate of Firm's Retesting Request: told verbally in 236th meeting held on 15-12-2021

Investigation Report Dated: 25-06-2021

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 46

PQCB SM-20-9/2022, SM-26-11/2022&

R-194/2022

Bosan Town, District Multan

ATTENDENCE

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

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Bosan Town, District Multan reported that: -His predecessor, on 07-09-2022, inspected the premises of M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan, recovered &seized five different types of articles/drug samples on Form-5. The Raw Material Store was locked & sealed due to following contraventions of Section 23 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under:

Sr. No.	Name of drug	Batch No.	Manufactured by	Quantity	Reason of seizure	Observations of Drug Inspector
1	Escitalopram oxalate-(1H) in Silver Color Aluminium Bag	E0-016/22	M/s India Sodhana Laboratories Ltd.	3.7 kg	1. Manufacturing/ Stocking of Drugs in violation of GMP and GSP. 2. Manufacturing/ Stocking of Misbranded Drugs 3. Manufacturing of Sub-Standard & Adulterated Drugs (vide DTL Lahore	In Raw Material Store: 1. API Record was not maintained 2. API & Non-API were placed in same store/ racks 3. Tablet section
2	White Color Powder in Transparent Polythene Bag labelled Estadol Tab. 500mg Item "Talcum Powder"	Nil	Nil	Talcum Powder Weight= 0.520 kg		

3	White color powder in a transparent polythene bag labelled "Primogel"	Nil	Nil	2.800 Kg	TRA No. 01-18300127/DTL dated 07-09-2022 in which Sildenafil identified in Tab. Citalem 10mg, Batch No. 46201	equipment was not labeled.
4	BMR of Tablet Citalem 3H 10mg	46201	Nil	94 Pages		
5	Tablet Citalem 10mg	46101	M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan.	15X10		

ii. The drug inspector Bosan Town, District Multan also took following drug samples on Form No 04 dated 07-09-2022 and sent to Drugs Testing Laboratory Multan vide Memorandum no. 0000139614, 0000139615 & 0000139616 dated 08-09-2022 for the purpose of test/analysis.

Sr. No.	Name of Drug	Batch No.	Name of Manufacturer	Registration No.	Quantity	Mfg Date	Expiry Date
1	Tab. Citalem 10mg	46202	M/S Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan	040726	30+30+30	Aug 2022	Aug 2025
2	Tab. Citalem 10mg	46201		040726	30+30+30	Apr 2022	Apr 2025
3	Tab. Citalem 10mg	46101		040726	100+100+100	March 2021	March 2024

iii. The then drug inspector Bosan Town Multan in continuation to the inspection on 07-09-2022, again on 17-09-2022, inspected the premises of M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan, recovered & seized following two items including one drug sample on Form-5 due to following contraventions of Section 23 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under:

Sr. No.	Name of drug	Batch No.	Manufactured by	Quantity	Reason of seizure
1	Tablet Citalem 10mg	46101	M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan	980 packs (1X10)	Manufacturing & Stocking of Misbranded drugs

			Road, Multan-Pakistan.	Packing	
2	BMR of Product Citalem 3H tablet 10mgTablet Citalem 3H 10mg	46101	Nil	95. Pages	

iv. The drug inspector took following drug sample on Form-3 with directions of "not to dispose of the stock"

Name of Drug	Batch No.	Name of Manufacturer	Quantity	Mfg Date	Expiry Date
Citalem 3H 10mg	46202	M/S Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan	2387 Strips	Aug 2022	Aug 2025

V. The drug samples Tablet Citalem 10mg, Batch Numbers 46202 and 46101 were declared of Standard quality by the Drugs Testing Laboratory Multan vide TRA No. 01-94005754/DTL & 01-94005756/DTL both dated 19-10-2022 respectively. Whereas, the following drug sample after test/analysis was declared as **Substandard (Suspected to contain Sildenafil)** by Government Analyst Drugs 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 No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Film Coated Tablet. Citalem 10mg [Suspected to conatin Label Claim Sildenafil]

Mfg Date:

Apr 2022

Expiry Date:

Apr 2025</td><td>46201</td><td>M/S Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan</td><td>01-94005755/DTL

dated

19-10-2022</td><td>Analysis with specifications applied: USP 2022

<u>Description:</u> Pink colored, round, film coated biconvex tablet with line of bisection on one side along with "HAMAZ" engraved on one side of line of bisection & plain on other side in ALU-ALU packing of 10 units, in a labeled outer hard carton. Each outer contains 1 blister of 10 units i.e 1*10=10 Tablets.

<u>Identification:</u> Escitalopram Oxalate Identified.

<u>Assay:</u>

<u>Escitalopram:</u>

<table><tr><td>Stated</td><td>10 mg/ Tablet</td></tr></table></td></tr>
</table>

Regn No. 040726				Determined	2.75 mg/ Tablet
				Percentage	**27.46%**
				Limit	90% - 110%
				(DOES NOT COMPLY)	
				<u>Identification of Sildenafil Citrate:</u> (USP) FTIR & retention time in the sample chromatogram corresponds to the retention time of the standard chromatogram as per "USP monograph of Sildenafil Tablets" **(Sildenafil Citrate identified).** **<u>Quantification of Sildenafil:</u>** By HPLC **Determined: 6.56mg/Tablet** **<u>RESULT:</u>** The above sample is **<u>Sub-Standard</u>**, on the basis of Assay test of Escitalopram & contains **<u>Suspected</u>** ingredient i.e Sildenafil.	

VI. A copy of test/analysis report of the subject drug sample was sent to M/s Hamaz Pharmaceuticals (Pvt.) Ltd., 13-Km, Lutfabad, Bosan Road, Multan-Pakistan with directions to explain their position and provide requisite information in this regard.

VII. The Provincial Inspector of Drugs, Bosan Town Multan declared the product as unregistered containing an unregistered adulterant (Sildenafil) and hence, requested to grant permission for registration of FIR under section 27 (1) of The Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under.

2. Drug Inspector requested for grant of permission for FIR 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 framed there under by the way of: -

    a. **Manufacture for Sale/ Sale of Substandard & Unregistered Drug**
    b. **Manufacture for Sale/ Sale of Adulterated & Misbranded Drugs**
    c. **Manufacturing of drugs in violation of Good Manufacturing Practices & Good Storage Practices**

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

4. Personnel hearing notice issued vide dated 28-11-2023.

7. Case is placed before the Board for Decision.

Summary of the case:

- Sampling date: 07-09-2022
- Form 6: 08-09-2022
- DTL Report Date: 19-10-2022
- 1st Visit Date of Form 5: 07-09-2022
- 2nd visit Date of Form 3 and 5: 17-09-2022
- DI 1st intimation to firm: 24-10-2022
- Retesting request if any: Yes in response of Show cause notice
- Investigation report Dated: 341/DDC/BTM, Dated. 06-11-2023
- Mfg Date: 08-2022
- Exp Date: 08-2025

CURRENT PROCEEDINGS & DECISION BY THE BOARD: