Health & Population Department
PROVINCIAL QUALITY CONTROL BOARD, PUNJAB.

291 Meeting of PQCB

Date: 27-05-2025

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

Tehsil Pind Dadan Khan, District Jhelum

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Weather folds Pharmaceuticals, 69/2 PhaseII, Industrial Area, Hattar, Islamabad,** through its Managing Director Malik Arshad Mehmood 2. Malik Arshad Mehmood MD 3. Aftab Alam Khan Quality Control Incharge/ Warrantor 4. Munawar Javed Khattak Production Incharge **Of M/s Weather folds Pharmaceuticals, 69/2 PhaseII, Industrial Area, Hattar, Islamabad**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Pind Dadan Khan, District Jhelum reported that:-

i. He, on 01-12-2024 inspected the premises of M/s Butt Pharmacy situated near Masjid Bilal, Main Bazar Dharyala Jalap, Tehsil Pind Dadan Khan, District Jhelum and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Faisalabad on Form No. 6 vide Memo No. 0000211804 Dated 02-12-2024.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tablet S-Kyne (Each Film Tablet contains: Dydrogesterone	335	M/s Weather folds Pharmaceutical, 69/2 PhaseII, Industrial Area,	01-74012721/ DTL dated: 17-01-2025	**Physical Description:** White colored, round shaped, biconvex tablets, plain from both sides, packed in ALU/ALU blister of 1*10's pack, further packed in labelled outer carton. (20

10mg) **Mfg. Date**: 11-2023 **Exp. Date:** 11-2025 **Regn. #** 100245		Hattar, Islamabad		tablets) **IDENTIFICATION:** Dydrogesterone is not identified **(FTIR) (USP-2024) (Does Not Comply)** **Assay:** Stated: 10mg/ Tablet **Determined: 0.000 mg/ Tablet (HPLC) (USP-2024)** **Percentage: 0.00% (DOES NOT COMPLY)** Limit: 90.0-110.0% **RESULT:** **The above sample is "Spurious" as defined under clause (i) of sub-section (z-b) of section 3 of The Drugs Act 1976**

iii. M/s Butt Pharmacy situated near Masjid Bilal, Main Bazar Dharyala Jalap, Tehsil Pind Dadan Khan provided invoice/ warranty No. 179 dated: 27-09-2024 issued by M/S Nasir Enterprises Pharma Distributor's at Street No. 6, Mirza Abad, Rohtas Road Jhelum , as proof of its purchase.

iv. Warrantor Portion of the subject drug sample was sent to M/S Nasir Enterprises Pharma Distributor's, who in-turn provided invoice / warranty No. 819/2023 dated: 16-12-2023 issued by M/s Weather folds Pharmaceuticals, 69/2 PhaseII, Industrial Area, Hattar, Islamabad.

v. A copy of Test/ Analysis reports was sent to M/s Weather folds Pharmaceuticals and were directed to explain their position in this regard.

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

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

3. Show-cause notice(s) issued to accused person(s) dated 23-04-2025

Firm replied to the show cause notice vide letter no. Nil dated 05-05-2025

Requisite documents were attached along with the letter.

Copy of Drug Manufacturing License.

Copy of Registration letter of S-Kyne 10mg tablets.

Copy of BMR.

Copy of Job Certificates and appointment letter of technical staff.

WhatsApp no for official correspondence.

Copy of CNIC of said persons.

4. Personal hearing notice(s) issued to accused person(s) dated 22-05-2025

5. Case is placed before the Board for decision.

Sr. No.		Summary of th
1	**Sampling Date (Form 4)**	01-12-2024
2	**Sample Sent to DTL (Form-6)**	02-12-2024
3	**Receipt Date in DTL**	09-12-2024
4	**Issuance of DTL Report**	17-01-2025
5	**Time Extension**	Not Time Barred
6	**DI First Communication with Firm**	30-01-2025
7	**Retesting Request**	-
9	**Investigation Report by DI**	25-02-2025
10	**SCN Permission**	289-M (27-03-2025)
11	**Show Cause Notice Issued**	23-04-2025
12	**Reply of Firm to Show Cause Notice**	Yes (05-05-2025) recei
13	**History (3 years)**	Firm’s Reported: 13
		Product’s Reported: 4 (S 2 Sargodha 1 Rahim Yar Khan 1 Jhelum

Case No. 2

PQCB/R-494/2023

Lahore General Hospital, Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Caraway Pharmaceuticals, Plot 12, St N-3, National Industrial Zone, Rawat, Islamabad-Pakistan** through its Managing Director, Umar Farooq 2. Umar Farooq Managing Director 3. Muhammad Javaid Production In-Charge 4. Murad Ali Quality Control Manager 5. Imran Gohar Quality Assurance Manager 6. Dr. Syed Tauqeer Ali Shah Warrantor of M/s Caraway Pharmaceuticals, Plot 12, St N-3, National Industrial Zone, Ra Islamabad-Pakistan.

BREIF FACTS OF THE CASE:

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

i. The then drug inspector, on 14-11-2022, inspected the premises of Main Medicine Store of Lahore General Hospital, District Lahore, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 148049 dated 14-11-2022.
ii. The following drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Injection. CARAWAT [Sterile Water for Injection BP 5ml] **Mfg Date:** March 2022 **Expiry**	22C054	M/S Caraway Pharmaceuticals , Plot 12, St. N-3, National Industrial Zone, Rawat, Islamabad-Pakistan	01-183002116/DTL Dated:03-02-2023	**Result of test/ analysis with specifications applied: BP 2022** **PHYSICAL DESCRIPTION**: Colorless liquid in sealed transparent glass ampoule with label printed on it. Claimed volume=5mL. **EXTRACTABLE VOLUME**: Limit: NLT nominal volume, i.e., 5mL Determined: 5mL (Complies) **WATER CONDUCTIVITY**: Limit: NMT 25µS/cm at 25 ± 1 ºC Determined: 11.99µS/cm at 24.3°C (Complies)

Date: Feb 2027 **Regn No.** 050085				**OXIDIZABLE SUBSTANCES:** Complies. **ACIDITY OR ALKALINITY:** Complies. **CALCIUM AND MAGNESIUM:** Complies. **SULPHATES:** Complies. **CHLORIDES:** Complies. **STERILITY TEST:** The sample is non-sterile. **(DOES NOT COMPLY)** **BACTERIAL ENDOTOXINS**: The sample complies the limit of less than 0.25IU/mL **RESULT:** The above sample is **SUB-STANDARD**, on the basis of Sterility test performed as per BP.

iii. The storekeeper, Main Medicine Store of Lahore General Hospital, District Lahore provided warranted delivery challan bearing No. CP/QR/WH/1010572 dated 04-11-2022 issued by M/s Caraway Pharmaceuticals, Plot 12, St N-3, National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/s Caraway Pharmaceuticals, Plot 12, St N-3, National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan.

v. A copy of test/analysis report was sent to M/s Caraway Pharmaceuticals, Plot 12, St N-3, National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report 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 21st committee meeting held on 06-06-2023, after due deliberation and discussion unanimously decide to turn down the firm's request for retesting of the subject drug sample. Firm's review petition against above mentioned decision of retesting request, has also been turned down in 272nd meeting held on 22-11-2023.

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

3. Show-cause notice issued to accused person(s) dated 04.11.2024.

4. Personal Hearing notice issued to the accused person(s) dated 20-05-2025

Sr.	**Summary of the case**	
1.	**Date of sampling**	14.11.2022

2.	**Sent to DTL**	14.11.2022
3.	**Date of receipt in DTL**	15.11.2022
4.	**Issuance of DTL Report**	03.02.2023
5.	**Time Extension**	Granted in 256th meeting dated 19.01.2023
6.	**DI 1st communication with firm**	28.03.2023
7.	**Retesting Request**	05.04.2023
8.	**Fate of retesting request**	Turn Down (21st-CM), RP also upheld (272nd-M)
9.	**Investigation Report of DI**	18.01.2024
10.	**Permission of SCN**	276th meeting dated 29.02.2024
11.	**SC Notice Issued**	04.11.2024
12.	**Reply of the firm**	
13	**History (3 years)**	22 cases of the firm including subject case 08 subject case of the product

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 3

PQCB/R-518/2023
Tehsil & District Okara

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case**. 1. **/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad** through its Managing Director, Umer Farooq. 2. Umer Farooq — Managing Director 3. Muhammad Javaid — Production Manager 4. Murad Ali — Quality Control Incharge 5. Imran Gohar — Quality Assurance Manager 6. Syed Tauqeer Ali Shah — Warrantor of **M/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad.**

BRIEF FACTS OF THE CASE

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

1. The then drug inspector, on 26.12.2022, inspected the premises of Medicine Store CEO DHA Office Okara, took drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 152378 dated 26-12-2022.
2. Following Drug samples after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Bahawalpur, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Injection. Carawat 5ml [water for injection 5ml] **Mfg Date:**	22C054	M/S Caraway Pharmaceuticals, Plot12, Street N-3 National Industrial zone, Rawat, Islamabad-Pakistan.	01-10097001666/DTL Dated: 10 Feb 2023	**Specification applied: BP 2023** **DESCRIPTION** Clear colorless transparent liquid in sealed transparent glass ampule. (stated volume: 05ml) **VOLUME (BP)** Limit: Not less than nominal (05mL) Determined: 5.0 mL

03.2022 **Expiry Date:** 02.2027				**CONDUCTIVITY (BP)** Limit: Not more than 25s/cm Determined: 8.763 s/cm **STERILITY (BP)** Limit: The product must be Sterile. Determined: ***The product is non-Sterile.*** **RESULT**: The sample is declared **Sub-Standard** on the basis of **Sterility Test** (i.e., The product is **Non-Sterile**).

1. Store Keeper of Medicine Store, CEO DHQ Okara provided invoice/warranty 1010696 dated 12-11-2022 issued by M/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad as a proof of its purchase.
2. Warrantor portion of drug sample was sent to M/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad.
3. A copy of test/analysis report was sent to M/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad and they were asked to provide the requisite information in this regard. In response firm requested retesting of sample. The retesting request of the sample was turn down 27th meeting dated 26-10-2023. The review petition was also turn down in 283rd meeting dated 08-08-2024.
4. The Provincial Inspector of Drugs requested for grant of permission for prosecution against you as you have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under by the way of:-

    i. **Manufacturing and sale of substandard drug**
    ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 13-05-2025
4. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025

Summary	
Sampling Date (Form 4):	26-12-2022
Sent to DTL (Form 6):	26-12-2022
Date of receipt in DTL	30-12-2022

DTL Report Date (Form 7):	10-02-2023
Time Extension granted	N/A
1st DI Communication with firm dated	12-02-2023
Date of Retesting Request of Firm:	27-02-2023
Fate of Retesting request	**Turn down in 27th Com** **RP upheld in 283rd Mee**
Investigation Report Dated	23-12-2024
Firm History 3 years	**Firm: 22** **Product:08**

PROCEEDING & DECISION BY THE BOARD:

PQCB/R-517/2023
Tehsil & District Okara

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case**. 1. **M/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad** through its Managing Director, Umer Farooq. 2. Umer Farooq — Managing Director 3. Muhammad Javaid — Production Manager 4. Murad Ali — Quality Control Incharge 5. Imran Gohar — Quality Assurance Manager 6. Syed Tauqeer Ali Shah — Warrantor of M/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad.

BRIEF FACTS OF THE CASE

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

1. The then drug inspector, on 27.11.2022, inspected the premises of Medicine Store CEO DHA Office Okara, took drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 149754 dated 27-11-2022.
2. 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. Carawat 5ml [water for injection 5ml] **Mfg Date:** 03.2022 **Expiry Date:** 02.2027	22C055	M/S Caraway Pharmaceuticals, Plot 12, Street N-3 National Industrial zone, Rawat, Islamabad-Pakistan.	01-10097001361 /DTL Dated: 20 Jan 2023	**Specification applied: BP 2022** **DESCRIPTION** Clear colorless transparent liquid in sealed transparent glass ampule. (Stated volume: 05ml) **VOLUME (BP)** Limit: Not less than nominal (05mL) Determined: 5.6 mL **CONDUCTIVITY (BP)** Limit: Not more than 25s/cm Determined: 10.830 s/cm **STERILITY (BP)** Limit: The product must be Sterile. Determined: ***The product is non-Sterile.*** **RESULT**: The sample is declared **Sub-Standard** on the basis of **Sterility Test** (i.e., The product is **NON-STERILE**.

4. Store Keeper of Medicine Store, CEO DHQ Okara provided invoice/warranty 1010696 dated 12-11-2022 issued by M/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad as a proof of its purchase.
5. Warrantor portion of drug sample was sent to M/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad.
6. A copy of test/analysis report was sent to M/S Caraway Pharmaceutical, Plot # 12, Street # 3, National Industrial Zone, (RCCI), Rawat, Islamabad and they were asked to provide the requisite information in this regard. In response firm requested retesting of sample. The retesting request of the sample was turn down 27th

meeting dated 26-10-2023. The review petition was also turn down in 283rd meeting dated 08-08-2024.

7. The Provincial Inspector of Drugs requested for grant of permission for prosecution against you as you have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under by the way of:-

iii. **Manufacturing and sale of substandard drug**
iv. **Issuance of false warranty**

2. Show cause notice(s) issued to accused person(s) dated 13-05-2025
3. Personal hearing notice(s) issued to accused person(s) dated 20-05-
4. Case is placed before the Board for decision.

Summary	
Sampling Date (Form 4):	27-11-2022
Sent to DTL (Form 6):	27-11-2022
Date of receipt in DTL	02-12-2022
DTL Report Date (Form 7):	20-01-2023
Time Extension granted	N/A
1st DI Communication with firm dated	12-02-2023
Date of Retesting Request of Firm:	27-02-2023
Fate of Retesting request	**Turn down in 27th Com** **RP upheld in 283rd Mee**
Investigation Report Dated	21-12-2024
Firm History 3 years	**Firm: 22** **Product:08**

PROCEEDING & DECISION BY THE BOARD:

Case No. 4

PQCB/ MSS-192474/2024

PESSI, Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Caraway Pharmaceuticals Plot No. 12 Street N-3 National Industrial Zone, Rawat Islamabad, Pakistan** through its Managing Director, Umar Farooq 2. Umar Farooq — Managing Director 3. Syed Tauqeer Ali Shah — Production In-charge 4. Murad Ali — Quality Control Manager/ Warrantor 5. Imran Gohar — Quality Assurance Manage **Of M/S Caraway Pharmaceuticals Plot No. 12 Street N-3 National Industrial Zone, Rawat Islamabad, Pakistan.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs Central Medical Store Depot, PESSI reported that:-

i. He, on 21-02-2024, inspected the premises of CMSD, PESSI and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug samples to Drug Testing Laboratory, Bahawalpur vide memo number 192474 dated 21-02-2024.

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

Drug Sample	**Batch**	**Manufacturer**	**TRA No. and Date**
Dispersible Tablet, ITSAL 10 mg [Escitalopram 10 mg(as Escitalopram Oxalate U.S.P)] Mfg. Date: Jan-2024 Exp. Date: Dec-2025 Reg. No. 063375	24A048	M/s Caraway Pharmaceuticals Plot No. 12 Street N-3 National Industrial Zone, Rawat Islamabad, Pakistan.	01-10097007703/DTL 26-03-2024
Specs Applied: MS **Composition:** Each dispersible tablet contains:			

Escitalopram Oxalate USP Eq. to Escitalopram…10mg

DESCRIPTION:

White to off-white color oblong biconvex tablet which is plain on one side and a line of bisect on the other side.

Packed in blister of 10 Tablets.

Disintegration Test:

Limit: All tablets must be disintegrated within specified time i.e., NMT 03 min.

Result: 13 out of 18 tablets were not disintegrated within specified time i.e., 03 min.

Does not comply with the applied specifications)

IDENTIFICATION: Escitalopram is identified.

ASSAY:

Escitalopram:

Stated:	10 mg / Tab
Determined:	9.214 mg/ Tab (92.14%)
Limit:	90.0 % - 110.0 %

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

iii. The Director Medical/ In-charge PESSI Central Medical Store Depot, Lahore provided invoice/ warranty no. 1015481 dated 15-02-2024 issued by M/s Caraway Pharmaceuticals Plot No. 12 Street N-3 National Industrial Zone, Rawat Islamabad, Pakistan as a proof of its purchase of the said drug.

iv. Warrantor portion was sent to M/s Caraway Pharmaceuticals Plot No. 12 Street N-3 National Industrial Zone, Rawat Islamabad, Pakistan.

v. A Copy of test report of the drug sample was sent to M/s Caraway Pharmaceuticals Plot No. 12 Street N-3 National Industrial Zone, Rawat Islamabad, Pakistan with directions to provide the requisite information and to explain their position in this regard. In response, the firm requested for re-test/ analysis of the drug sample.

vi. Pursuant to the request of manufacturer, PQCB allowed the request of firm in 42nd Committee meeting dated 30-07-2024 and, the PQCB portion of the drug sample was sent to Appellate Laboratory, National Institute of Health, Islamabad. The sample was declared Substandard from NIH as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Report No. & Date	Results of DTL Report
Itsal Dispersible Tablets 10 mg	24A048	M/s Caraway Pharmaceuticals Plot No. 12 Street N-3 National Industrial Zone,	0152-P/2024 dated 28th August, 2024	**Specs Applied: MS** **Disintegration**

		Rawat Islamabad, Pakistan		Determined: 4 tablets out of 6 did not c Limit: Not more than 3.0 minutes. **Does not comply with Manufacturer** **Remarks:** As Four tablets out of six di **RESULT:** The sample is of **"Sub-Stan**

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

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

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 15-11-2024

4. Personal hearing notice(s) issued to accused person(s) dated 22-05-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of th	
1	**Sampling Date (Form 4)**	21-02-2024
2	**Sample Sent to DTL (Form-6)**	21-02-2024
3	**Receipt Date in DTL**	22-02-2024
4	**Issuance of DTL Report**	26-03-2024
5	**Time Extension**	-
6	**DI First Communication with Firm**	17-04-2024
7	**Retesting Request**	24-04-2024
9	**Investigation Report by DI**	08-10-2024
10	**SCN Permission**	286-M
11	**Show Cause Notice Issued**	15-11-2024

12	**Reply of Firm to Show Cause Notice**	-
13	**History (3 years)**	Firm’s Reported: 18
		Product’s Reported: 1 (S

Case No. 5

PQCB/ MSS-194914, 194915/2024

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

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi,** through its Director, M. Muzammil Nazar 2. Muhammad Muzammil Nazar — Managing Director 3. Ghulam Nabi Khoso — Production Manager 4. Naima Khanam — Quality Control Incharge/Warrantor **of M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.**

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 12-03-2024, inspected the premises of MSD CEO (DHA), DG Khan situated at RHC Sarwar Wali (Tehsil DGK) and took 05 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 samples, sent vide memo no. 194914 and 194915, dated: 13-03-2024, after test/analysis were declared as **Substandard** by Government Analyst Drug Testing Laboratory, **Multan**, as detailed below:

Sr #	Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date
1	**Parapol Paediatric Suspension** **Mfg. date: 11-2023** **Exp. Date: 11-2025** **Reg. # 002772**	181-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-105005961/DTL Dated: 07.06.2024
	Specifications applied for test/analysis: USP 2024/Others/In house **PHYSICAL DESCRIPTION:** **Stated:** Pinkish red **sweet** suspension. **Determined:** Parapol is a pinkish red, viscous liquid having **bitter** taste, **free from any dispersed solid particles** in a labeled amber colored plastic bottle sealed with white screw cap packed in a labeled outer hard carton.			

As per USP <1151> Pharmaceutical Dosage Forms; ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."*** **(Does not Comply)**

IDENTIFICATION Paracetamol is Identified.

ASSAY by HPLC:

Paracetamol Stated: 120 mg /5mL

Determined: 112.91 mg /5mL

Percentage: 94.08 %

Limit: 90 - 110% **(Complies)**

pH Range: 4.0-6.9

Determined: 5.27 at 26.2^0C **(Complies)**

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL by GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol:	**Diethylene Glycol:**
Stated: NMT 0.1%	Stated: NMT 0.1%
Determined: Not Detected	Determined: Not Detected
(Complies)	**(Complies)**
Propylene Glycol	
Determined: 9.74%w/v	

"Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-38/2024,

Dated 21-05-2024".

Result: The above-mentioned sample is declared **Sub-Standard** on the basis of Physical Characteristics

2	Parapol Paediatric Suspension **Mfg. date: 11-2023** **Exp. Date: 11-2025** **Reg. # 002772**	182-24	M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01-105005902/DTL Dated: 07.06.2024

Specifications applied for test/analysis: USP 2024/Others/In house

PHYSICAL DESCRIPTION:

Stated: Pinkish red **sweet** suspension.

Determined: Parapol is a pinkish red, viscous liquid having **bitter** taste, **free from any dispersed solid particles** in a labeled amber colored plastic bottle sealed with white screw cap packed in a labeled outer hard carton.

As per USP <1151> Pharmaceutical Dosage Forms; ***"A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase."***

(Does not Comply)

IDENTIFICATION Paracetamol is Identified.

ASSAY by HPLC:

Paracetamol Stated: 120 mg /5mL

Determined: 110.95 mg /5mL

Percentage: 92.46 %

Limit: 90 - 110% **(Complies)**

pH Range: 4.0-6.9

Determined: 5.30 at 26.5^0C **(Complies)**

TEST FOR ETHYLENE GLYCOL, DIETHYLENE GLYCOL & PROPYLENE GLYCOL BY GAS CHROMATOGRAPHY

Note: The given sample was analyzed for Test of Ethylene Glycol, Diethylene Glycol & Propylene Glycol.

WHO Working Document QAS/23.922/rev3 Dated 31 October 2023

Ethylene Glycol: Stated: NMT 0.1% Determined: Not Detected **(Complies)**	**Diethylene Glycol:** Stated: NMT 0.1% Determined: Not Detected **(Complies)**
Propylene Glycol Determined: 9.23%w/v	

"Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-38/2024,

Dated 21-05-2024".

	Result: The above-mentioned sample is declared **Sub-Standard** on the basis of Physical Characteristics.

iii. Store Keeper, MSD CEO (DHA), DG Khan situated at RHC Sarwar Wali (Tehsil DGK), provided invoice/ warranty No. 000690 dated 23-02-2024, issued by M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi., as a proof of its purchase
iv. Warrantor portions of drug samples were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.
v. Copies of test/analysis reports were sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi 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 firm's retesting request the Provincial Quality Control Board in its **42nd Committee meeting** held on **30-07-2024**, after due deliberation and discussion unanimously decided to **Turn Down** the subject request for retesting.
viii. Firm filed a **Review Petition** against the order dated 30-07-2024, which was also **Turned down** in **287th meeting dated; 08-01-2025** and the previous decision to Turn down the retesting request was upheld.

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

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

3. Show cause notice(s) was issued to accused person(s) on 09-05-2025.

Personal Hearing notice(s) were issued to the other nominated accused on 20-05-2025.

Case is placed before the Board for Decision.

Sr. No.	**SUMMARY OF THE CASE**	
1	**Sampling Date (Form 4)**	12-03-2024
2	**Sample Sent to DTL (Form-6)**	13-03-2024
3	**Receipt Date in DTL**	16-03-2024
4	**Issuance of DTL Report**	07-06-2024
5	**Time Extension**	Not Time Barred (as DTL seek time extension of 60 days in 38th Committee meeting dated 21-05-2024)
6	**Retesting Request**	Yes

7	**Fate of Retest Request**	Placed in 42nd Committee meeting held on 30-07-2024 and the Board decided to **turn down** the retesting request
8	**Investigation Report by DI**	28-04-2025
9	**Show Cause Notice Issued**	Show Cause Issued
10	**History (3 years)**	Firm: 110 cases Product: 87 cases reported

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 6

PQCB/ R-519/2023

Tehsil & District Nankana Sahab

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Cotton Craft (PVT) Ltd., 407-408 Sundar Industrial Estate, Raiwind Road, Lahore** through its Managing Director Salman Shahid 2. Salman Shahid — Managing Director 3. Hafiz Tariq Mahmood — Production Manager/ Warrantor 4. Nuzhat Kauser Mumtaz — Quality Control Incharge **Of M/s Cotton Craft (PVT) Ltd., 407-408 Sundar Industrial Estate, Raiwind Road, Lahore**

BRIEF FACTS OF THE CASE:

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

i. She, on 16-05-2023, inspected the premises of Main Medicine Store, Chief Executive Officer (Health), DHA, Nankana Sahib and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Lahore vide Memo no. 166830 Dated 16-05-2023.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Absorbant Cotton Wool **Mfg. Date**: 03-2023 **Exp. Date:** 02-2026 **Regn. #** 006271	88 C 23	M/s Cotton Craft (PVT) Ltd., 407-408 Sundar Industrial Estate, Raiwind Road, Lahore	01-10194001840/ DTL Dated: 23-06-2023	**Result of test/ analysis with specifications applied:** BPC **Physical Description:** White cotton wool bleached to white, free from leaf shell and offer appreciable resistance when pulled, **having foreign pieces of red, blue, brown and black threads. (Does not**

				comply) **<u>SOLUBILITY:</u>** **Limit:** Soluble at 20°C, in 66% v/v sulphuric acid. **Result:** Soluble. **(Complies)** **<u>ABSORBENCY:</u>** **<u>Sinking Time:</u>** **Limit:** NMT 10 seconds at 20°C (BPC) NMT 15 seconds at 20-25 °C (F.6-6/2005-Reg-II(South) **Result:**7 seconds at 23.1°C **(Complies)** **<u>Water Holding Capacity:</u>** **Limit:** NLT 23gm per gm of sample (BPC 1973) NLT 20 gm per gm (F.6-6/2005-Reg-II(South) **Result:** 21.7 g/g **(Complies)** **<u>ACIDITY/ ALKALINITY:</u>** **Limit:** Should be Neutral **Result:** Neutral **(Complies)** **<u>FIBER IDENTIFICATION:</u>** **Limit:** Fiber should become violent on treatment with iodinated zinc Chloride solution. **Result:** Fiber becomes violent. **(Complies)** **<u>RESULT:</u>** The above sample is **"SUB-STANDARD"**, on the basis of Physical Description performed as per BPC and F.6-6/2005-Reg-II (South).

iii. The Store Keeper of Main Medicine Store, Chief Executive Officer (Health), DHA, Nankana Sahib

provided warranty/invoice No.786/1156/2023 Dated 11-05-2023 issued by M/s Cotton Craft (PVT) Ltd., 407-408 Sundar Industrial Estate, Raiwind Road, Lahore.

iv. Warrantor Portion along with warranty and a copy of Test/ Analysis report was sent to M/s Cotton Craft (PVT) Ltd., 407-408 Sundar Industrial Estate, Raiwind Road, Lahore and were directed to explain their position in this regard.

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

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

3. Show-cause notice(s) issued to accused person(s) dated 12-05-2025

4. Personal hearing notice(s) issued to accused person(s) dated 22-05-2025

5. Case is placed before the Board for decision.

Sr. No.		Summary of th
1	**Sampling Date (Form 4)**	16-05-2023
2	**Sample Sent to DTL (Form-6)**	16-05-2023
3	**Receipt Date in DTL**	19-05-2023
4	**Issuance of DTL Report**	23-06-2023
5	**Time Extension**	Not Time Barred
6	**DI First Communication with Firm**	28-12-2023
7	**Retesting Request**	-
9	**Investigation Report by DI**	10-03-2024
10	**SCN Permission**	289-M (27-03-2025)
11	**Show Cause Notice Issued**	12-05-2025
12	**Reply of Firm to Show Cause Notice**	-
13	**History (3 years)**	Firm’s Reported: 15
		Product’s Reported: 6 (S

Case No. 7

PQCB/ MSS-208379, 208381/2024

Mumtaz Abad Town, District 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**.

BREIF FACTS OF THE CASE:

Provincial Inspector of drugs Mumtaz Abad Town, Multan reported that: -

i. He, on 26-10-2024, inspected the premises of Main Medicine Store, O/o Chief Executive Officer (DHA), situated at BHU Jhok Lashkar, Multan and took samples of eleven (11) different types of drugs on Form No. 04 for the purpose of test and analysis.
ii. Following drug samples, sent on Form 6 vide memorandum no. 208379 and 208381 dated: 26-10-2024 and 27-10-2024, respectively, after test/ analysis were declared **Substandard** by Government Analyst Drug Testing Laboratory, Multan as detailed below:

Sr #	Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date
1	Absorbent cotton wool [Cotton wool 500gm] **Mfg. date: 10-2024** **Exp. date: 09-2027** **MDME-0000159**	84J24	M/s Cotton Craft Pvt Ltd, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore.	TRA No.01-105008262/DTL 24-12-2024
	Analysis with specifications applied: BP 2024 **Physical Appearance:** **Stated:** Well-carded cotton fibers 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 shaken.			

Determined: Cotton fibers bleached to good white but containing pieces of threads and foreign matter. It shed appreciable quantity of dust when gently shaken. **(Does Not Comply)**

Sinking Time: Limit: NMT 15 seconds **(BP/MOH)**

Determined: 9.0 seconds **(Complies)**

Water Holding Capacity: Limit: NLT 20 g/ g **(BP/MOH)**

Determined: 18.5169 g/g **(Does Not Comply)**

Alkalinity: **Limit: should show no pink color with phenolphthalein indicator.** **(BP/MOH)**

Determined: Filtrate gives no pink color with phenolphthalein **(Complies)**

Acidity: **Limit: should show yellow color with Methyl Orange Indicator.** **(BP/MOH)**

Determined: Filtrate gives yellow color with Methyl Orange. **(Complies)**

Color of Aqueous

Extract: **Limit:** The filtrate does not differ in color from the water used to prepare the extract **(BP)**

Determined: No difference in color observed **(Complies)**

RESULT: The above sample is **Sub-standard** on the basis of tests performed.

2	Curay Gauze Swab Absorbent Cotton Gauze 10*10 (Sterile Absorbent Cotton Gauze swab 10*10 cm (8Ply) **Mfg. date: 10-2024** **Exp. date: 09-2027** **MDMR-000236**	93J24	M/s Cotton Craft Pvt Ltd, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore.	TRA No.01-105008264/DTL 24-12-2024

Specification applied for test/analysis: **BP 1993**

DESCRIPTION: Absorbent cotton gauze consists of fabric of plain weave, bleached to good white, reasonably free from weaving defects, leaf & shell.

Warps:	Stated: 69-77/10 cm Determined: 70.86/ 10 cm **(Complies)**
Wefts:	Stated: 53-61/10cm Determined: 55.11/10 cm **(Complies)**

Weight g/ m^2:	Stated: NLT 14.0 g/m^2
Sinking Time	Determined: 47.76 g/m^2 **(Complies)** Limit: NMT 10 seconds Determined: **20.8 seconds** **(Does Not Comply)**

Alkalinity: **Limit:** should show no pink color with phenolphthalein indicator.

Determined: Filtrate shown no pink color with phenolphthalein indicator**.** **(Complies)**

Acidity: **Limit:** should show yellow color with Methyl Orange Indicator.

Determined: Filtrate gives yellow color with Methyl Orange. **(Complies)**

Sterility It conforms to sterility test **(Complies)**

RESULT: The above-mentioned sample is **Sub-standard** on the basis of **Sinking Time**.

iii. Store keeper, Main Medicine Store, O/o Chief Executive Officer (DHA), Multan provided invoice/ warranty No. 786/0198/2024 dated 19-10-2024 issued by M/s Cotton Craft Pvt Ltd, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore, as a proof of its purchase.

iv. Warrantor Portions were sent to M/s Cotton Craft Pvt Ltd, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore.

v. Copies of test reports were 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 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 Product/Therapeutic Good**
b. **Issuance of false warranty**

3. Show-cause Hearing notice issued to accused person(s) dated 12-05-2025.

Sr.	**Summary of the case**	
1.	**Date of sampling**	26-10-2024
2.	**Sent to DTL**	26-10-2024, 27-10-2024
3.	**Date of receipt in DTL**	29-10-2024
4.	**Issuance of DTL Report**	24-12-2024

5.	**Time Extension**	N/A
6.	**Retesting Request**	No
7.	**Fate of retesting request**	NA
8.	**Investigation Report of DI**	25-03-2025
9.	**Permission of SCN**	290th meeting dated 07-05-2025
10.	**SC Notice Issued**	12-05-2025
11.	**Reply of the firm**	Not received
12	**History (3 years)**	Total cases: 15 cases of product: Absorbent Cotton Wool= 06 Gauze Curay= 02

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 8

PQCB/R-635/2018, 636/2018

Civil Hospital, Bahawalpur

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s S.J. & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E., Karachi-Pakistan** through its Director Iftikhar Hasan 2. Iftikhar Hasan Director 3. Farhat Begum Production Incharge (for WFI batch no. 7436P) 4. Muhammad Usman Production Incharge (for WFI batch no. 8024P) 5. Ghulam Abbass Quality Control Incharge 6. Saeed Ahmed Danishmandi Warrantor of M/s S.J. & G. Fazul Ellahie Pvt Ltd., E-46, S.I.T.E Karachi-Pakistan

BREIF FACTS OF THE CASE:

Provincial Inspector of Drugs, Civil Hospital, Bahawalpur reported that: -

i. He, on 10-02-2018 inspected the Central pharmacy Civil Hospital Bahawalpur, took subject batches of drug samples on Form No. 4 for the purpose of test/analysis.
ii. Following drug samples, after test/analysis were declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

Sr. no	Name of drug	Batch no.	Name of manufacturer	DTL Test Report No. & Date	DTL Test Report Results
1	Injection Sterile water for injection 10ml S.J & G [sterile water for injection 10ml] **Mfg. Date**: 01-2018 **Exp date**: 01-2021 **Registration No**. 002128	8024P	M/s S.J. & G Fazul Ellahie Pvt. Ltd., E-46, SITE Karachi-Pakistan.	01-01010789/DTL dated: 11-04-2018	**Result of Test/Analysis with Specifications Applied:** BP 2015 **COMPOSITION**: Sterile water for injection…10ml **DESCRIPTION:** colorless liquid in transparent glass sealed ampoule. 2 out of 20 ampoules containing undissolvable visible particulate matter (**Does not comply with parenteral specifications**) **Volume:** Stated: 10mL Determined: 10mL **pH**:

					Limit: 5.0-7.0 Determined: 6.88 **Sterility:** the product is sterile **RESULT**: The sample is **Substandard** on the basis of physical test.
2	Injection water for injection SJG [5ml] **Mfg**. **Date**: 05-2017 **Exp date**: 05-2020 **Registration No**. 002128	7436P	M/s S.J. & G Fazul Ellahie Pvt. Ltd., E-46, S.I.T.E Karachi Pakistan.	01-01010785/DTL dated: 11-04-2018	**Result of Test/Analysis with Specifications Applied:** BP 2015 **COMPOSITION**: Sterile water for injection…5ml **DESCRIPTION:** colorless liquid in transparent glass sealed ampoule. 2 out of 40 ampoules containing undissolvable visible particulate matter (**Does not comply with parenteral specifications**) **Volume:** Stated: 5ml Determined: 5.06mL **pH**: Limit: 5.0-7.0 Determined: 7.0 **Sterility:** product is sterile **RESULT**: The sample is **Substandard** on the basis of physical test.

iii. Central Pharmacy Civil Hospital Bahawalpur provided invoice/warranty No. 116 dated 01-02-2018 issued by M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, SITE Karachi-Pakistan.

iv. Warrantor Portions of subject batches were sent to M/s S.J & G Fazul Ellahie Pvt Ltd., Karachi.

v. Copies of Test/Analysis report was sent to M/s S.J & G Fazul Ellahi Pvt Ltd. Karachi-Pakistan and they were directed to provide requisite information in this regard. Firm requested for retesting of the sample from NIH. The Committee decided to turn down the subject retesting request in 3rd meeting dated 13-10-2018.

Firm filed writ petition 13432/2019 against the order of the Board to turn-down the request of the firm for retest/ analysis of the drug sample.

Honorable Lahore High Court, Lahore vide its order dated 31-01-2024 has dismissed the above mentioned writ petition. The operative part of order is as below:

"The relief claimed in this petition has become infructuous which seeks setting aside of the

impugned order dated 24.10.2018 and further relief has been sought for the sample of the petitioner to be sent for retesting by the laboratory at Islamabad. Suffice to say that the sample cannot be retested at this belated stage and there is no cause for this Court to dilate and determined this matter as the issue has become moot. This petition is dismissed."

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

b. **Issuance of false warranty**

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

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

PREVIOUS PROCEEDINGS BY THE COMMITTEE:

PQCB 44th Committee Meeting dated 19-09-2024:

5. Case 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 **44th Committee Meeting** held on **19-09-2024** under the Convenorship of Director General, Drugs Control. Mr. Jahangir Khan Secretary DQCB District Bahawalpur attended the meeting online via zoom link and Mr. Irfan Aslam Drug Inspector Civil Hospital, Bahawalpur was present along-with original case record. No-one among nominated accused was present, however, Counsel of the firm Shiekh Irfan Saeed (Advocate) appeared before the Board on behalf of M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan. And pleaded his case on following grounds:

i. These cases pertain to Government supplies and the firm has already given replacement that was declared of standard quality.
ii. In these cases, the right of the firm to re-test was infringed by the Board by not sending the samples to NIH for retest, whereas, the samples of same drug on similar parameters which were sent to NIH were declared standard from NIH. He presented the standard quality reports of those samples before the Board.
iii. He submitted his grievance regarding the report of drug testing laboratory, Faisalabad that:

- the Govt., Analyst did not mention the full protocols of the tests applied, therefore, the reports were not to be relied upon being not admissible in evidence Reliance was placed on PLD 2003 Lahore 115.
- That it was mentioned in the report of analyst that he found the visible particles with the naked eye whereas according USP 42 in Physical Test Chapter under <790> inspected units must be free of visible particulates when without magnification except for optical correction as may be establish normal vision against a black background and examined required against a background. The reference book further states that illumination inspection point is maintained at a minimum intensity at to white between 2000 and 3750 lux. This can be achieved through the use of two 13- W or 15-W fluorescent lamps (e.g.F13/T5 or F15/T8). The use of a high frequency ballast to reduce flicker from the fluorescent lamps is recommended. In the report of the case the Analyst was failed to mention any kind of above referred procedure or method for analyzing the particulates therefore, the analyst's report was not reliable, hence inadmissible.
- That the analyst failed to mention size of particles, if any, and according to the GUIDELINES OF AMERICAN SOCIETY OF PARENTAL AND ENTERAL NUTRITION, particles of 5 to 20 um and large are capable of obstructing blood flow through the pulmonary capillaries. Now if the analyst did not mention the size of the particulate then how it could be claimed as injurious to health.
- That according to USP 42 if the particulate matter is found the analyst was bound to repeat the test and analysis, whereas it was an admitted fact that analyst failed to repeat the test and analysis therefore, the report was not an admissible in evidence, hence not sustainable in the eyes of law.

iv. He further submitted that no unit of the supply was used in the hospital, therefore, it caused no harm to any patient. He requested for lenient view from the Board.

6. The Committee of the Board after careful perusal of the case record observed that two batches of the Sterile water for injection 10ml and Injection water for injection SJG [5ml] were declared substandard from drug testing Laboratory Faisalabad on the basis of presence of particulate matter. The committee showed serious concerns on the matter of the considerate opinion that in order to dig out the root cause of the defect, the production, quality control and assurance procedures of the firm needs to be evaluated. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case** and **constitute a committee** comprising of following members to conduct **Section Specific Inspection (SSI)** of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan** and submit report before the Board:

Prof. Dr Mehmood Ahmed (Member)	**Convener**
Mr. Waseem Mehmood (Director Operations PQCB)	**Member**

7. The committee is further directed to submit report within ninety days otherwise secretary PQCB would be authorized to change the members of committee.

INSPECTION REPORT OF M/S S. J & G FAZUL ELLAHIE (PVT) LTD, E-46 S.I.T.E. KARACHI.

8. Committee submitted the inspection report to the office of PQCB

Panel Members:

Prof. Dr. Mahmood, Ahmad, Member, PQCB.

Waseem Mahmood, Director Operations, PQCB.

Date of Inspection: 19-12-2024

Inspection was conducted with reference to order dated 19-09-2024 & 17-12-2024 in case No. PQCB/R-637, 638, 639, 640/2018, PQCB/R-634, 635, 636/2018 & PQCB/R-689-11/2016.

Premises:

S.J. & G. Fazul Elahi (Pvt.) Ltd. started local manufacturing in 1967. The manufacturer bears a Drug Manufacturing License No. 000083. The manufacturing plant is certified by ISO 9001:2015, 14001:2015, 45001:2018 and 17025:2015. There are different sections i.e., Tablet, Capsule, Dry Powder Injectable, Dry Powder Suspension, Liquid Injectable (Ampoule, vials and Infusions), Ointments, Cream, Gel, Oral Liquid (Syrup /suspension), Lyophilized (Sterile area) Powder Injection, Liquid Injectable (Veterinary), Oral Powder (Veterinary). A total number of 330 different products are registered with DRAP and currently 298 products are being manufactured in the mentioned premises.

Product details:

Name of drug	Injection Sterile water for injection 10 ml
Batch number	8024P, 7436P, 8043P, 8044P, 8045P & 8046P.
Registration number	002128

Date of manufacturing 05-2017, 01-2018, 02-2018

Date of expiry 05-2020, 01-2021, 02-2021

Declared **Substandard** from **DTL Faisalabad & DTL Bahawalpur** on the basis of Physical test.

Product details:

Name of drug Injection VIFY 40 mg

Batch number 632LP

Registration number 050696

Date of manufacturing Apr 2016

Date of expiry Apr 2018

Declared **Substandard** from **DTL Lahore** on the basis of Sterility test.

Staff

Designation	**Name**
Iftikhar Hasan	Group Director Plant & Technical Operation
Muhammad Raza	Head of Production
Sahar Owais	Head of Quality Assurance
Saeema Shahid	Head of Quality Control
Syed Abbas Haider	Manager Quality Control (In charge)

Batch Processing Record of specific product:

1. BMR Record: Available.
2. Testing method: MS for Injection VIFY & B.P. for Injection Sterile water for injection.
3. Batch manufacturing date: April 2016 for Injection VIFY.
4. Batch manufacturing date: 05-2017, 01-2018 & 02-2018.
5. Line clearance certificate: Available.
6. Batch size: 1000 liters for injection Sterile water for injection.
7. Batch size: 72830 Injections for VIFY.

Observations:

1. The batch size of Sterile Water for injection is 1000 liters. The product is manufactured as per B.P. specifications.
2. The batch size of Injection VIFY (omeprazole sodium) is 72830 Injections. The product is

manufactured as per Manufacturer's Specifications.

3. Process flow of Injectable Section was presented along with flow chart and process flow was checked and inspected by the team.
4. There were proper air showers, cross over bench, separate entrance and separate change rooms for male and female staff.
5. The firm has established Quality Control Department and Quality Assurance Departments.
6. According to viewpoint of the manufacturer, both the products were of standard quality.
7. Quality Control Manager provided the certificate of calibration for different apparatus used in the quality control department.
8. The batch manufacturing record of Injection VIFY 40 mg Batch No. 632LP and Sterile water for injection Batch No. 8024P, 7436P, 8043P, 8044P, 8045P & 8046P reflecting that batches were released after clearance of all the quality control tests.
9. The trainings of the HR especially the personals related to quality control department is conducted as endorsed by the personnel's currently working there.
10. The sample for PDTRC was taken during inspection from the available batch of Sterile water for injection, Batch No. P241067.
11. The firm has established a new area for optical inspection and strengthened the human resource for optical section.
12. The firm has also established a microbiology section with dedicated human resource. It was also informed that VIFY 40 mg was not declared substandard after this batch on the parameter of sterility.

Recommendations:

1. SOPs must be made more stringent for in-process quality control and finished product quality control to identify any out of specification product before its issuance from the manufacturing unit to the market.
2. The firm is further directed to add an optical inspection desk at Quality Control Department, to ensure the quality of the products.
3. The screens pertaining to optical inspection of the injectable must be replaced after a reasonable time to enhance the flux.
4. The recruitment procedure of the human resource related to optical inspection of the injectable must be made more stringent. The human resource performing the duties in the optical inspection area must be given ample rest to eliminate the chances of error.
5. The supervision of the optical inspection team must be strengthened for production of quality medicines.
6. Trainings of the technical staff at more frequent intervals is recommended for the Quality Control Department including the microbiology section, particularly for the workers employed in the optical inspection area.
7. The filters used at different steps during the manufacturing of the injectable must be replaced at the lower limit of the recommended frequency of filter replacement.

Conclusion:

The panel is of the opinion that products namely injection VIFY 40 mg Batch No. 632LP declared substandard from DTL Lahore and Sterile water for injection Batch No. 8024P, 7436P, 8043P, 8044P, 8045P & 8046P declared substandard from DTL Faisalabad & DTL Bahawalpur, are due to a weak quality control, weak optical inspection and may be due to delayed replacement of the filters. Hence, the firm could not identify the error during in-process as well as during finished product testing. The further upgradation of quality control procedures under current guidelines is strongly recommended and also suggested frequent trainings of the personnel pertaining to optical inspection of injectable and related to microbiology section. The samples for PDTRC were taken during inspection from the available batch of Sterile water for injection Batch No. P241067.

CAPA SUBMITTED BY M/S S.J. & G. FAZUL ELAHI (PVT.) LTD.

M/S S.J. & G. FAZUL ELAHI (PVT.) LTD. submitted CAPA in lieu of the recommendations of the committee vide letter number SJG/REG/1737/2025 dated 10-03-2025 as follows:

Sr.	Recommendations	Proposed CAPA
01	SOPs must be made more stringent for in-process quality control and finished product quality control to identify any out of specification product before its issuance from the manufacturing unit to the market.	Procedure for in process checks & Line clearance defined in SOP for "Procedure for line clearance and in-process checks "Doc NO QA-SOP-PLCIPC-119"Version no 02. Furthermore, SOP for Optical inspection (Visual checking inspection) (GM-SOP-PWCI-005) has been revised in which following point related to recommendation has been incorporated i.e., Stringent in-process checks for production and QA-IPC incorporated. Sampling Criteria of optical checking for whole batch representative has been developed as per ISO 2859-1 standard.
02	The firm is further directed to add an optical inspection desk at Quality Control Department, to ensure the quality of the products.	The quality control department has liquid particle count for checking sub visible partical before release of each batch as per SOP "Handling, operation of LS-20 Liquid particle counter and particular matter in injection, Doc. No. QC-SOP-HOLPCI-243"
03	The screens pertaining to optical inspection of the injectable must be replaced after a reasonable time to enhance the flux.	The preventive maintenance Plan (ENG-PL-PM-019) has been revised and maintenance of optical booth has been incorporated in Plan. Preventive maintenance of optical booth will be conducted every 06 months and it is also mentioned in plan.
04	The recruitment procedure of the human resource related to optical inspection of the injectable must be made more stringent. The human resource performing the duties in the optical inspection area must be given ample rest to eliminate the chances of error.	Qualifications of optical checkers (Eye Test) is carried out at the time of recruitment and frequency of eye testing is every 6 months, which is also mentioned in SOP for "Visual checking inspection Doc No.GM-SOP-PVVCI-005, version No. 02" point no. 4.4. The rest time is also provided to the optical staff which is also mentioned in point no 4.13 of above-mentioned SOP and log of this activity also maintained through logbook. Record of Rest Time for Optical Checkers, Doc No.GM-LB-RRTOP-257" Challenge test is also performed on daily basis for the verification of optical staff as per mentioned SOP, as per i.e., SOP #GM-SOP-PVVCI-005.
05	The supervision of the optical inspection team must be strengthened for production	The optical inspection process has been more strengthened by the addition of challenge test (point #4.2) which covered in SOP for "Qualification of

	of quality medicines.	optical checker at optical checking of ampoule and vials" Doc. No. PR-SOP-PAR-075" and by the addition of acceptance quality limit test (AQL) which also recorded through "Acceptance quality limit test (AQL) Sheet for optical inspection, Doc. No. GM-SOP-PVVCI-005-A".
06	Trainings of the technical staff at more frequent intervals is recommended for the Quality Control Department including the microbiology section, particularly for the workers employed in the optical inspection area.	The training calendar of QC and Production department Parenteral section has been revised and optical training frequency increased from annually basis. to quarterly basis and same has been incorporated in training calendars.
07	The filters used at different steps during the manufacturing of the injectable must be replaced at the lower limit of the recommended frequency of filter replacement.	The filter replacement frequency from 05 batches to 03 batches has been revised and record has been developed via bubble point verification & log has been maintained.

Sr.	**Summary of the case**	
1.	**Date of sampling**	10-02-2018
2.	**Sent to DTL**	10-02-2018
3.	**Date of receipt in DTL**	15-02-2018
4.	**Issuance of DTL Report**	11-04-2018
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	24-04-2018
7.	**Retesting Request**	04-05-2018
8.	**Fate of retesting request**	Turn-Down in 3rd committee meeting dated 13-10-2018
9.	**Investigation Report of DI**	02-07-2024
10.	**Permission of SCN**	282nd meeting dated 24-07-2024
11.	**SC Notice Issued**	26-08-2024

12.	**Reply of the firm**	Not received
13	**History (3 years)**	03 cases of the firm No case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-634/2018

Govt Haji Abdul Qayyum Hospital, Sahiwal

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S S.J. & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E., Karachi-Pakistan** through its Director Iftikhar Hassan 2. Iftikhar Hassan — Director 3. Muhammad Usman — Production Incharge 4. Ghulam Abbas — Quality Control Incharge 5. Saeed Ahmed Danishmandi — Warrantor of M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, SITE Karachi-Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Government Haji Abdul Qayyum Hospital, Sahiwal reported that: -

i. The then drug Inspector, on 06-03-2018 inspected the Medicine Store of the Government Haji Abdul Qayyum Hospital, Sahiwal, took following drug sample on Form No. 4 for the purpose of test/analysis.
ii. The subject drug sample, after test/ analysis was declared as **Substandard** by Government Analyst, Drug Testing Labora-+tory, **Bahawalpur** as detailed below:

Name of drug	Batch no.	Name of manufacturer	Test Report No. & Date	DTL Test Report Results
Injection Sterile water for injection S.J & G [10ml]	8024P	M/s S.J. & G Fazul Ellahie Pvt Ltd., E-46, SITE Karachi-Pakistan.	01-25000082/DTL dated: 11-04-2018	**Result of Test/Analysis with Specifications Applied:** BP 2015 **DESCRIPTION:** colorless liquid in transparent glass sealed ampoule. 2 out of 45 ampoules containing undissolvable visible particulate matter (**Does not comply with parenteral specifications**)

Mfg. **Date**: 01-2018 **Exp date**: 01-2021 **Registration No**. 002128				**<u>Volume:</u>** Stated**:** 10ml Determined: 10ml **<u>pH</u>**: Limit: 5.0-7.0 Determined: 6.973 **Sterility:** product is sterile **<u>RESULT</u>**: The sample is **<u>Substandard</u>** on the basis of physical test.

iii. Medicine Store of the Government Haji Abdul Qayyum Teaching Hospital, Sahiwal provided invoice/Warranty No. 129 dated 16-02-2018 issued by M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, SITE Karachi-Pakistan.

iv. Warrantor Portion and a copy of test/analysis report was sent to M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, SITE Karachi-Pakistan.

v. A copy of Test/ Analysis report was sent to M/s S.J & G Fazul Ellahi Pvt Ltd., E-46, SITE Karachi-Pakistan and they were directed to provide requisite information in this regard. Firm requested for retesting of the sample from NIH. The Committee decided to turn down the subject retesting request in 3rd meeting dated 13-10-2018.

Firm filed writ petition 13431/2019 against the order of the Board to turn-down the request of the firm for retest/ analysis of the drug sample.

Honorable Lahore High Court, Lahore vide its order dated 31-01-2024 has dismissed the above-mentioned writ petition. The operative part of order is as below:

> ……*"The relief claimed in this petition has become infructuous which seeks setting aside of the impugned order dated 24.10.2018 and further relief has been sought for the sample of the petitioner to be sent for retesting by the laboratory at Islamabad. Suffice to say that the sample cannot be retested at this belated stage and there is no cause for this Court to dilate and determined this matter as the issue has become moot.* ***This petition is dismissed."***

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

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

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

Reply of the show cause notice

We refer to your letter No. P¿C/R-634/2018 dated 08.11.2024 received on 25.1 1.2024, regarding the subject matter (Copy of letter and Pakistan Post tracking attached for reference). Following submissions are made in this regard;

1. That the facts of the case are that on 06.03.2018, Inspector of Drugs, Haji Abdul Qayyum Teaching Hospital took the samples of Water for injection 10mL Batch No. 8024P manufactured by M/s S.J. & G. Fazul Ellahie (Pyt.) Ltd, Karachi on Form No.4, from the premises of Medicine store of said institution for test and analysis.
2. That the Drug Inspector sent the samples to the Drug Testing Laboratory Bahawalpur and Government Analyst Drug Testing Laboratory Bahawalpur vide test report No. TRA 01-25000082 dated 11 April 2018 declared it Sub-Standard on the basis of 2 out of 45 ampoules containing undissolved visible particulate matter.
3. That the Government Analyst did not mention the full protocols of the tests applied like procedure or method for analyzing the particulates, size of the particulate, storage conditions which may cause turbid solution, therefore, the reports were not to be relied upon.
4. That the firm on the basis of above stated discrepancies in the Test Report, requested retesting of the sample from NIH which was turned down by the Committee in its 3rd meeting held on 13.10.2018.
5. That the same Batch No.8024P of the subject product was also supplied to Allied Hospital Faisalabad which was declared of Standard quality (Copy of test report attached) which creates doubts.
6. That in case No. PQCB/R-635/2018 (Copy of respective Order dated 19-09-2024 attached for reference) Committee of Provincial Quality Control Board, Punjab pended the case of the same Batch No.8024P of the subject product supplied to Civil Hospital Bahawalpur and has constituted a two membered committee to conduct Section Specific Inspection of the firm.

Under circumstances explained above it, it is therefore respectfully requested that this case may kindly be dropped in true spirit of justice for the reasons mentioned above. Firm confirmed the names of accuse persons

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

PROCEEDINGS AND DECISION OF THE COMMITTEE:

5. Case was considered by the Committee of Provincial Quality Control Board, as empowered by Board in its **46th Committee Meeting** held on **17-12-2024** under the Convenorship of Director General, Drugs Control. Mr. Umair Jilani Secretary DQCB District Sahiwal attended the meeting online via zoom link and Mst Aqsa Irshad Drug Inspector Govt Haji Abdul Qayyum Hospital Sahiwal was present along-with original case record. No-one among nominated accused was present, however, Mr. Tehseen Irshad Ahmed (Head of Regulatory Affairs) appeared the Committee on behalf of M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan and pleaded the case that the same Batch No. 8024P of the subject product was also supplied to Allied Hospital Faisalabad, which was declared of Standard quality. He further requested that same Batch No.8024P of the subject product supplied to Civil Hospital Bahawalpur in which a two membered committee was directed to conduct Section Specific Inspection of the firm.

6. The Committee after careful perusal of the case record observed that subject batch no. 8024P of the Sterile water for injection 10ml was declared substandard from drug testing Laboratory Bahawalpur on the basis of physical test i.e., 2 out of 45 ampoules containing undissolvable visible particulate matter. The committee was of unanimous opinion that in order to dig out the root cause of the defect, the production, quality control and assurance procedures of the firm needs to be evaluated. Keeping in view the facts of the case, the Committee after due deliberation and discussion

unanimously decided to **Pend the case** and **constitute a committee** comprising of following members to conduct **Section Specific Inspection (SSI)** of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.**

1	**Prof. Dr Mehmood Ahmed (**Member, PQCB**)**	**Convener**
2	**Mr. Waseem Mehmood (**Director Operations, PQCB)	**Member**

7. Furthermore, the Committee directed the members of SSI to submit its report in this regard at earliest. The Committee further directed committee members of SSI to take a sample of said drug product & **send the sample** of drug to the Pakistan Drug Testing and Research Centre (**PDT&RC**) for testing on firm's expenditure. The PDT&RC will submit the test/ analysis report to the office of the Secretary PQCB which will be then placed before the Board for decision of the case.

Note: Inspection report of M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan and CAPA submitted by the firm is placed in case R-635/2018& R-636/2018

8. The sample of Sterile water for injection Batch Number P241067 was submitted to Pakistan Drug Testing and Research Centre (PDT&RC), Lahore, from where the sample was declared **Standard** as detailed below:

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>Test Report No. & Date</th><th>PDTRC Reort Results</th></tr>
<tr><td>Sterile Water for injection</td><td>P241067</td><td>M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan</td><td>PDTRC/TR-Pharma/093/2025 dated 19.03.2025</td><td><u>Method/ Specs Applied:</u> USP

<u>Detail of Test/ Analysis and Result:</u>

<u>Clarity Test:</u>
<table><tr><td>Determined</td><td>Clear and free from particulate matter</td></tr><tr><td>Limit</td><td>Must be clear and free from particulate matter</td></tr></table>
<u>Result:</u> The Sample is of Standard Quality on the basis of Test Performed.</td></tr>
</table>

Summary	
Sampling Date (Form 4):	06-03-2018

Sent to DTL (Form 6):	06-03-2018
Date of receipt in DTL	09-03-2018
DTL Report Date (Form 7):	11-04-2018
1st DI Communication with firm dated	24-04-2018
Date of Retesting Request of Firm:	04-05-2018
Fate of Retesting Request:	3rd Committee meeting dated 13-10-2018
Investigation Report Dated	21-10-2024
Show cause notice dated	08-11-2024
Reply of show cause notice	28-11-2024
Firm History	**Firm: 3, Product: 0 (3 years)**

Personal hearing Notice issued to the accused

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 9

PQCB/R-637/2018

Allied Hospital, Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan** through its Director Iftikhar Hassan 2. Iftikhar Hassan Director 3. M. Usman Production In-charge 4. Ghulam Abbass Quality Control In-charge 5. Saeed Ahmad Danishmandi Warrantor Of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.**

BREIF FACTS OF THE CASE:

Provincial Inspector of drugs Allied Hospital, Faisalabad reported that:-

i. Her Predecessor, on 27-03-2018, inspected the premises of Central Pharmacy, Allied Hospital, Faisalabad and took samples of following drugs on Form No.04 for the purpose of test/analysis and sent the subject drug samples to Drug Testing Laboratory, Faisalabad vide memo number 8125 dated 27-03-2018.

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

iii. Store keeper of Central Pharmacy, Allied Hospital, Faisalabad provided invoice/ warranty no. 149 dated 06-03-2018 issued by M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug samples were sent M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.

v. A copy of test reports of the drug samples were sent to M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan with directions to provide the requisite information and to explain their position 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 191st (A) committee meeting held on 18-08-2018 **turn-down** the retesting request of the firm. Retesting review of the firm was turn-down by the committee of the Board in it's 3rd meeting dated 13-10-2018.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection Sterile water for injection 10 ml [Sterile water for injection 10 ml BP]	8043P	M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan	TRA 01-44001472/DTL dated 23-05-2018	**Specs Applied: BP 2018** **DESCRIPTION** Colorless liquid having undissolved visible particulate matter, contained in transparent glass ampoule.

Mfg Date: 02-2018 Exp. Date:02-2021 Reg. No. 002128				**<u>Tests:</u>** **<u>Acidity/ Alkalinity:</u>** Determined: No acidity or alkalinity observed (Comply) **<u>Oxidizable Substances:</u>** Determined: The solution remains faintly pink. (Comply) **<u>Sulphates:</u>** Determined: No change in appearance for 1 hour (Comply) **<u>Chlorides:</u>** Determined: Chlorides NMT 0.5ppm (Comply) **<u>Extractable volume:</u>** Stated: Not less than nominal volume (10 ml) Determined: 10.3 ml (Comply) **<u>Particulate matter:</u>** Stated: According to BP and/ or USP, "inspected unit must be free of visible particulates when examined without magnification against a black background and against a white background". Determined: **Particles are observed upon visual inspection. (Does not comply)** Sterility Test: Stated: Complies with the test for sterility. Determined: Sterile (Comply) **<u>RESULT:</u>** <u>The above sample is **"Sub-Standard"** on the basis of tests performed.</u>

Firm filed writ petition 13432/2019 against the order of the Board to turn-down the request of the firm for retest/ analysis of the drug sample.

Honorable Lahore High Court, Lahore vide its order dated 31-01-2024 has dismissed the above mentioned writ petition. The operative part of order is as below:

> ***"The relief claimed in this petition has become infructuous which seeks setting aside of the impugned order dated 24.10.2018 and further relief has been sought for the sample of the petitioner to be sent for retesting by the laboratory at Islamabad. Suffice to say that the sample cannot be retested at this belated stage and there is no cause for this Court to dilate and determined this matter as the issue has become moot. This petition is dismissed."***

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

b. **Issuance of false warranty**

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

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

PREVIOUS PROCEEDINGS BY THE COMMITTEE:

44th Committee Meeting held on 19-09-2024:

5. Case 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 **44th Committee Meeting** held on **19-09-2024** under the Convenorship of Director General, Drugs Control. Mr. Rubina Akhtar Secretary DQCB District Faisalabad attended the meeting online via zoom link and Ms. Iqra Fayyaz Drug Inspector Allied Hospital, Faisalabad was present along-with original case record. No-one among nominated accused was present, however, Counsel of the firm Shiekh Irfan Saeed (Advocate) appeared before the Board on behalf of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.** And pleaded his case on following grounds:

i. These cases pertain to Government supplies and the firm has already given replacement that was declared of standard quality.
ii. In these cases, the right of the firm to re-test was infringed by the Board by not sending the samples to NIH for retest, whereas, the samples of same drug on similar parameters which were sent to NIH were declared standard from NIH. He presented the standard quality reports of those samples before the Board.
iii. He submitted his grievance regarding the report of drug testing laboratory, Faisalabad that:

- the Govt., Analyst did not mention the full protocols of the tests applied, therefore, the reports were not to be relied upon being not admissible in evidence Reliance was placed on PLD 2003 Lahore 115.
- That it was mentioned in the report of analyst that he found the visible particles with the naked eye whereas according USP 42 in Physical Test Chapter under <790> inspected units must be free of visible particulates when without magnification except for optical correction as may be establish normal vision against a black background and examined required against a background. The reference book further states that illumination inspection point is maintained at a minimum intensity at to white between 2000 and 3750 lux. This can be achieved through the use of two 13- W or 15-W fluorescent lamps (e.g.F13/T5 or F15/T8). The use of a high frequency ballast to reduce flicker from the fluorescent lamps is recommended. In the report of the case the Analyst was failed to mention any kind of above referred procedure or method for analyzing the particulates therefore, the analyst's report was not reliable, hence inadmissible.
- That the analyst failed to mention size of particles, if any, and according to the GUIDELINES OF AMERICAN SOCIETY OF PARENTAL AND ENTERAL NUTRITION, particles of 5 to 20 um and large are capable of obstructing blood flow through the pulmonary capillaries. Now if the analyst did not mention the size of the particulate, then how it could be claimed as injurious to health.
- That according to USP 42 if the particulate matter is found the analyst was bound to repeat the test and analysis, whereas it was an admitted fact that analyst failed to repeat the test and analysis therefore, the report was not an admissible in evidence, hence not sustainable in the eyes of law.

iv. He further submitted that no unit of the supply was used in the hospital, therefore, it caused no harm to any

patient. He requested for lenient view from the Board.

6. The Committee of the Board after careful perusal of the case record observed that four different batches of the same product were declared substandard from drug testing Laboratory Faisalabad on the basis of presence of particulate matter. Among them, in one of the product, fibers were also observed along-with particulate matter. The committee showed serious concerns on the matter of the considerate opinion that in order to dig out the root cause of the defect, the production, quality control and assurance procedures of the firm needs to be evaluated. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case** and **constitute a committee** comprising of following members to conduct **Section Specific Inspection** (**SSI**) of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan** and submit report before the Board:

Prof. Dr Mehmood Ahmed (Member)	**Convener**
Mr. Waseem Mehmood (Director Operations PQCB)	**Member**

7. The committee is further directed to submit report within ninety days otherwise secretary PQCB would be authorized to change the members of committee.

Note: Inspection report of M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan and CAPA submitted by the firm is placed in case R-635/2018& R-636/2018

Sr.	**Summary of the case**	
1.	**Date of sampling**	27-03-2018
2.	**Sent to DTL**	27-03-2018
3.	**Date of receipt in DTL**	28-03-2018
4.	**Issuance of DTL Report**	23-05-2018
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	01-06-2018
7.	**Retesting Request**	07-06-2018
8.	**Fate of retesting request**	Turn-Down 191st (A) Committee meeting dated 18-08-2018, review upheld in 3rd committee meeting dated 13-10-2018
9.	**Investigation Report of DI**	29-06-2024
10.	**Permission of SCN**	282nd meeting dated 24-07-2024
11.	**SC/ PH Notice Issued**	11-09-2024

12.	**Reply of the firm**	Not received
13	**History (3 years)**	03 cases of the firm No case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 10

PQCB/R-638/2018

Allied Hospital, Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan** through its Director Iftikhar Hassan 2. Iftikhar Hassan Director 3. M. Usman Production In-charge 4. Ghulam Abbass Quality Control In-charge 5. Saeed Ahmad Danishmandi Warrantor Of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.**

BREIF FACTS OF THE CASE:

Provincial Inspector of drugs Allied Hospital, Faisalabad reported that:-

i. Her Predecessor, on 27-03-2018, inspected the premises of Central Pharmacy, Allied Hospital, Faisalabad and took samples of following drugs on Form No.04 for the purpose of test/analysis and sent the subject drug samples to Drug Testing Laboratory, Faisalabad vide memo number 8129 dated 27-03-2018.

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

iii. Store keeper of Central Pharmacy, Allied Hospital, Faisalabad provided invoice/ warranty no. 149 dated 06-03-2018 issued by M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug samples were sent M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.

v. A copy of test reports of the drug samples were sent to M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan with directions to provide the requisite information and to explain their position 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 191st (A) committee meeting held on 18-08-2018 **turn-down** the retesting request of the firm. Retesting review of the firm was turn-down by the committee of the Board in it's 3rd meeting dated 13-10-2018.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection Sterile water for injection 10 ml [Sterile water for injection 10 ml BP]	8045P	M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan	TRA 01-44001474/DTL dated 23-05-2018	**Specs Applied: BP 2018** **DESCRIPTION** Colorless liquid having undissolved **visible undissolved particles and small threads** contained in transparent glass

Mfg Date: 02-2018 Exp. Date:02-2021 Reg. No. 002128				ampoule. **Tests:** **Acidity/ Alkalinity:** Determined: No acidity or alkalinity observed (Comply) **Oxidizable Substances:** Determined: The solution remains faintly pink. (Comply) **Sulphates:** Determined: No change in appearance for 1 hour (Comply) **Chlorides:** Determined: Chlorides NMT 0.5ppm (Comply) **Extractable volume:** Stated: Not less than nominal volume (10 ml) Determined: 10.2 ml (Comply) **Particulate matter:** Stated: According to BP and/ or USP, "inspected unit must be free of visible particulates when examined without magnification against a black background and against a white background". Determined: **Particles and threads are observed upon visual inspection. (Does not comply)** **Sterility Test:** Stated: Complies with the test for sterility. Determined: Sterile (Comply) **RESULT:** The above sample is **"Sub-Standard"** on the basis of tests performed.

Firm filed writ petition 13432/2019 against the order of the Board to turn-down the request of the firm for retest/ analysis of the drug sample.

Honorable Lahore High Court, Lahore vide its order dated 31-01-2024 has dismissed the above mentioned writ petition. The operative part of order is as below:

> ***"The relief claimed in this petition has become infructuous which seeks setting aside of the impugned order dated 24.10.2018 and further relief has been sought for the sample of the petitioner to be sent for retesting by the laboratory at Islamabad. Suffice to say that the sample cannot be retested at this belated stage and there is no cause for this Court to dilate and determined this matter as the issue has become moot. This petition is dismissed."***

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

b. **Issuance of false warranty**

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

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

PREVIOUS PROCEEDINGS BY THE COMMITTEE:

44th Committee Meeting held on 19-09-2024:

5. Case 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 **44th Committee Meeting** held on **19-09-2024** under the Convenorship of Director General, Drugs Control. Mr. Rubina Akhtar Secretary DQCB District Faisalabad attended the meeting online via zoom link and Ms. Iqra Fayyaz Drug Inspector Allied Hospital, Faisalabad was present along-with original case record. No-one among nominated accused was present, however, Counsel of the firm Shiekh Irfan Saeed (Advocate) appeared before the Board on behalf of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.** And pleaded his case on following grounds:

i. These cases pertain to Government supplies and the firm has already given replacement that was declared of standard quality.
ii. In these cases, the right of the firm to re-test was infringed by the Board by not sending the samples to NIH for retest, whereas, the samples of same drug on similar parameters which were sent to NIH were declared standard from NIH. He presented the standard quality reports of those samples before the Board.
iii. He submitted his grievance regarding the report of drug testing laboratory, Faisalabad that:

- the Govt., Analyst did not mention the full protocols of the tests applied, therefore, the reports were not to be relied upon being not admissible in evidence Reliance was placed on PLD 2003 Lahore 115.
- That it was mentioned in the report of analyst that he found the visible particles with the naked eye whereas according USP 42 in Physical Test Chapter under <790> inspected units must be free of visible particulates when without magnification except for optical correction as may be establish normal vision against a black background and examined required against a background. The reference book further states that illumination inspection point is maintained at a minimum intensity at to white between 2000 and 3750 lux. This can be achieved through the use of two 13- W or 15-W fluorescent lamps (e.g.F13/T5 or F15/T8). The use of a high frequency ballast to reduce flicker from the fluorescent lamps is recommended. In the report of the case the Analyst was failed to mention any kind of above referred procedure or method for analyzing the particulates therefore, the analyst's report was not reliable, hence inadmissible.
- That the analyst failed to mention size of particles, if any, and according to the GUIDELINES OF AMERICAN SOCIETY OF PARENTAL AND ENTERAL NUTRITION, particles of 5 to 20 um and large are capable of obstructing blood flow through the pulmonary capillaries. Now if the analyst did not mention the size of the particulate, then how it could be claimed as injurious to health.
- That according to USP 42 if the particulate matter is found the analyst was bound to repeat the test and analysis, whereas it was an admitted fact that analyst failed to repeat the test and analysis therefore, the report was not an admissible in evidence, hence not sustainable in the eyes of law.

iv. He further submitted that no unit of the supply was used in the hospital, therefore, it caused no harm to any

patient. He requested for lenient view from the Board.

6. The Committee of the Board after careful perusal of the case record observed that four different batches of the same product were declared substandard from drug testing Laboratory Faisalabad on the basis of presence of particulate matter. Among them, in one of the product, fibers were also observed along-with particulate matter. The committee showed serious concerns on the matter of the considerate opinion that in order to dig out the root cause of the defect, the production, quality control and assurance procedures of the firm needs to be evaluated. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case** and **constitute a committee** comprising of following members to conduct **Section Specific Inspection** (**SSI**) of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan** and submit report before the Board:

Prof. Dr Mehmood Ahmed (Member)	**Convener**
Mr. Waseem Mehmood (Director Operations PQCB)	**Member**

7. The committee is further directed to submit report within ninety days otherwise secretary PQCB would be authorized to change the members of committee.

Note: Inspection report of M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan and CAPA submitted by the firm is placed in case R-635/2018& R-636/2018

Sr.	**Summary of the case**	
1.	**Date of sampling**	27-03-2018
2.	**Sent to DTL**	27-03-2018
3.	**Date of receipt in DTL**	28-03-2018
4.	**Issuance of DTL Report**	23-05-2018
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	01-06-2018
7.	**Retesting Request**	07-06-2018
8.	**Fate of retesting request**	Turn-Down 191st (A) Committee meeting dated 18-08-2018, review upheld in 3rd committee meeting dated 13-10-2018
9.	**Investigation Report of DI**	29-06-2024
10.	**Permission of SCN**	282nd meeting dated 24-07-2024
11.	**SC/ PH Notice Issued**	11-09-2024

12.	**Reply of the firm**	Not received
13	**History (3 years)**	03 cases of the firm No case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 11

PQCB/R-639/2018

Allied Hospital, Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan** through its Director Iftikhar Hassan 2. Iftikhar Hassan Director 3. M. Usman Production In-charge 4. Ghulam Abbass Quality Control In-charge 5. Saeed Ahmad Danishmandi Warrantor Of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.**

BREIF FACTS OF THE CASE:

Provincial Inspector of drugs Allied Hospital, Faisalabad reported that:-

i. Her Predecessor, on 27-03-2018, inspected the premises of Central Pharmacy, Allied Hospital, Faisalabad and took samples of following drugs on Form No.04 for the purpose of test/analysis and sent the subject drug samples to Drug Testing Laboratory, Faisalabad vide memo number 8130 dated 27-03-2018.

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

iii. Store keeper of Central Pharmacy, Allied Hospital, Faisalabad provided invoice/ warranty no. 149 dated 06-03-2018 issued by M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug samples were sent M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.

v. A copy of test reports of the drug samples were sent to M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan with directions to provide the requisite information and to explain their position 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 191st (A) committee meeting held on 18-08-2018 **turn-down** the retesting request of the firm. Retesting review of the firm was turn-down by the committee of the Board in it's 3rd meeting dated 13-10-2018.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection Sterile water for injection 10 ml [Sterile water for injection 10 ml BP]	8046P	M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan	TRA 01-44001475/DTL dated 23-05-2018	**Specs Applied: BP 2018** **DESCRIPTION** Colorless liquid having undissolved visible particulate matter, contained in transparent glass ampoule

Mfg Date: 02-2018 Exp. Date:02-2021 Reg. No. 002128				**<u>Tests:</u>** **<u>Acidity/ Alkalinity:</u>** Determined: No acidity or alkalinity observed (Comply) **<u>Oxidizable Substances:</u>** Determined: The solution remains faintly pink. (Comply) **<u>Sulphates:</u>** Determined: No change in appearance for 1 hour (Comply) **<u>Chlorides:</u>** Determined: Chlorides NMT 0.5ppm (Comply) **<u>Extractable volume:</u>** Stated: Not less than nominal volume (10 ml) Determined: 10..3 ml (Comply) **<u>Particulate matter:</u>** Stated: According to BP and/ or USP, "inspected unit must be free of visible particulates when examined without magnification against a black background and against a white background". Determined: **Particles are observed upon visual inspection. (Does not comply)** **<u>Sterility Test:</u>** Stated: Complies with the test for sterility. Determined: Sterile (Comply) **<u>RESULT:</u>** <u>The above sample is **"Sub-Standard"** on the basis of tests performed.</u>

Firm filed writ petition 13432/2019 against the order of the Board to turn-down the request of the firm for retest/ analysis of the drug sample.

Honorable Lahore High Court, Lahore vide its order dated 31-01-2024 has dismissed the above mentioned writ petition. The operative part of order is as below:

> ***"The relief claimed in this petition has become infructuous which seeks setting aside of the impugned order dated 24.10.2018 and further relief has been sought for the sample of the petitioner to be sent for retesting by the laboratory at Islamabad. Suffice to say that the sample cannot be retested at this belated stage and there is no cause for this Court to dilate and determined this matter as the issue has become moot. This petition is dismissed."***

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

b. **Issuance of false warranty**

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

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

PREVIOUS PROCEEDINGS BY THE COMMITTEE:

44th Committee Meeting held on 19-09-2024:

5. Case 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 **44th Committee Meeting** held on **19-09-2024** under the Convenorship of Director General, Drugs Control. Mr. Rubina Akhtar Secretary DQCB District Faisalabad attended the meeting online via zoom link and Ms. Iqra Fayyaz Drug Inspector Allied Hospital, Faisalabad was present along-with original case record. No-one among nominated accused was present, however, Counsel of the firm Shiekh Irfan Saeed (Advocate) appeared before the Board on behalf of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.** And pleaded his case on following grounds:

i. These cases pertain to Government supplies and the firm has already given replacement that was declared of standard quality.
ii. In these cases, the right of the firm to re-test was infringed by the Board by not sending the samples to NIH for retest, whereas, the samples of same drug on similar parameters which were sent to NIH were declared standard from NIH. He presented the standard quality reports of those samples before the Board.
iii. He submitted his grievance regarding the report of drug testing laboratory, Faisalabad that:

- the Govt., Analyst did not mention the full protocols of the tests applied, therefore, the reports were not to be relied upon being not admissible in evidence Reliance was placed on PLD 2003 Lahore 115.
- That it was mentioned in the report of analyst that he found the visible particles with the naked eye whereas according USP 42 in Physical Test Chapter under <790> inspected units must be free of visible particulates when without magnification except for optical correction as may be establish normal vision against a black background and examined required against a background. The reference book further states that illumination inspection point is maintained at a minimum intensity at to white between 2000 and 3750 lux. This can be achieved through the use of two 13- W or 15-W fluorescent lamps (e.g.F13/T5 or F15/T8). The use of a high frequency ballast to reduce flicker from the fluorescent lamps is recommended. In the report of the case the Analyst was failed to mention any kind of above referred procedure or method for analyzing the particulates therefore, the analyst's report was not reliable, hence inadmissible.
- That the analyst failed to mention size of particles, if any, and according to the GUIDELINES OF AMERICAN SOCIETY OF PARENTAL AND ENTERAL NUTRITION, particles of 5 to 20 um and large are capable of obstructing blood flow through the pulmonary capillaries. Now if the analyst did not mention the size of the particulate, then how it could be claimed as injurious to health.
- That according to USP 42 if the particulate matter is found the analyst was bound to repeat the test and analysis, whereas it was an admitted fact that analyst failed to repeat the test and analysis therefore, the report was not an admissible in evidence, hence not sustainable in the eyes of law.

iv. He further submitted that no unit of the supply was used in the hospital, therefore, it caused no harm to any

patient. He requested for lenient view from the Board.

6. The Committee of the Board after careful perusal of the case record observed that four different batches of the same product were declared substandard from drug testing Laboratory Faisalabad on the basis of presence of particulate matter. Among them, in one of the product, fibers were also observed along-with particulate matter. The committee showed serious concerns on the matter of the considerate opinion that in order to dig out the root cause of the defect, the production, quality control and assurance procedures of the firm needs to be evaluated. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case** and **constitute a committee** comprising of following members to conduct **Section Specific Inspection** (**SSI**) of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan** and submit report before the Board:

Prof. Dr Mehmood Ahmed (Member)	**Convener**
Mr. Waseem Mehmood (Director Operations PQCB)	**Member**

7. The committee is further directed to submit report within ninety days otherwise secretary PQCB would be authorized to change the members of committee.

Note: Inspection report of M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan and CAPA submitted by the firm is placed in case R-635/2018& R-636/2018

Sr.	**Summary of the case**	
1.	**Date of sampling**	27-03-2018
2.	**Sent to DTL**	27-03-2018
3.	**Date of receipt in DTL**	28-03-2018
4.	**Issuance of DTL Report**	23-05-2018
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	01-06-2018
7.	**Retesting Request**	07-06-2018
8.	**Fate of retesting request**	Turn-Down 191st (A) Committee meeting dated 18-08-2018, review upheld in 3rd committee meeting dated 13-10-2018
9.	**Investigation Report of DI**	29-06-2024
10.	**Permission of SCN**	282nd meeting dated 24-07-2024
11.	**SC/ PH Notice Issued**	11-09-2024

12.	**Reply of the firm**	Not received
13	**History (3 years)**	03 cases of the firm No case of the product

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 12

PQCB/R-640/2018

Allied Hospital, Faisalabad

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan** through its Director Iftikhar Hassan 2. Iftikhar Hassan Director 3. M. Usman Production In-charge 4. Ghulam Abbass Quality Control In-charge 5. Saeed Ahmad Danishmandi Warrantor Of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.**

BREIF FACTS OF THE CASE:

Provincial Inspector of drugs Allied Hospital, Faisalabad reported that:-

i. Her Predecessor, on 27-03-2018, inspected the premises of Central Pharmacy, Allied Hospital, Faisalabad and took samples of following drugs on Form No.04 for the purpose of test/analysis and sent the subject drug samples to Drug Testing Laboratory, Faisalabad vide memo number 8128 dated 27-03-2018.

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

iii. Store keeper of Central Pharmacy, Allied Hospital, Faisalabad provided invoice/ warranty no. 149 dated 06-03-2018 issued by M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug samples were sent M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.

v. A copy of test reports of the drug samples were sent to M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan with directions to provide the requisite information and to explain their position 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 191st (A) committee meeting held on 18-08-2018 **turn-down** the retesting request of the firm. Retesting review of the firm was turn-down by the committee of the Board in it's 3rd meeting dated 13-10-2018.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection Sterile water for injection 10 ml [Sterile water for injection 10 ml BP]	8044P	M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan	TRA 01-44001473/DTL dated 23-05-2018	**Specs Applied: BP 2018** **DESCRIPTION** Colorless liquid having undissolved visible particulate matter, contained in transparent glass ampoule

Mfg Date: 02-2018 Exp. Date:02-2021 Reg. No. 002128				**<u>Tests:</u>** **<u>Acidity/ Alkalinity:</u>** Determined: No acidity or alkalinity observed (Comply) **<u>Oxidizable Substances:</u>** Determined: The solution remains faintly pink. (Comply) **<u>Sulphates:</u>** Determined: No change in appearance for 1 hour (Comply) **<u>Chlorides:</u>** Determined: Chlorides NMT 0.5ppm (Comply) **<u>Extractable volume:</u>** Stated: Not less than nominal volume (10 ml) Determined: 10.2 ml (Comply) **<u>Particulate matter:</u>** Stated: According to BP and/ or USP, "inspected unit must be free of visible particulates when examined without magnification against a black background and against a white background". Determined: **Particles are observed upon visual inspection. (Does not comply)** **<u>Sterility Test:</u>** Stated: Complies with the test for sterility. Determined: Sterile (Comply) **<u>RESULT:</u>** <u>The above sample is **"Sub-Standard"** on the basis of tests performed.</u>

Firm filed writ petition 13432/2019 against the order of the Board to turn-down the request of the firm for retest/ analysis of the drug sample.

Honorable Lahore High Court, Lahore vide its order dated 31-01-2024 has dismissed the above mentioned writ petition. The operative part of order is as below:

> ***"The relief claimed in this petition has become infructuous which seeks setting aside of the impugned order dated 24.10.2018 and further relief has been sought for the sample of the petitioner to be sent for retesting by the laboratory at Islamabad. Suffice to say that the sample cannot be retested at this belated stage and there is no cause for this Court to dilate and determined this matter as the issue has become moot. This petition is dismissed."***

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

b. **Issuance of false warranty**

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

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

PREVIOUS PROCEEDINGS BY THE COMMITTEE:

44th Committee Meeting held on 19-09-2024:

5. Case 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 **44th Committee Meeting** held on **19-09-2024** under the Convenorship of Director General, Drugs Control. Mr. Rubina Akhtar Secretary DQCB District Faisalabad attended the meeting online via zoom link and Ms. Iqra Fayyaz Drug Inspector Allied Hospital, Faisalabad was present along-with original case record. No-one among nominated accused was present, however, Counsel of the firm Shiekh Irfan Saeed (Advocate) appeared before the Board on behalf of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan.** And pleaded his case on following grounds:

i. These cases pertain to Government supplies and the firm has already given replacement that was declared of standard quality.
ii. In these cases, the right of the firm to re-test was infringed by the Board by not sending the samples to NIH for retest, whereas, the samples of same drug on similar parameters which were sent to NIH were declared standard from NIH. He presented the standard quality reports of those samples before the Board.
iii. He submitted his grievance regarding the report of drug testing laboratory, Faisalabad that:

- the Govt., Analyst did not mention the full protocols of the tests applied, therefore, the reports were not to be relied upon being not admissible in evidence Reliance was placed on PLD 2003 Lahore 115.
- That it was mentioned in the report of analyst that he found the visible particles with the naked eye whereas according USP 42 in Physical Test Chapter under <790> inspected units must be free of visible particulates when without magnification except for optical correction as may be establish normal vision against a black background and examined required against a background. The reference book further states that illumination inspection point is maintained at a minimum intensity at to white between 2000 and 3750 lux. This can be achieved through the use of two 13- W or 15-W fluorescent lamps (e.g.F13/T5 or F15/T8). The use of a high frequency ballast to reduce flicker from the fluorescent lamps is recommended. In the report of the case the Analyst was failed to mention any kind of above referred procedure or method for analyzing the particulates therefore, the analyst's report was not reliable, hence inadmissible.
- That the analyst failed to mention size of particles, if any, and according to the GUIDELINES OF AMERICAN SOCIETY OF PARENTAL AND ENTERAL NUTRITION, particles of 5 to 20 um and large are capable of obstructing blood flow through the pulmonary capillaries. Now if the analyst did not mention the size of the particulate, then how it could be claimed as injurious to health.
- That according to USP 42 if the particulate matter is found the analyst was bound to repeat the test and analysis, whereas it was an admitted fact that analyst failed to repeat the test and analysis therefore, the report was not an admissible in evidence, hence not sustainable in the eyes of law.

iv. He further submitted that no unit of the supply was used in the hospital, therefore, it caused no harm to any patient. He requested for lenient view from the Board.

6. The Committee of the Board after careful perusal of the case record observed that four different batches

of the same product were declared substandard from drug testing Laboratory Faisalabad on the basis of presence of particulate matter. Among them, in one of the product, fibers were also observed along-with particulate matter. The committee showed serious concerns on the matter of the considerate opinion that in order to dig out the root cause of the defect, the production, quality control and assurance procedures of the firm needs to be evaluated. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case** and **constitute a committee** comprising of following members to conduct **Section Specific Inspection** (**SSI**) of **M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan** and submit report before the Board:

Prof. Dr Mehmood Ahmed (Member)	**Convener**
Mr. Waseem Mehmood (Director Operations PQCB)	**Member**

7. The committee is further directed to submit report within ninety days otherwise secretary PQCB would be authorized to change the members of committee.

Note: Inspection report of M/s S.J & G Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E Karachi Pakistan and CAPA submitted by the firm is placed in case R-635/2018& R-636/2018

Sr.	**Summary of the case**	
1.	**Date of sampling**	27-03-2018
2.	**Sent to DTL**	27-03-2018
3.	**Date of receipt in DTL**	28-03-2018
4.	**Issuance of DTL Report**	23-05-2018
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	01-06-2018
7.	**Retesting Request**	07-06-2018
8.	**Fate of retesting request**	Turn-Down 191st (A) Committee meeting dated 18-08-2018, review upheld in 3rd committee meeting dated 13-10-2018
9.	**Investigation Report of DI**	29-06-2024
10.	**Permission of SCN**	282nd meeting dated 24-07-2024
11.	**SC/ PH Notice Issued**	11-09-2024
12.	**Reply of the firm**	Not received

13	**History (3 years)**	03 cases of the firm No case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 13

PQCB/R-649/2018

Bahawal Victoria Hospital, Bahawalpur

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S S.J & G Fazul Ellahie Pvt. Ltd. E-46, S.I.T.E.,** Karachi through its Chief Executive Officer Iftikhar Hassan 2. Iftikhar Hassan Chief Executive Officer 3. Muhammad Usman Production Incharge 4. Ghulam Abbas Quality Control Manager 5. Saeed Ahmad Danishmandi Warrantor 6. Of **M/S S.J & G Fazul Ellahie Pvt. Ltd. E-46, S.I.T.E., Karachi.**

BREIF FACTS OF THE CASE:

Provincial Inspector of drugs B.V. Hospital, Bahawalpur reported that:-

i. His Predecessor, on 06-03-2018, inspected the premises of Central Pharmacy, Bahawal Victoria Hospital, Bahawalpur and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug samples to Drug Testing Laboratory, Bahawalpur vide memo number 236/DI/BVH/ Bahawalpur dated 06-03-2018.

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

Drug Sample	**Batch**	**Manufacturer**	**TRA No. and Date**
Sterile water for injection Mfg. Date: 01-2018 Exp. Date: 01-2021 Reg. No. 002128	8026P	M/S S.J & G Fazul Ellahie Pvt. Ltd. E-46, S.I.T.E., Karachi.	01-54000159/DTL 11-04-2018

Specification applied: BP 2015

COMPOSITION: Sterile Water for Injection…..10mL

DESCRIPTION: Colorless liquid in transparent glass sealed ampoule. 3 out of 45 ampoules containing un-dissolvable visible particulate matter. **(Does not comply with the parenteral specifications)**

Volume:

Stated: 10 mL

Determined: 10 mL

pH:

Limit: 5.0-7.0

Determined: 6.765

STERILITY:

The product is sterile.

RESULT: **Then sample is Sub-Standard on the basis of Physical Test.**

iii. Medical Superintendent, Bahawal Victoria Hospital, Bahawalpur provided invoice/ warranty no. 123 dated 08-02-2018 issued by M/S S.J & G Fazul Ellahie Pvt. Ltd. E-46, S.I.T.E., Karachi. as a proof of its purchase of the said drug.

iv. Warrantor portion was sent to M/S S.J & G Fazul Ellahie Pvt. Ltd. E-46, S.I.T.E., Karachi.

v. A Copy of test report of the drug sample was sent to M/S S.J. & G Fazul Ellahie Pvt. Ltd. E-46, S.I.T.E., Karachi with directions to provide the requisite information and to explain their position in this regard. In response, the firm requested for re-test/ analysis of the drug sample. The committee of the Board turn-down the retesting request of the firm in its 3rd meeting dated 13-10-2018.

Firm filed writ petition 13432/2019 against the order of the Board to turn-down the request of the firm for retest/ analysis of the drug sample.

Honorable Lahore High Court, Lahore vide its order dated 31-01-2024 has dismissed the above mentioned writ petition. The operative part of order is as below:

> ***"The relief claimed in this petition has become infructuous which seeks setting aside of the impugned order dated 24.10.2018 and further relief has been sought for the sample of the petitioner to be sent for retesting by the laboratory at Islamabad. Suffice to say that the sample cannot be retested at this belated stage and there is no cause for this Court to dilate and determined this matter as the issue has become moot. This petition is dismissed."***

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

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

Sr.	**Summary of the case**	
1.	**Date of sampling**	06-03-2018
2.	**Sent to DTL**	06-03-2018
3.	**Date of receipt in DTL**	08-03-2018

4.	**Issuance of DTL Report**	11-04-2018
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	24-04-2018
7.	**Retesting Request**	04-05-2018
8.	**Fate of retesting request**	Turn-Down in 3rd committee meeting dated 13-10-2018
9.	**Investigation Report of DI**	30-06-2024 & 28-11-2024
10.	**Permission of SCN**	286th meeting dated 30-10-2024
11.	**SC/ PH Notice Issued**	20-05-2025
12.	**Reply of the firm**	Not received
13	**History (3 years)**	03 cases of the firm No case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 14

PQCB/ MSS-174458/2023

Govt. M. Nawaz Sharif Teaching Hospital Yakki Gate, Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan** through its Chief Executive Officer, Chaudhary Pervaiz 2. Chaudhary Pervaiz — Chief Executive Officer 3. Anees Ur Rehman — Production Manager/ Warrantor 4. Rashid Ullah Khan — Quality Control Incharge **Of M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Govt M. Nawaz Sharif Teaching Hospital, Yakki Gate Lahore reported that:

i. He on 30-08-2023, inspected the Main Medicine Store of Govt Muhammad Nawaz Sharif Teaching Hospital, Yakki Gate Lahore, took following drug sample on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Lahore vide memo no. 174458 dated 31-08-2023.
ii. The subject drug sample, after test/analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report**	**DTL Test Report Result**
Injection. AQUA-P [Sterile Water for Injection 5ml] **Mfg. Date**: July-2023 **Exp. Date**: July-2028	P-656	M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan	01-10194003235/DTL dated 21-10-2023	**Result of test/ analysis with specifications applied:** USP 2023 **PHYSICAL DESCRIPTION**: Colorless liquid in sealed transparent glass ampoule with label printed on it. Claimed volume= 5mL **EXTRACTABLE VOLUME:** Determined: 5 mL Stated: NLT nominal volume i.e., 5.4mL **WATER CONDUCTIVITY:** Limit= NMT 25 µS/cm at 25 ± 1°C

Regn. **No**: 034290				Determined= 5.993µS/cm at 24.0°C **<u>OXIDIZABLE SUBSTANCES:</u>** Complies **<u>STERILITY TEST:</u>** The product is **non-Sterile.** **(DOES NOT COMPLY)** **<u>BACTERIAL ENDOTOXINS TEST:</u>** The sample does not comply the Endotoxin limit of less than 0.25 USP Endotoxin Units/mL. **(DOES NOT COMPLY)** **RESULT:** The above sample is **<u>Sub-Standard,</u>** on the basis of Bacterial Endotoxin test and Sterility tests performed as per USP.

iii. Store keeper, Govt M. Nawaz Sharif Teaching Hospital, Lahore, provided invoice/ warranty no. T-6295, both dated 24-08-2023 issued by M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan as a proof of its purchase.

iv. Warrantor Portion of drug sample was sent to M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to the request of M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan the Board in its 34th Committee Meeting held on 22-02-2024 unanimously decided to turn down the subject request for retesting of the sample. Firm's review petition against above mentioned decision of retesting request, has also been turned down in 283rd meeting held on 08-08-2024.

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

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

3. Show-cause notice(s) issued to accused person(s) dated 23-04-2025

4. Personal hearing notice(s) issued to accused person(s) dated 22-05-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	30-08-2023

2	**Sample Sent to DTL (Form-6)**	31-08-2023
3	**Receipt Date in DTL**	31-08-2023
4	**Issuance of DTL Report**	21-10-2023
5	**Time Extension**	-
6	**DI First Communication with Firm**	31-10-2023
7	**Retesting Request**	18-12-2023
9	**Investigation Report by DI**	17-02-2025
10	**SCN Permission**	288-M (25-02-2025)
11	**Show Cause Notice Issued**	23-04-2025
12	**Reply of Firm to Show Cause Notice**	-
13	**History (3 years)**	Firm's Reported: 34
		Product's Reported: 29 (Subject Case) 12 decided

Case No. 15

PQCB/MSS-176023/2023
Tehsil Renala Kurd

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case**. 1. **M/s Bio-Mark Pharmaceuticals, 527-Sundar Industrial Estate, Lahore** through its Managing Director. Nasrullah Khan 2. Dr. Nasrullah Khan Managing Director 3. Mrs. Rehana Koser Quality Control Incharge/Warrantor 4. Mr. Gulam Bari Director Technical operation/Incharge Production of M/s Bio-Mark Pharmaceuticals, 527-Sundar Industrial Estate, Lahore

BRIEF FACTS OF THE CASE

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

i. She, on 19-09-2023 inspected the premises of M/s Hafiz Medical Store situated at Mopalky, Tehsil Renala Kurd&, District Okara took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, **Bahawalpur** vide memorandum no**.**176023 dated 20-09-2023.
ii. Following drug sample after test/analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below: -

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report** **TRA No. & Date**
Sustained/Extended-Release Tablet Vovion SR [Diclofenac Sodium 100mg] Mfg :05-2023 Exp : 04-2025 Reg No: 094504	23E336	M/S Bio-Mark Pharmaceuticals, 527-Sundar Industrial Estate, Lahore	01-10097005097/DTL 16-11-2023

Specs Applied: USP 2023

COMPOSITION: Each sustained release tablet contains:

Diclofenac Sodium ……. 100mg

DESCRIPTION Pink colored, round biconvex shaped film coated tablet with line of bisect on one side and plain on other side. Packed in blister packaging of ten tablet.

WEIGHT VARIATION ***Limit*** L1 = 15.0

Determined 13.6

IDENTIFICATION Diclofenac Sodium is identified.

ASSAY OF DICLOFENAC SODIUM

Stated 100mg/Tab

Determined 105.67mg/Tab (105.67%)

Limit 90.0-110.0%

DISSOLUTION TEST: Does not comply with USP specifications as below: -

TIME	ACCEPTANCE CRITERIA						
	No individual values lie outside each of the stated ranges and no individual value is less than the stated amount at final test time. NMT 02 units are more than 10% of the labeled content outside each of the stated range and NMT 01 unit are more than 20% the labeled amount each of the stated range.						
	Limit	**1**	**2**	**3**	**4**	**5**	**6**
After 01st Hour	**15-35%**	15.70%	15.38%	15.32%	15.49%	15.35%	15.47%
After 05th Hour	**45-65%**	62.75%	59.17%	59.46%	60.17%	59.31%	63.47%
After 10th Hour	**65-85%**	**106.96%**	**106.96%**	**106.25%**	**107.81%**	**107.53%**	**108.80%**
After 16th Hour	**75-95%**	**109.81%**	**107.99%**	**107.43%**	**106.45%**	**108.13%**	**108.83%**
After 24th Hour	**NLT 80%**	111.18%	110.77%	113.67%	113.26%	109.94%	111.32%

Result: The Product does not comply with applied specs. as all of 06 units are more than 10% & 20% of the stated ranges after 10th Hour and all units are more than 10% of the stated ranges after 16th hour.

RESULT: The sample is declared **Sub-Standard** on the basis of **Dissolution Test**.

iii. M/s, Hafiz Medical Store Mopalky, Tehsil Renala Kurd&, District Okara provided invoice/warranty No. 2276 dated 30-07-2023 issued by M/s Kazmash Pharmaceuticals (Pvt) Ltd Okara.

iv. Warrantor Portion was sent to M/s Kazmash Pharmaceuticals (Pvt) Ltd Okara.who in turn provided invoice/warranty no.57457 dated 02-06-2023 issued by M/s. Prime Care as a proof of their purchase who in turn provided the invoice/warranty no: 1175 dated 25-05-2023

v. A copy of Test/ Analysis report was sent to M/s. Bio-Mark Pharmaceuticals, 527-Sundar Industrial Estate, Lahore, Firm requested for retesting of sample. In Response, the firm

challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.

vi. Pursuant to the request of manufacturer, the retesting request was **turn down** in **46th** Committee meeting dated 17-12-2024.

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

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

Show-cause notice(s) issued to the accused persons(s) dated 24-04-2025

Reply of show cause notice dated nil received in the office of PQCB DATED 10-06-2025

With reference of your show cause notice No. letter No. PQCB/MSS-176023/23 dated 24-04-2025, we received on 26/04/2025 we hereby requested:

1. That Bio-Mark Pharmaceuticals is a manufacturing company and it is manufacturing, number of medicines in Pakistan.

2. That M/S Bio-Mark Pharmaceuticals distribute VOVION SR 100mg Tablet in the market with warranty which is manufactured by company under the strict supervision of Production Manager & Quality Control Manger (Approved by DRAP). After the manufacturing of said medicine, required in-process & for Finished Goods tests are performed in laboratory for Quality Control and Quality Assurance. After the complete satisfaction of GMP compliance during manufacturing process and on finished good, the medicine was distributed in market for patent use

3. That on 19/09/2023 the sample was collected by Drugs inspector from Hafiz Medical Store, Mopikay Tehsil Renata Khurd, District Okara. Analysis report was issued on 16-11-2023 and copy of the report was delivered to distributor (Kazmash Pharmaceuticals Pvt. Ltd. Okara) and distributor Prime Care Lahore by the drug inspector to Bio-Mark on 10/06/2024.

4. That apart from all above facts, being a responsible company, M/S Bio-Mark recalled Vovion SR 100mg Tablet from all distributor on 11-06-2024 after receiving the report of drugs analysis. After a week the company again sent a reminder, of recall to all distributors. Bio-Mark initiated legal procedure for the appraisal of actual & factual status.

5.On the other hand, That Quality Control Department of M/S Bio-Mark has performed dissolution & disintegration test along with assay test many time on retaining sample of Vovion SR 100mg Tablet (Each sustained released tablet contain: Diclofenac Sodium 100mg USP Specification) of the same batch and found repeatedly the same results. The above sample of sustained /extended release tablet. Vovion SR (Diclofenac Sodium 100mg) Batch No. 23E336 is of standard quality with regards to test, Physical test, (Dissolution & Disintegration). The Testing report issued by Quality control Department of Bio-Mark is being attached for ready reference

6.

.It is worth mentioning that Assay (Label claimed Quantity/tablet) of Diclofenac Sodium declared by Government Analyst (Mr. Hamza Altar) wide the same test report TRA 01-10097005097/DTL Dated 16-Nov-2023 is as given below.

Stated……..100mg/Tab

Determined…..105.67mg/Tab (105.67%)

Limit…….90.0-110%

7. **However, it is evident from examining the DTL, report results that the USP Dissolution Test-1 procedure was used on the relevant tablet as given in monograph.**

For the same tablet, Bio-Mark uses USP Dissolution Test-2 as given in monograph. According to USP if the product complies USP Dissolution Test-2 the labeling indicate that it meet "USP Dissolution Test 2

8. Mistakenly label claim specification was not mentioned on unit carton of Vovion SR 100mg Tablet as prescribed that the product "USP Dissolution Test 2".

9. Bio-Mark immediately changed specification and mentioned labeling specification of said product, as "USP Dissolution Test 2" as prescribed in USP (New packaging material Unit carton and printed foil are submitted for reference).

10. Punjab Drug Rules 2007, Chapter 2, Provincial Rule 5, Sub-Rule 5, The Provincial or the District Board may in case of a minor contravention, direct the manufacture or the seller to bring Improvement, issue a warning to him order the de-sealing and take any other action including recall of batches."

11.DRAP Act 2012 and Rules (5) of the Punjab Drug Rules 2007 (as amended) by the Board in its 289th meeting dated 27-03-2025.

This privision empowers the Preveal Quality Conte (¿¿¿¿¿ to ignore the case, or he format warming, or conductant of the manufacturing and suathy control process of the product manufactured try M/S Bis-Mars by experts appointed by the PQCB

PRAYER

Under the circumstance and difference of testing result of report it is prayed that

1. The Hon'ble PQCB Board may constitute a committee to conduct inspections of on-site testing facilities, quality control procedures, standard operating protocols, and manufacturing sites to ascertain the facts.

Or

2. In exercising the powers conferred under the DRAP Act, 2012 and Rule 5 of the Punjab Drug Rules, 2007 (as amended by the Board in its 289th meeting held on 27-03-2025), the Board may refer the matter to the Licensing and Drug Registration Board (DRAP).

Or,

3. Please consider our request sympathetically and ignore the case. We would greatly obliged.

2. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025
3. Case is placed before the Board for decision.

Summary	
Sampling Date (Form 4):	19-09-2023

Sent to DTL (Form 6):	20-09-2023
Date of receipt in DTL	21-09-2023
DTL Report Date (Form 7):	16-11-2023
Time Extension granted	N/A
1st DI Communication with firm dated	24-04-2024
Date of Retesting Request of Firm:	05-09-2024
Fate of Retesting request	**Turn down in 46th Committee Meeting Dated 17-12-2024**
Investigation Report Dated	14-03-2025
Firm History 3 years	**Firm: 02** **Product:1**

PROCEEDING & DECISION BY THE BOARD:

Case No. 16

PQCB/ SM-15-07/2021

Drug Inspector Licensed Manufacturing Premises, District Sheikhupura

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Elite Pharma 9.5 km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura** through its Chief Executive Officer Tahir Mehmood S/o Muhammad Ayub 2. Tahir Mehmood S/o Muhammad Ayub Chief Executive Officer 3. Khalid Mehmood S/o Bashir Ahmad Quality Control Incharge 4. Muhammad Tahir S/o Abdul Aziz Production Incharge of **M/S Elite Pharma 9.5 km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura**.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs Tehsil Ferozewala, District Sheikhupura reported that:-

i. He, on 23-06-2021, alongwith other team members, inspected the premises of M/s Elite Pharma, 9.5 Km Sheikhupura Road, Ferozewala and recovered and seized following different types of drugs on Form 5:

Sr. No.	Name of drugs	Batch No.	Name of Manufacturer	Quantity	Reason of Seizure
1.	Injection Rocelite 500mg	C21344	Elite Pharma	80 vials/ pack+ Lignocain 1% (B. No. 112)	Violation of GMP
2.	Injection Lignocaine 1 %	112	Elite Pharma	30 x 100 ampoules	Packed on outer carton of Adrenaline, Maridine (Metoclopramide), Lignocaine and Ashtec (Nalbuphin), Misbranded drugs / unwarranted drugs/ Violation of GMP
Above mentioned drugs have been seized by drug inspector from packing/ production area. Item mentioned at Sr. No. 2 were placed in different cartons out of negligence of workers as these injections (Lignocain 1%) were to be placed in Inj. Rocelite (Dry Powder Inj.)					

ii. He locked and sealed the packaging/ Production area of Cephalosporin Section for the contravention of the Drugs Act 1976/ The DRAP Act 2012.

iii. He also took sample of two different types of drugs on Form 4 for the purpose of test/ analysis. These samples were declared of standard Quality from Drug Testing Laboratory, Lahore.

Drug Inspector sought permission to keep the custody of seized drugs/ API and extension in sealing period. Drug Inspector was granted to keep the seized stock in custody in 239th meeting held on 24-02-2021.

Whereas, the premises has already been de-sealed upon the directions of Honorable Drug Court Lahore dated 28-06-2021.

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. **Violation of GMP (Packing and Stocking of Inj. Lignocaine in outer cartons of Adrenaline, Maridine** (Metoclopramide), **Lignocaine and Ashtec** (Nalbuphin)

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

Firm submitted reply to the show cause notice vide letter dated 23-02-2023

Refer your letter no. PQCB/SM-15-07/2021 dated 06-02-2023 which was received by us on 22-02-2023.

We would like to bring your kind attention to the fact that during the inspection of the esteemed team members along with the Provincial Inspector of Drugs lignocaine 1% (Batch No. 112) was being blistered with Injection Rocelite 500mg (Batch No. C21344) for IM purposes. The Lignocaine 1% injection was not kept for sale purposes but was solely present to be used with our Rocelite Injection in blister pack.

These injection of Lignocaine 1% however were packed in the outer cartons of other products which was due to the negligence of our working staff.

Furthermore, all observations made by the team were rectified and all SOPs are being strictly followed on our part. All injections being used with our Dry Injections are being properly packed and labelled.

Therefore, in this regard you are requested not to take any legal actions on our part and not recommend DRAP for the cancellation/suspension of our license.

In addition, as required by your goodself the following documents and information have been attached with this letter.

Name of CEO Mr. Tahir Mahmood

Name of Production Incharge Muhammad Tahir

Name of Quality Control Incharge Mr. Khalid Mahmood

4. Show cause notice was revised on 31-12-2024 keeping in view the name of Quality Control Incharge as provided by the firm in its reply to show cause notice.

5. Personal hearing notice(s) issued to accused person(s) dated 20-03-2025

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. The above-mentioned case was placed in the agenda of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **289th** meeting held on 27-03-2025 under the chairmanship of Special

Secretary, (Operations) Health & Population Department, Punjab. The case was **Left Over** due to time constraint.

7. Personal hearing notice(s) issued to accused person(s) dated 29-04-2025

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **290th meeting** held on **07-05-2025** under the Chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB Punjab. Ms. Asma Faisal, Secretary DQCB, District Sheikhupura and Mr. Saqib Zaka, DI Industries/ GMP Auditor District Sheikhupura was present along with the original case record. No one among the nominated accused persons was present. However, Mr. Sulman Tahir (Advocate) appeared before the Board on behalf of M/s Elite Pharma, 9.5 Km Sheikhupura Road, Ferozewala and submitted written request for adjournment.

9. Keeping in view firm's request, the Board unanimously decided to **adjourn the case** with directions to provide another opportunity of hearing in the best interest of justice.

10. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025

11. Case is placed before the Board for decision.

Sr. No.	**Summary of the Case**	
1	**Form-5 (Seizure date)**	21-12-2021
2	**Investigation Report by DI**	08-03-2023
3	**SCN Permission**	258-M (05-04-2023)
4	**Show Cause Notice Issued**	06-02-2023, 31-12-2024 (Revised)
5	**Reply of Firm to Show Cause Notice**	23-02-2023
6	**History (3 years)**	Firm's Reported: Nil
		Product's Reported: Nil

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 17

PQCB/MSS-171200/2023
Tehsil Depalpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case**. 1. **M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II, PCSIR Laboratories Complex Shahrah-e-Dr Salim Uz Zaman Siddiqui off: University Road Karachi Pakistan** through its Chief Executive, Muhammad Imran 2. Muhammad Imran — Chief Executive 3. Gada Hussain Channa — Production Manager 4. Mohsin Ali Rind — Quality Control Manager/Warrantor of M/s Espoir Pharmaceuticals PCSIR KLC TBIC-II, PCSIR Laboratories Complex Shahrah-e-Dr Salim Uz Zaman Siddiqui off: University Road Karachi Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Depalpur, Okara reported that: -

i. He, on 06-07-2023, inspected the business premises of M/s Abbas Medical Store main road Ghallah Mandi near Darbar Sain Sahib Tehsil Depalpur, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 171200 dated 07-07-2023.
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**
Capsule Refuge 40mg [enteric coated pellets of omeprazole eq to omeprazole 40mg] **Mfg. Date** 04-2022	CD 08	M/s Espoir Pharmaceuticals PCSIR KLC TBIC-II, PCSIR Laboratories Complex Shahrah-e-Dr Salim Uz Zaman Siddiqui off: University Road Karachi Pakistan	01-10097004453/DTL dated 31-08-2023	**Analysis with specifications applied: MS** **DESCRIPTION:** The description mentioned in manufacturer method states, “Hard gelatin capsule with yellow colored cap and body size “2” containing white to off-white enteric coated pellets. ***Observed***: white to off white color enteric coated pellets, filled in purple color hard gelatin color capsule (Both cap and body are of same color). Packed in blister pack of 07capsules. **THEREFORE**, **THE PRODUCT** D**OES NOT COMPLY.** **DISSOLUTION TEST** ***Tolerance limit: (Acid stage***): Each unit is NMT 15.00% in 2 hrs. .

Expiry Date

04-2024

ACCEPTANCE CRITERIA					
Each unit is NMT 15.00% in 2 hours					
1	2	3	4	5	6
4.94%	3.02%	4.37%	3.86%	4.28%	3.89%

Tolerance limit: (buffer stage): Each unit is NLT 70.00% in 30 minutes

ACCEPTANCE CRITERIA					
Each unit is NLT 70.00% in 30minutes					
1	2	3	4	5	6
81.13%	80.25%	80.56%	79.92%	82.41%	82.52%

IDENTIFICATION: Omeprazole is identified.

ASSAY Omeprazole

Stated:	40 mg /cap
Determined	37.20mg/cap
Percentage	93.01%
Limit:	90%–110%

RESULT: The sample is declared as **SUB-STANDARD,** on the basis of physical test i.e., **PHYSICAL DESCRIPTION**.

iii. Proprietor M/s Abbas Medical Store main road Ghallah Mandi near Darbar Sain Sahib Tehsil Depalpur provided invoice/warranty No. 3055 dated 22-10-2022 issued by M/s Raza Distribution, 27-A Agha Bashir Town, Sahiwal as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent to M/s Raza Distribution, 27-A Agha Bashir Town, Sahiwal who in-turn provided invoice/warranty no. nil dated 09-09-2022 issued by M/s Espoir Pharmaceuticals PCSIR KLC TBIC-II, PCSIR Laboratories Complex Shahrah-e-Dr Salim Uz Zaman Siddiqui off: University Road Karachi Pakistan.

v. A copy of test/analysis report was sent to M/s Espoir Pharmaceuticals PCSIR KLC TBIC-II, PCSIR Laboratories Complex, Shahrah-e-Dr. Salim-uz-Zaman Siddiqui off, University Road, Karachi Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

ii. **Issuance of false warranty**

Show-cause notice(s) issued to the accused persons(s) dated 05-03-2025

Reply of show cause notice dated 14-03-2025

We write with reference to your Show Cause Notice vide letter No. PQCB/MSS-171200/2023 dated 05.03.2025, received by us on 07-03-2025, requiring us to submit our response on alleged declaration of the drug Capsule Refuge 40mg [Enteric Coated Pellets Of Omeprazole Eq to Omeprazole), Batch No. CD 08, as substandard vide the Test Report No. TRA 01-10097004453/DTL, dated 23-10-2023, by DTL Bahawalpur subsequent to samples drawn by Inspector of Drugs from the premises of M/s Abbas Medical Store, main road Ghallah Mandi near Darbar Sain Sahib Tehsil Depalpur. In this connection we would like to inform;

That the Govt. Analyst Drug Testing Lab, Bahawalpur via his test/analysis report TRA No. 01-10097004453/DTL, dated 23-10-2023 has given following opinion related to Capsule Refuge 40mg [Enteric Coated Pellets of Omeprazole Eq to Omeprazole, Batch No. CD 08.

a) That Capsule Refuge 40mg [Enteric Coated Pellets of Omeprazole Eq to Omeprazole], Batch No. CD 08 is of standard quality with respect to product specification as it contains therapeutic active ingredient 93.01% against the prescribed limit of 90-110%.

b) That the drug is Sub-Standard on the basis of "Physical Description" while, dissolution test & assay test comply with MS specification.

It is pertinent to mention here that inadvertently initial draft of Manufacturer's Specification of Capsule Refuge 40mg was sent to Govt. Analyst by our QC Incharge wherein "Hard Gelatin Capsule with yellow colored cap and body instead of purple colored cap and body".

It is further submitted that M/s ESPOIR Pharmaceuticals, PCSIR KLC TBIC-II, PCSIR Laboratory Complex, University Road Karachi-Pakistan has been **closed since July 2022 due to some sort of issues with PCSIR Laboratories, Karachi.**

All company Documents, Systems, Machines and Equipment under custody of PCSIR Laboratories, so we are unable to provide the detail information.

It is requested that case may please be dropped on merit and in accordance with law. Every citizen of Pakistan is entitled to be dealt in accordance with law and due process as per requirement of 1973 constitution of Islamic Republic of Pakistan.

Looking forward for your kind attention.

2. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025
3. Case is placed before the Board for decision.

Summary

Sampling Date (Form 4):	06-07-2023
Sent to DTL (Form 6):	07-07-2023
Date of receipt in DTL	10-07-2023
DTL Report Date (Form 7):	31-08-2023
Time Extension granted	N/A
1st DI Communication with firm dated	21-12-2023
Date of Retesting Request of Firm:	29-12-2023
Fate of Retesting request	Firm did not adduce evidence and sample expired
Investigation Report Dated	26-01-2025
Firm History 3 years	**Firm: 03** **Product:1**

PROCEEDING & DECISION BY THE BOARD:

Case No. 18

PQCB/MSS-174249/2023

Aziz Bhatti Town, Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Friends Pharma (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore** through its CEO, Naveed Zafar. 2. Naveed Zafar — CEO 3. Saba Shakoor — Production Manager 4. Rana Anwaar — Quality Control Manager/ Warrantor **of M/s Friends Pharma (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore.**

BREIF FACTS OF THE CASE:

Provincial Inspector of Drugs, Aziz Bhatti Town, Lahore reported that: -

i. The then Provincial Inspector of Drugs, on 25.08.2023, inspected the business premises of M/s Premier Sales Private Limited, Plot no. 100 Saeed Block Canal Bank Housing Society, Fatehgarh, Lahore and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 174249 dated 29.08.2023.
ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, Lahore, as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**TRA No. & Date**
Chewable Tablet C-Kast (Each Chewable Tablet Contains Montelukast Sodium BP Eq. to Montelukast: 5mg) **Mfg. Date Exp. Date**: **Reg. No**.: 10.2022 10.2024 042645	22PU02	M/S Friends Pharma (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore	01-10194003227/DTL Dated: 07.10.2023

DTL Test Report Result

Analysis with specifications applied: BP 2023

Physical Characteristics: White round tablet plain on one side engraved with line of bisection on other side packed in ALU-ALU blister of 1 x 7 tablets.

Identification: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Montelukast sodium identified).

Assay Of Montelukast: Complies

<u>Dissolution Test:</u> Does not comply with the BP Specifications as detailed below:-

Tolerance Limit: NLT 80% (Q) of the stated amount of Montelukast is dissolved in 20minutes.

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						AVERAGE (%)	REMARKS
S1	6	Each individual unit should NLT Q + 5% (85%)						-	**Does not Comply**
		UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6		
Determined (%)		**48**	**20**	**35**	**24**	**28**	**27**		

The sample fails to comply the release limit at S1 stage, as %release of all 06 units is found below Q-25% (i.e., 55%).

Result: The above sample is **<u>SUB-STANDARD</u>**, on the basis of DISSOLUTION TEST performed as per BP.

iii. M/s Premier Sales Private Limited, Plot No. 100, Saeed Block Canal Bank Housing Society, Fatehgarh, Lahore provided Invoices/ warranties No. 22377 dated 26.04.2023 issued by M/s Premier Sales Private Limited, Plot No. D-3, D-4, D-5, SEC, 6F, Mehran Town, Korangi Karachi as proof of its purchase.

iv. M/s Premier Sales Private Limited, 1-A/15, Sector-15, Korangi Industrial Area, Karachi provided Invoices/ warranties No. 1586/04/23 dated 14.04.2023 issued by M/s Chiesi Pharmaceuticals (Pvt.) Limited, Officer # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Bouleward, Gulberg-III Lahore as proof of its purchase.

v. Warrantor portion of drug sample was provided to M/s Chiesi Pharmaceuticals (Pvt.) Limited, Officer # 4, 4 th Floor, Askari Corporate Tower, 75/76 D-1, Main Bouleward, Gulberg-III Lahore.

vi. M/s Chiesi Pharmaceuticals (Pvt.) Limited, Officer # 4, 4th Floor, Askari Corporate Tower, 75/76 D-1, Main Bouleward, Gulberg-III Lahore provided Invoices/ warranties No. GD/12/22/FPL/G/57 dated 21.12.2022 issued by M/s Friends Pharma (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore as proof of its purchase.

vii.

viii. A copy of test/analysis report was sent to M/s Friends Pharma (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore and they were asked to provide the requisite information in this regard. In response the firm submitted requested for retesting.

ix. PQCB portion of the drug sample was sent to Appellate Laboratory. The drug was declared substandard from Appellate Laboratory, National Institute of Health, Islamabad as detailed below:

Name of drug	Batch No.	Name of manufacturer	test Report	NIH Test Report Results

C-Kast Chewable Tablets 5mg	22PU02	M/s Friends Pharma (Pvt.) Ltd., 31-Km Ferozepur Road, Lahore	046-P/2024 Dated: 28.06.2024	**Analysis with specifications applied:** B.P. 2022 **Dissolution Test:** All the six tablets deviated from the limit. **Limit:** The amount of montelukast released is Not less than 80% (Q) of the stated amount Does not comply with BP-2022.. **Remarks:** Percentage release of drug among all six units tested at first level is found less than 85% (Q+5) of the stated amount of Montelukase. Moreover, drug release in all six units found less than Q-25% at S1 level. Therefore, Dissolution test is stopped at first stage. **Conclusion**: The sample is of **Substandard** quality on the basis of test performed.

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

a. **Manufacture for sale of/ sale of Substandard Drug**
b. **Issuance of False Warranty**

3. Show-cause notice issued to accused person(s) dated 12.05.2025.

4. Personal Hearing notice issued to the accused person(s) dated 20-05-2025

Sr.	**Summary of the case**	
1.	**Date of sampling**	25.08.2023
2.	**Sent to DTL**	29.08.2023
3.	**Date of receipt in DTL**	30.08.2023
4.	**Issuance of DTL Report**	07.10.2023
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	14.01.2024 received by firm on 22.01.2024
7.	**Retesting Request**	27.01.2024

8.	**Fate of retesting request**	Substandard by NIH
9.	**Investigation Report of DI**	10.08.2024
10.	**Permission of SCN**	289th meeting dated 27.03.2025
11.	**SC Notice Issued**	12.05.2025
12.	**Reply of the firm**	
13	**History (3 years)**	13 cases of the firm including subject case 01 subject case of the product

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 19

Government Kot Khawaja Saeed Hospital, Lahore.

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Hafiz Pharma Industry, G.T Road (Ghania) Kamoke, District Gujranwala Pakistan** through its Managing Director, Dr. Ans Rehman 2. Dr. Ans Rehman — Managing Director 3. Dr. Fiaz Ahmad — Production Manager 4. Dr. Sultan — Quality Control Manager 5. Hafiz Abdul Rehman — Warrantor **Of M/s Hafiz Pharma Industry, G.T Road (Ghania) Kamoke, District Gujranwala Pakistan.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Government Kot Khawaja Saeed Hospital Lahore reported that: -

i. She, on 02-05-2023, inspected the premises of Main Medicines Store of Government Kot Khawaja Saeed Hospital Lahore, took following sample on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Lahore vide memorandum no. 165373 dated 02-05-2023.
ii. The following sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Bandages. Surgeon Cotton Crepe Bandage [Cotton Crepe Bandage 10cm*4.5m] **Mfg Date:** Jan 2023 **Expiry Date:** Jan 2026	1012316	M/s Hafiz Pharma Industry, G.T Road (Ghania) Kamoke, District Gujranwala Pakistan.	01-10194001684/DTL dated 31-05-2023	**Analysis with specifications applied:** BPC 1973 **DESCRIPTION:** Characteristic fabric of plain weave in one continuous length, containing no joins, clean, free from weaving defects leaf and shell. The warp thread consists of two-fold cotton threads. Claimed size=10cm*****4.5m (+/-5%) **WARPS:** Limits: NLT 17/cm Determined: **15/cm** **(DOES NOT COMPLY)** **WEFTS:** Limits: NLT 78/10cm

Regn No. 0000046				Determined: **77/10cm** **(DOES NOT COMPLY)** **<u>WEIGHT PER UNIT AREA:</u>** Limits: NLT 140g/m^2 Determined: **114g/m^2** **(DOES NOT COMPLY)** **<u>LENGTH:</u>** Determined: 4.5m Labelled: 4.5m (+/-5%) **<u>WIDTH:</u>** Determined: 10 cm Labelled: 10 cm (+/-5%) **<u>Result:</u>** The above sample is **<u>SUBSTANDARD</u>** on the basis of **Warps, Wefts** and **Weight per unit area** as per BPC 1973.

iii. The storekeeper of the Main Medicines Store of Government Kot Khawaja Saeed Hospital Lahore provided warranty bearing No. ARC-4/23 dated 29-04-2023 issued by M/s A. Rehman Corporation, 13-Fane Road, Near Old Bar Council, Lahore as a proof of its purchase.

iv. Warrantor portion of subject sample was sent to M/s A. Rehman Corporation, 13-Fane Road, Near Old Bar Council, Lahore who in-turn provided invoice/ warranty bearing No. HPI-1/23 dated 01-01-2023 issued by M/s Hafiz Pharma Industry, G.T Road (Ghania) Kamoke, District Gujranwala Pakistan as a proof of its purchase.

v. A copy of test/analysis report was sent to M/s Hafiz Pharma Industry, G.T Road (Ghania) Kamoke, District Gujranwala 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 subject 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 34th committee meeting held on 22-02-2024, after due deliberation and discussion unanimously decide to turn down the firm's request for retesting of the subject sample.

2. In this way You have contravened the provisions of DRAP Act 2012 and Medical Device Rules framed there under by the way of: -

a. **Manufacture for Sale/Sale of Substandard Therapeutic goods/Medical device**
b. **Issuance of false warranty**

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

4. Personal hearing notice(s) issued to accused person(s) dated 22-05-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	02-05-2023
2	**Sample Sent to DTL (Form-6)**	02-05-2023
3	**Receipt Date in DTL**	04-05-2023
4	**Issuance of DTL Report**	31-05-2023
5	**Time Extension**	-
6	**DI First Communication with Firm**	07-07-2023
7	**Retesting Request**	12-10-2023
9	**Investigation Report by DI**	28-09-2024
10	**SCN Permission**	286-M
11	**Show Cause Notice Issued**	12-11-2024
12	**Reply of Firm to Show Cause Notice**	-
13	**History (3 years)**	Firm's Reported: 5 cases
		Product's Reported: 4 (Subject Case) 2 warned in 278-M

Case No. 20

PQCB MSS-193701/2024

Government Mozang Teaching Hospital, Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Kohinoor Industries, 160/B, Small Industrial Estate, Sahiwal-Pakistan** through its Managing Director, Muhammad Nadeem Akram 2. Muhammad Nadeem Akram Managing Director/ Warrantor 3. Khuram Shehzad Production Incharge 4. Raheel Akhtar Quality Control/ Quality Assurance Incharge of **M/s Kohinoor Industries, 160/B, Small Industrial Estate, Sahiwal-Pakistan.**

BREIF FACTS OF THE CASE:

Provincial Inspector of Drugs, Government Mozang Teaching Hospital, District Lahore reported that: -

i. She, on 26-02-2024 inspected the Main Medicine Store of Government Mozang Teaching Hospital, District Lahore, took following sample on Form No. 4 for the purpose of test/analysis and sent the subject sample to Drug Testing Laboratory, Lahore vide memorandum no. 193701 dated 29-02-2024.
ii. The 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** **TRA No. & Date**	**DTL Test Report Result**
Bandages. PRIME BANDAGE (BPC) [OPEN WOVE BANDAGE 6.5cm x 6M] **Mfg Date:** Jan 2024 **Expiry Date:**	3656515	M/S Kohinoor Industries, 160/B, Small Industrial Estate, Sahiwal-Pakistan.	01-10200000720/ DTL dated 20-04-2024	**Analysis with specifications applied:** BPC **DESCRIPTION: BPC Standard:** B.P.C. monograph of Open Wove Bandage describes Standard description as "Cotton cloth of plain weave, bleached to a good white, in one continuous length containing no joins, clean, and reasonably free from weaving defects, leaf and shell; the edges are evenly cut, parallel with the warp threads, and are reasonably free from loose threads." **Observed:** Cotton cloth of plain weave, **not well bleached, not clean and contains black threads along the entire length,** free from leaf and shell. **Moreover, edges are not evenly cut. (DOES NOT COMPLY)**

Dec 2026 **Regn No.** MDME0000085				**WARPS:** Limits: Average 17.1/cm Determined: 18.1/ cm **WEFTS:** Limits: Average 10.7/cm Determined: 11.8/ cm **WEIGHT PER UNIT AREA:** Limits: Average 71 g/m² Determined: 73 g/m² **LENGTH:** Determined: 6 m Labelled: 6.2 m **WIDTH:** Determined: 6.5 cm Labelled: 6.5 cm **RESULT:** The above sample is **SUB-STANDARD**, on the basis of Description as per BPC.

iii. Storekeeper, Main Medicine Store of Government Mozang Teaching Hospital, District Lahore provided Invoice/Warranty No. 01-21-6602 dated 26-02-2024 issued by M/s Kohinoor Industries, 160/B, Small Industrial Estate, Sahiwal-Pakistan as a proof of its purchase.

iv. Warrantor portion of sample was sent to M/s Kohinoor Industries, 160/B, Small Industrial Estate, Sahiwal-Pakistan.

v. A copy of test/analysis report was sent to M/s Kohinoor Industries, 160/B, Small Industrial Estate, Sahiwal-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. **Manufacture for sale/sale of Substandard Therapeutic goods (Drug/Medical device)**
b. **Issuance of false warranty**

3. Show-cause notice issued to accused person(s) dated 25-10-2024

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/s Kohinoor Industries, 160/B, Small Industrial Estate, Sahiwal-Pakistan submitted written reply in response to show-cause notice vide ref no. KCi/961024 dated 31-10-2024 as detailed below:

With reference to letter no, PQCB/MSS-193701/2024, we are providing the following details which are mentioned below,

1. Name of the Technical Staff,

2. Muhammad Nadeem Akram S/O Muhammad Akram. (Managing Director) 3. Dr Khuram Shehzad S/O 3. Muhammad Saleem, (Production Incharge)

4**. Muhammad Ahsan Shaker, (Quality Control Manager)**

5. Attested copy of Drug Manufacturing License.

6. We are also providing.

i) Copy of Drug Manufacturing License.

ii) Copy of Drug Registration Certificate.

5. Personal Hearing notice issued to the accused person(s) dated 28-04-2025

PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **290th meeting held on 07.05.2025** under the chairmanship of Vice-Chairperson, Provincial Quality Control Board, Punjab. Hassan Saeed, Secretary DQCB, Lahore was present alongwith original case record. No one among nominated accused persons appeared before the Board on behalf of M/s Kohinoor Industries, 160/B, Small Industrial Estate, Sahiwal-Pakistan. However, the firm submitted request for adjournment due to unavailability of their technical staff.

7. The Board unanimously decided to accept the request of firm and **adjourn** the case for next meeting.

8. Personal Hearing notice issued to the accused person(s) dated 20.05.2025.

Sr.	**Summary of the case**	
1.	**Date of sampling**	26-02-2024
2.	**Sent to DTL**	29-02-2024
3.	**Date of receipt in DTL**	01-03-2024
4.	**Issuance of DTL Report**	20-04-2024
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	16-05-2024
7.	**Retesting Request**	Nil

8.	**Fate of retesting request**	N/A
9.	**Investigation Report of DI**	17-08-2024
10.	**Permission of SCN**	285th meeting dated 26-09-2024
11.	**SC Notice Issued**	25-10-2024
12.	**Reply of the firm**	31-10-2024
13	**History (3 years)**	21 cases of the firm 05 cases of the product

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 21

PQCB/ SM-12-08/2024

Sundar Industrial Estate & Manga Road, Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Livewell Capsules (Pvt.) Ltd., Plot No. 107, Sunder Industrial Estate, Raiwind Road, Lahore** through its Chief Executive Officer, Hamza Raees. 2. Hamza Raees S/o Raees Iftikhar — Chief Executive Officer 3. Dawood Raees S/o Raees Iftikhar — Director 4. Raees Iftikhar — Director 5. Irtaza Naveed S/o Muhammad Naveed — Production Incharge 6. Hamza Javed Iqbal S/o Javed Iqbal — Quality Control Incharge of **M/S Livewell Capsules (Pvt.) Ltd., Plot No. 107, Sunder Industrial Estate, Raiwind Road, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs (Industries), Sundar Industrial Estate & Manga Road, Lahore reported that:

i. He, on 05.08.2024, alongwith other team members, inspected the premises of M/s Livewell Capsules (Pvt) Ltd, Plot No. 107, Sundar Industrial Estate, Raiwind, Lahore and recovered and seized following different types of drugs/ articles/ documents on Form 5:

Sr.	Drugs/ Articles/ Documents Seized on form 5	Reason of Seizure
i.	Batch Manufacturing Record of Hard Gelatin Capsule, Capsule Size ‘3’, Batch Number; CF020, 28 Pages	1. Production/manufacturing in the absence of production incharge. 2. The Microbiology Department was not functional 3. ATCC-type/Reference cultures were not available. 4. Validation of R.O. water was not available. 5. The quality assurance manager was not available/present. 6. Validation of HVAC system and compressed air was not available.
ii.	Batch Manufacturing Record of Hard Gelatin Capsule, Capsule Size ‘3’, Batch Number; CF019, 26 Pages	
iii.	Batch Manufacturing Record of Hard Gelatin Capsule, Capsule Size ‘3’, Batch Number; CG038, 27 Pages	
iv.	Capsule Shells of Batch CG038- (30)	
v.	Capsule Shells of Batch CF019- (20)	
vi.	Capsule Shells of Batch CF020- (30)	

ii. He locked and sealed the manufacturing room of the premises that was later de-sealed by the order of Drug Court, Lahore dated 16.08.2024.

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

1. **Production/manufacturing in the absence of production incharge.**
2. **The Microbiology Department was not functional**
3. **ATCC-type/Reference cultures were not available.**
4. **Validation of R.O. water was not available.**
5. **The quality assurance manager was not available/present.**
6. **Validation of HVAC system and compressed air was not available.**

3. Permission to keep the custody of seized drugs/ articles was granted to Provincial Inspector of Drugs by PQCB in its 283rd Special Meeting held on 20.08.2024.

4. Show-cause notice(s) issued to accused person(s) dated 20.12.2024.

5. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025

6. Case is placed before the Board for decision.

Sr. No.	**Summary of the Case**	
1	**Form-5 (Seizure date)**	05.08.2024
2	**Investigation Report by DI**	16.09.2024
3	**SCN Permission**	285-M (26.09.2024)
4	**Show Cause Notice Issued**	20.12.2024
5	**Reply of Firm to Show Cause Notice**	No Reply Received
6	**History (3 years)**	Firm’s Reported: Nil
		Product’s Reported: Nil

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 22

PQCB/R-906/2024

Govt. Teaching Hospital Shahdara, Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Macter international Limited, F-216, S.I.T.E Karachi** through Chief Operating Officer, Amjad Mansoor 2. Amjad Mansoor — Chief Operating Officer 3. Farooq Mustafa Chaudhry — Director Quality Operations 4. Muhammad Zeeshan — Production Manager 5. Farooq Sami — Quality Control Manager 6. Muzammil Siddiqui — Warrantor of M/s Macter international Limited, F-216, S.I.T.E Karachi.

BREIF FACTS OF THE CASE:

Provincial Inspector of Drugs, Govt. Teaching Hospital Shahdara, Lahore reported that: -

i. The then drug inspector, on 27-12-2018 inspected the premises of Main Medicine Store of Govt. Teaching Hospital Shahdara, Lahore, took following drug sample on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Lahore vide memorandum no. 24776 dated 27-12-2018.
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 TRA No. & Date**
Tabs. TAVIST [Atorvastatin: 10mg] **Mfg date** **Exp date** **Regn No.** Oct-2018 Oct-2021 037056	8011	M/s Macter International (Pvt.) Ltd. F-216, S.I.T.E Karachi-75700 Pakistan.	01-132003094/DTL dated 21-02-2019

Analysis with Specifications Applied: USP 2018

PHYSICAL CHARACTERISTICS: White colored oblong shaped tablet with "W" engraved on one side and line of bisection on other side packed in blister packing of ten units.

WEIGHT VARIATION: The sample meets BP acceptance criteria for uniformity of weight or mass. Limits: +/- 7.5% of Avg. Weight (141.2 mg)

FRIABILITY: Limit: NMT 1%

%Loss determined: 0.006%

IDENTIFICATION: The retention time of the major peak in sample chromatogram corresponds to retention time of major peak in standard chromatogram. (ATORVASTATIN CALCIUM IDENTIFIED)

ASSAY OF ATORVASTATIN:

Stated:	10 mg / tab
Determined:	10.08 mg / tab
Percentage:	100.8%
Limit:	94.5%–105% of stated amount

DISSOLUTION TEST: Does not comply the Dissolution of Atorvastatin with the USP (Test 1) Specifications as detailed below:

Tolerance Limit: Not less than 80% (Q) of the labeled amount of Atorvastatin is dissolved.

S1 Stage: Each unit is NLT Q+5%

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

S3 Stage: 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						AVERAGE (%)	REMARKS
S1	6	Each individual unit should NLT (80%)						-	**Does not Comply**
		UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6		
Determined (%)	Atorvastatin	**59.0**	**55.2**	70.4	85.5	66.4	71.1	-	
S2	6	Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15%						S1+S2	**Does not Comply**
		UNIT 7	UNIT 8	UNIT 9	UNIT 10	UNIT 11	UNIT 12		
Determined (%)	Atorvastatin	73.2	**60.6**	**64.3**	**59.7**	75.8	**63.4**	**67.1**	

The average of 12 units is less than Q (80%). 6 out of 12 units are less than Q-15% (65%) so sample fails to comply the Dissolution of Atorvastatin at S2.

RESULT: The above sample is **SUB-STANDARD** on the basis of DISSOLUTION TEST OF ATORVASTATIN performed as per USP.

iii. The Storekeeper, Central Pharmacy, Govt. Teaching Hospital Shahdara, Lahore provided Invoice/Warranty bearing No. 90265030 dated 12-12-2018 issued by M/s Macter international Limited, F-216, S.I.T.E Karachi as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent M/s Macter international Limited, F-216, S.I.T.E Karachi.

v. A copy of test/analysis report was sent to M/s Macter international Limited, F-216, S.I.T.E Karachi with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the subject 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 10th committee meeting held on 22-07-2019, after due deliberation and discussion unanimously decide to turn down the firm's request for retesting of the subject drug sample. Firm's review petition against above mentioned decision of retesting request, has also been turned down in 213rd meeting held on 16-11-2019.

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

3. Show-cause notice issued to accused person(s) dated 12.11.2024.

Reply of Show Cause Notice:

We M/s. Macter International Limited (the "Company") acknowledge to receipt of your Letter No. PQCB/R-906/2019 Dated November 12, 2024 (the "Letter"), which is received to us on November 20th, 2024.

In this connection we would like to inform you that;

1. Assay is more than 100% as per the DTL report.

2. Weight variation of tablets meet requirements as per the DTL report.

3. DT of the product is about 1 minutes.

4. The USP recommended dissolution in 15 minutes due to the highly soluble molecule.

5. We tested the retention sample & warrantor sample of the product and both sample were found satisfactory as per dissolution method & criteria defined in USP. (Reports are enclosed).

6. Warrantor sample has shown average of 95.27% dissolution result while the average dissolution result of retention sample are 97.15%.

7. Historically no adverse event /complaints has been received related to this product.

8. Based on points 1-5, it is obvious that the product meets standard quality criteria regarding dissolution and would likely have been cleared if sent to NIH.

Pray; we request that all evidences indicate that the batch is of standard quality if appellate lab testing was allowed batch would have been cleared. At the time of this batch manufacturing our label claim was manufacturer specification. We have upgraded in 2019 to pharmacopoeia specifications. All of our current batches are being passed by DTLs. Please find attached form 7 of batch no. 8012, 8004 & 9002.

Since product is now meeting pharmacopoeia specifications we request that this case may be closed. As we have also replaced the batch with fresh batch.

In this context we are also enclosing the required information as mentioned in your letter copy of Drug Manufacturing License, Drug Sale License and Drug registration certificate.

Personal details of concern person is given below;

S.No.	Name	Designation
1	Muhammad Zeeshan	Production Manager
2	Farooq Sami	Quality Control Manager
3	Muzammil Siddiqui	Warrantor

Hope this will suffice your requirements to your good office and we are looking forward your utmost support in this regard.

5. Personal Hearing notice issued to the accused person(s) dated 20-05-2025

Sr.	**Summary of the case**	
1.	**Date of sampling**	27.12.2018
2.	**Sent to DTL**	27.12.2018
3.	**Date of receipt in DTL**	02.01.2019
4.	**Issuance of DTL Report**	21.02.2019
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	30.03.2019

7.	**Retesting Request**	20.04.2019
8.	**Fate of retesting request**	Turn Down (10st-CM), RP also upheld (213nd-M)
9.	**Investigation Report of DI**	08.10.2024
10.	**Permission of SCN**	286th meeting dated 30.10.2024
11.	**SC Notice Issued**	12.11.2024
12.	**Reply of the firm**	22.11.2024
13	**History (3 years)**	05 cases of the firm 00 case of the product

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 23

PQCB/ SM-06-03/2023

Quaid-e-Azam Industrial Estate, Multan Road & Raiwind Road, Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S N.B.S. Pharma, 8-Km, Raiwind Road, Lahore** through its Chief Executive Officer/ Owner Sheikh Shehzad Nabi S/o Sheikh Iftikhar Nabi. 2. Sheikh Shehzad Nabi S/o Sheikh Iftikhar Nabi Chief Executive Officer/ Owner 3. Waseem Ahmed Chughtai S/o Rasheed Ahmed Chughtai Quality Control Incharge 4. Muhammad Abdullah S/o Abdul Rashid Production Incharge of **M/S N.B.S. Pharma, 8-Km, Raiwind Road, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Quaid-e-Azam Industrial Estate, Multan Road & Raiwind Road reported that:-

i. The then Provincial Inspector of Drugs, on 08.03.2023, alongwith other team members, inspected the premises of M/s N.B.S. Pharma, 8-Km, Raiwind Road, Lahore and recovered and seized following different types of drugs on Form 5:

Sr.	Name of drugs	Batch No.	Name of Manufacturer	Quantity	Reason of Seizure
1.	Povidone-I 400ml Solution USP (Povidone-Iodide)	D381	N.B.S. Pharma, Raiwind Road, Lahore	150 Bottles	Manufacturing of Drugs for sale 1. Under Unhygienic Condition (productions in dirty/dusty condition/ Premises Dirty/ Dusty) Different Violations of GMP. 2. In the absence of Qualified / Expert Staff (in the absence of Production Incharge). 3. Manufacturing of Drugs during renovation of the premises without the pemission of DRAP or any Competent Authority. 4. HVAC was not functional.
2.	Label of Povidone –I 400ml Solution USP (Povidone-Iodide)	D381	-do-	30	-do-

3.	White coloured Empty Bottles without label approx. Vol. 400ml	N/A	N/A	30 Bottles	-do-
4.	White coloured filled Bottles without label approx. Vol. 400ml (Povidone-I)	N/A	N/A	12 Bottles	-do-

ii. He locked and sealed the premises that was later de-sealed by the order of Drug Court, Lahore dated 10.03.2023.
iii. He also took sample of one drug on Form 4 for the purpose of test/ analysis which was declared of standard Quality from Drug Testing Laboratory, Lahore vide TRA No. 01-177005151/DTL dated 07.04.2023.

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. **Under Unhygienic Condition (productions in dirty/dusty condition/ Premises) Different Violations of GMP.**
b. **Production/ manufacturing in the absence of Qualified / Expert Staff (in the absence of Production Incharge).**
c. **Manufacturing of Drugs during renovation of the premises without the permission of DRAP or any Competent Authority.**
d. **HVAC was not functional.**

3. Show-cause notice(s) issued to accused person(s) dated 10.01.2025.

Reply of Show Cause Notice:

We are in receipt of your letter (Ref. No. PQCB/SM-06.03.2023) issued by your esteemed office, received on 12 April 2025, and dated 10 January 2025.

We sincerely apologize for any inconvenience caused. We would like to respectfully clarify that the production in-charge was out on official work at the time of inspection but immediately returned upon being informed. Additionally, another qualified production pharmacist was present on-site during the inspection.

We assure you that we are committed to maintaining full compliance with all regulatory requirements and such instances will not occur in the future.

Once again, we humbly apologize and seek your kind understanding in this matter

Please find enclosed the required documents as per your directions.

NOTE:

1. Names of the concerned person of NBS Pharma are Correct/Verified

2. We never got chance to sale the product so no Re-called information provided.

3. I have also send you this reply via e-mail

5. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025

6. Case is placed before the Board for decision.

Sr. No.	**Summary of the Case**	
1	**Form-5 (Seizure date)**	08.03.2023
2	**Investigation Report by DI**	24.09.2024
3	**SCN Permission**	287-M (08.01.2025)
4	**Show Cause Notice Issued**	10.01.2025
5	**Reply of Firm to Show Cause Notice**	15.04.2025
6	**History (3 years)**	Firm’s Reported: 01 substandard case reported
Note: Custody of Seized Drugs/ articles was not granted.		

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 24

PQCB/ R-407/2023

SERVICES HOSPITAL, LAHORE

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore- Pakistan** through its Chief Executive Officer, Waleed Rizwan 2. Waleed Rizwan — Chief Executive Officer/ Warrantor (Warrantor as per Warranty) 3. Muhammad Ali — Managing Director 4. Khair-un-Nisa — Production Incharge 5. Tajammal Hussain — Quality Control Incharge/ Warrantor (Warrantor as per Firm's Reply) **Of M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore-Pakistan.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Services Hospital Lahore reported that: -

i. The then drug inspector, on 29-05-2023, inspected the premises of Main Surgical Store, situated at Services Hospital Lahore, took following product's sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 168244 dated 29-05-2023.
ii. The subject sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Surgee Bandages [Surgee Bandage 15cm*6m] **Mfg Date** May 2023 **Expiry Date** Apr 2026	B716-23	M/S Rehman Rainbow (Pvt) Ltd, 82-Industrial Estate, Kot Lakhpat Lahore Pakistan	01-129005781/DTL dated 23-06-2023	**Analysis with specifications applied: BPC** **PHYSICAL DESCRIPTION:** B.P.C monograph of Open wove Bandage describes Standard description as "Cotton cloth of plain weave, bleached to a good white, in one continuous length containing no joins, clean, and reasonably free from weaving defects, leaf and shell; the edges are evenly cut, parallel with the wrap threads, and are reasonably free from loose threads". **Observed:** Cotton Cloth of plain weave bleached to white, it is clean and reasonably Free from Weaving Defects, Leaf and Shell. Claimed Size=15cm*6m **11 units are observed and out of which 05 units are found to have joins (Not in one continuous length). Therefore, 05 out of 11 units are not complying the standard specifications.**

Regn No. 030774				**(DOES NOT COMPLY)** **NOTE:** Below are the results of 06 units that are complying the physical description and are in one continuous length. **WARPS:** Limit: Average 17.1/cm Determined: 17.5/cm **WEFTS:** Limit: Average 10.7/cm Determined: 11.1/cm **WIDTH:** Limit: 15cm (LABEL) Determined: 15cm **LENGTH:** Limit: 6M (LABEL) Determined: 6M **Weight per unit area:** Limit: Not less than 71g/m^2 Determined: 75 g/m^2 **RESULT**: The above sample is **SUB-STANDARD** on the basis of Physical Description as per BPC.

iii. The storekeeper, Main Surgical Store of Services Hospital Lahore provided invoice/ warranty bearing No. RR02306 dated 29-05-2023 issued by M/s Roys & Roys International 1st Floor Rehman Center-2 near Askari-11, Gate No.3, Lahore who, in-turn, provide invoice/ warranty bearing No. 10508 dated 10-05-2023 issued by M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore- Pakistan as a proof of its purchase.

iv. Warrantor portion of the drug sample was sent to M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore- Pakistan.

v. A copy of test/analysis report was sent to M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore- Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to the request of M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore- Pakistan, the retesting request of the subject drug sample was considered in 26th Committee Meeting of the Board held on 11-10-2023 and the subject drug sample was sent to NIH, Islamabad, from where the sample was declared **Sub-standard** as detailed below:

Name of	**Batch**	**Name of**	**NIH Test**	**NIH Test Report Result**

Drug	No.	Manufacturer	Report No.	
Surgee Bandages B.P.C **Mfg Date** May 2023 **Expiry Date** Apr 2026	B716-23	M/S Rehman Rainbow (Pvt) Ltd, 82-Industrial Estate, Kot Lakhpat Lahore Pakistan	0217-P/2023 dated 20-12-2023	**DESCRIPTION:** Cotton cloth of plain weave, bleached not to a good white containing joins, and having weaving defects and loose threads, the edges are unevenly cut, parallel with the warp threads. **Does not comply with BPC-73** which states that Cotton cloth of plain weave, bleached to a good white, in one continuous length containing no joins, clean and reasonably free from weaving defects, leaf and shell; the edges are evenly cut, parallel with the warp threads, and are reasonably free from loose threads. **CONCLUSION:** The sample is **Sub-Standard** quality on the basis of test performed.

vii. A copy of NIH test report was sent to M/s Rehman Rainbow (Pvt) Ltd., 82-Industrial Estate, Kot Lakhpat, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard

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

a. **Manufacturing for sale/ Sale of Substandard Therapeutic Good/ Medical Device**

b. **Issuance of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 06-11-2024

4. Personal hearing notice(s) issued to accused person(s) dated 22-05-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	29-05-2023
2	**Sample Sent to DTL (Form-6)**	29-05-2023
3	**Receipt Date in DTL**	30-05-2023
4	**Issuance of DTL Report**	23-06-2023
5	**Time Extension**	-
6	**DI First Communication with Firm**	13-07-2023

7	**Retesting Request**	17-07-2023
9	**Investigation Report by DI**	15-10-2023
10	**SCN Permission**	286-M
11	**Show Cause Notice Issued**	06-11-2024
12	**Reply of Firm to Show Cause Notice**	-
13	**History (3 years)**	Firm’s Reported: 18
		Product’s Reported: 7 (Subject Case) 4 decided in 290-M

Case No. 25

PQCB/SM-17-09/2024

Ferozepur Road & District Lahore

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Samreen Harbal Pharma, New Jail Road, Ferozepur Road, Kot Lakhpat, Lahore** through its Chief Executive Officer/ Director, Muhammad Tayyab Aziz Mehar. 2. Muhammad Tayyab Aziz Mehar Chief Executive Officer/ Director of **M/S Samreen Harbal Pharma, New Jail Road, Ferozepur Road, Kot Lakhpat, Lahore.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs (Industries), Ferozepur Road, Lahore & District Kasur reported that:

i. He, on 28.08.2024, alongwith other team members, inspected the premises of M/s Samreen Harbal Pharma, New Jail Road, Ferozepur Road, Kot Lakhpat, Lahore and recovered and seized following different types of drugs/ therapeutic goods/ articles on Form 5:

Sr.	Name of Drugs	Batch No.	Name of Manufacturer	Quantity	Reason of Seizure
i.	Syp. Gastopax	004	Samreen Herbal Pharma	50	1. Manufacturing/Manufacturing for sale of therapeutic goods without form 7. 2. Approved/Qualified vendor list was not available. 3. Violations of GMP. 4. Status labeling was missing in raw material and finished goods store. 5. BMR of Syrup GastoPax B#004 was not available at the time of inspection. 6. Storage conditions of API and Finished goods was not properly maintained.
ii.	Gastopax (Unit Carton)	N/A	-do-	100	
iii.	Veforce Capsule (Unit Carton)	N/A	-do-	100	

ii. He also ordered under section 18(1) of The Drugs Act 1976 regarding not to dispose of stock mentioned on Form-3, 4800 packs of Syrup GastoPax B# 4, Manufactured by M/S Samreen Harbal Pharma, Manufacturing date: 06.2024 and Expiry Date: 06.2026.

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

a. **Manufacturing/Manufacturing for sale of therapeutic goods without form 7.**
b. **Approved/Qualified vendor list was not available.**
c. **Violations of GMP.**
d. **Status labeling was missing in raw material and finished goods store.**
e. **BMR of Syrup GastoPax B#004 was not available at the time of inspection.**
f. **Storage conditions of API and Finished goods was not properly maintained.**

3. Permission to keep the custody of seized drugs/ articles and extension in sealing period upto ninety (90) days was granted to Provincial Inspector of Drugs by Committee of PQCB in its 44th Meeting held on 19.09.2024.

3. Show-cause notice(s) issued to accused person(s) dated 31.12.2024.

Reply of Show Cause Notice:

With due respect, in reply of show cause notice we received regarding the inspection of our industry. In the view of the allegation mentioned in the subclause 2 we are obliged to give the following information to Provincial quality control board, Punjab.

a) Manufacturing/ Manufacturing for sale of therapeutics goods without form-7

The syrup gastopax manufactured by Samreen herbal pharma were not for the purpose of sale, instead it was made on trial basis for research and development purposes. We manufactured total 600 litre batch ie 5000 u/c bottles. 50 packs were seized by the drug inspector. We manufacture a large quantity of batch because we provide our samples to hakeem to check the efficacy and stability of the syrup. Hence, we supply 50 u/c to 100 hakeem for the feedback. The authority can assure that the gastopax syrup is not saled in market.

b) Approved/Qualified vendor list:

The list of our vendors is as following

Fafico Pet Industries (Syrup bottles vendor)	0322-8090420
Ahmad Pansar store (Herbs Vendor)	03227663318
Ahmed Mahtab Chemicals (Excipients vendor)	0331-0404565

c) GMP Violations:

My firm is manufacturing the alternative medicines under the prescribed conditions of GMP as in SRO 412/12 Many inspections done by DRAP/Punjab Inspectors and in this visiting officer not pointed out any specific GMP violation. However I assure that I will further improve the GMP conditions as there is room for improvement at anywhere.

d) Labelling status was missing in raw material and finished goods store:

With due respect I assure that now I will properly label the Raw material/ Finished goods stores

e) BMR Of Syrup Gastopax batch no.004 was not available at the time of inspection:

The BAMR of the syrup gastopax is attached with the file.

f) Storage conditions of API and Finished goods store:

Temperature/ Humidity monitoring sheets are handed along with every monitor.

Necessary documents have been attached with the letter.

5. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025

6. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Form-5 (Seizure date)**	28.08.2024
2	**Investigation Report by DI**	09.10.2024
3	**SCN Permission**	286-M (30.10.2024)
4	**Show Cause Notice Issued**	31.12.2024
5	**Reply of Firm to Show Cause Notice**	30.04.2025
6	**History (3 years)**	Firm’s Reported: Nil

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 26

PQCB/ MSS-160985/2023

Tehsil Ahmedpur Sial, District Jhang

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Standpharm Pakistan (Pvt) LTD., 20Km Ferozepur Road, Lahore-Pakistan,** through its Chief Executive Officer/ Managing Director Farooq Ahmed Alvi 2. Farooq Ahmed Alvi Chief Executive Officer/ Managing Director 3. Hasnat Dastgir Production Incharge 4. Sohail Bashir Quality Control Incharge/ Warrantor **Of M/S Standpharm Pakistan (Pvt) LTD., 20Km Ferozepur Road, Lahore-Pakistan**

BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs, Tehsil Ahmedpur Sial, District Jhang reported that:

1. 1. He, on 17-03-2023 inspected the premises M/s Shamsi Medical Store, Opposite Bhutto Nagar Layyah Road, Garh Morh, Tehsil Ahmedpur Sial, District Jhang took sample of subject drug, on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide memo number 0000160985 dated 20-03-2023.
   2. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, Faisalabad as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Sugar Coated Tablet Bludol [Each sugar coated tablet contains: Ibuprofen USP…200mg] **Mfg Date:** 10-2022 **Exp Date:** 10-2024 **Reg number: 013103**	CTK710	M/S Standpharm Pakistan (Pvt) LTD., 20Km Ferozepur Road, Lahore-Pakistan	01-68023236/ DTL dated: 19 July 2023	**Result of test/ analysis with specifications applied:** USP-2023 **DESCRIPTION:** Blue colored round shaped, sugar coated tablet, blistered in Alu-PVC foil with 1*10's units. **IDENTIFICATION** Ibuprofen is identified. **ASSAY:** Stated: 200mg/ Tablet Determined: 207.176mg/ Tablet Percentage:103.588 % (Complies) Limit: 90-110 % (USP 2023)

DISSOLUTION TEST:

Complies with the dissolution test as per USP (2023) as detailed below:-

Tolerance Limit: NLT 80% (Q) of the labeled amount of ibuprofen (C13H18O2) is dissolved.

LEVEL	NUMBER TESTED	ACCEPTANCE CRITERIA						REMARKS
S1	6	Each Unit is not less than Q + 5 percent						Complies
	Time	UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6	
	60 minutes	102.0%	96.4%	96.4%	97.4%	93.9%	98.5%	

IMPURITY TEST

Impurity Name	Acceptance Criteria, NMT (%)	Determined (%)	Remarks
Ibuprofen related compound J	0.2%	**0.211%**	**Does not comply**
Ibuprofen related compound C	0.25%	0.006%	Complies

RESULT: Given sample is Sub-Standarad with regards to Impurities test.

ii. M/s Shamsi Medical Store, provided warranty/invoice No. 71869 dated 12-02-2023 issued by M/S Mushtaq Marketing, Yousaf Shah Road, Jhang Sadar
iii. Warrantor Portion was sent to M/S Mushtaq Marketing, Yousaf Shah Road, Jhang Sadar.
iv. M/S Mushtaq Marketing, Yousaf Shah Road, Jhang Sadar provided invoice/warranty No. IV221102325 dated 18-11-2022 issued by M/S Standpharm Pakistan (Pvt) LTD., 20Km Ferozepur Road, Lahore-Pakistan.
v. A copy of test report/ analysis from DTL was sent to M/S Standpharm Pakistan (Pvt) LTD.,with the direction to explain their position and provide requisite information in this regard. In response the firm challenged the DTL report and requested for re-testing of sample from Appellate Laboratory, National Institute of Health, Islamabad.
vi. Pursuant to the firm's request, the sample was sent to Appellate Laboratory, National Institute of Health, Islamabad, from where it was declared **Substandard**.

Name of drug	Batch No.	Name of Manufacturer	NIH Test Report No. & Date	NIH Test Report Results

<table>
<tr>
<td>Tablet Bludol 200mg</td>
<td>CTK710</td>
<td>M/S Standpharm Pakistan (Pvt) LTD., 20Km Ferozepur Road, Lahore-Pakistan</td>
<td>Test Report No. 0320-P/2023

Dated 09-04-2024</td>
<td><u>Reference:</u> USP 2022

<u>IMPURITY TEST</u>
<table>
<tr><th>Impurity Name</th><th>Determined (%)</th><th>Limit</th></tr>
<tr><td>Ibuprofen related compound J</td><td>0.23%

Does not comply with USP-2022</td><td>Not more than 0.2%</td></tr>
<tr><td>Ibuprofen related compound C</td><td>0.008

Complies with USP-2022</td><td>Not more than 0.25%</td></tr>
</table>
<u>CONCLUSION:</u> The sample is of Sub-Standard quality on the basis of test performed.</td>
</tr>
</table>

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

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

3. Show-cause notice(s) issued to accused person(s) dated 15-05-2025

4. Personal hearing notice(s) issued to accused person(s) dated 22-05-2025

5. Case is placed before the Board for decision.

Sr. No.	Summary of the Case	
1	**Sampling Date (Form 4)**	17-03-2023
2	**Sample Sent to DTL (Form-6)**	20-03-2023
3	**Receipt Date in DTL**	23-03-2023
4	**Issuance of DTL Report**	19-07-2023
5	**Time Extension**	
6	**DI First Communication with Firm**	19-09-2023
7	**Retesting Request**	02-10-2023

9	**Investigation Report by DI**	10-06-2024
10	**SCN Permission**	282-M (24-07-2024)
11	**Show Cause Notice Issued**	15-05-2025
12	**Reply of Firm to Show Cause Notice**	-
13	**History (3 years)**	Firm’s Reported: 1
		Product’s Reported: 1 (Subject Case)

Case No. 27

PQCB/MSS-178668/2024
Tehsil Renala Kurd, District Okara

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case**. 1. **M/SVetz Pharmaceutical (Pvt) Ltd. Plot # Q1, S.I.T.E, Kotri Sindh** through its CEO Muhammad Ishaque Memon 2. Muhammad Ishaque Memon — CEO/ Warrantor 3. Muhammad Hanif — Quality Control Incharge 4. Javed Ahmad Pitafi — Production Incharge Of **M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q1, S.I.T.E, Kotri Sindh**. 5. Muhammad Haseeb S/o Muzzamil Hussain — Proprietor 6. Muhammad Shafi s/o Muhammad Yousaf — Qualified Person **Of M/s Al Hafiz Veterinary Right Side National Bank Left Side Moazam Steel works opposite Bismillah Krakery store near Qasim Filling Station chowk 4/GD Tehsil Renala Khurd.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Renala Khurd, Okara reported that: -

i. She, on 10-10-2023 inspected the business premises of M/s Al Hafiz Veterinary Right Side National Bank Left Side Moazam Steel works opposite Bismillah Krakery store near Qasim Filling Station chowk 4/GD Tehsil Renala Khurd took following sample of the drug on Form No. 4 for the purpose of test/analysis and sent to Drug testing Laboratory, Lahore vide memo no. 178668 dated 14-10-2023.
ii. Following drug sample, after test/analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below:

Name of Drug	**Batch No**	**Manufacturer**	**TRA No and Date**
Injection Ivovectin (Each ml contains ivermectin USP …20mg) Mfg date: 08-2022, **Exp** date: 07-2024	**2223114**	M/S Vetz Pharmaceuticals (Pvt) Ltd, Plot # Q1, S.I.TE., Karachi Sindh	TRA # 01-10206000372/DTL dated 24-11-2023

Specs Applied: BP Vet

PHYSICAL DESCRIPTION: A clear light pale colored liquid preparation in an opaque plastic vial with rubber stopper, aluminum seal, transparent flip-off cover, and red colored cap having company logo printed on it and label pasted on vial. Claimed Volume=50mL

IDENTIFICATION OF IVERMECTIN: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in the standard chromatogram (Ivermectin identified).

ASSAY OF IVERMECTIN:

Stated = 20mg/mL

Determined = **13.91mg/mL**

Percentage = **69.56%**

Limit = 95.0-105.0% of the stated amount

(DOES NOT COMPLY)

STERILITY TEST: The sample is sterile.

BACTERIAL ENDOTOXIN TEST: The sample complies the Bacterial Endotoxin test.

RESULT: The above sample is **SUBSTANDARD** on the basis of Assay test performed as per **B.P Vet.**

iii. Al Hafiz Veterinary Right Side National Bank Left Side Moazam Steel works opposite Bismillah Krakery store near Qasim Filling Station chowk 4/GD, Tehsil Renala Khurd provided invoice/Warranty No. 11955$$$ dated 03-09-2023 issued by M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri

iv. Warrantor Portion was sent to M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri.

v. A copy of Test/ Analysis report was sent to Vetz Pharmaceutical (Pvt) Ltd. Plot # Q1, S.I.T.E, Kotri Sindh and they were directed to provide requisite information in this regard. Firm requested retesting of sample. Pursuant to request, the retesting request was turn down in 35th committee meeting dated 14-03-2024.

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

1. **M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q1, S.I.T.E, Kotri Sindh** through its CEO Muhammad Ishaque Memon 2. Muhammad Ishaque Memon CEO/ Warrantor 3. Muhammad Hanif Quality Control Incharge 4. Javed Ahmad Pitafi Production Incharge Of M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q1, S.I.T.E, Kotri Sindh	i. **Manufacturing for Sale/stock/Sale of Substandard Drug.** ii. **Issuance of false warranty.**
1. Muhammad Haseeb S/o Muzzamil Hussain Proprietor 2. Muhammad Shafi s/o Muhammad Yousaf Qualified Person Of M/s **Al Hafiz Veterinary Right Side National Bank Left Side Moazam Steel works opposite Bismillah Krakery store near Qasim Filling Station chowk 4/GD Tehsil Renala Khurd.**	i. **Sale/stock/exhibiting for sale of Substandard Drug.**

3. Show-cause notice(s) issued to the accused persons(s) dated 31-01-2025

Reply of show cause notice dated nil received in the office of PQCB DATED 27-02-2025

This is with reference to Show Cause Notice No. PQCB/MSS-178668/2023 Dated 31 January, 2025, has received us on 22nd February, 2025; regarding our registered drug Ivovectin Injection Batch No 2223114 (the "Product") has been allegedly declared as 'Substandard by DTL Lahore vide the DTL Report TRA No. 01-10206000372/DTL on dated 24-11-2023. details as under

We explain an d clarify as under:

Name of Drug	**Batch No**	**DTL Report No and Date**	**TRA No and Date**
Injection Ivovectin 20mg/5ml **Mfg date**: 08-2022, **Exp** date: 07-2024	**2223114**	TRA # 01-10206000372/DTL dated 24-11-2023	**D Specs Applied: BP Vet 2022** **Composition** Each ml contains 20mg **DESCRIPTION:** Clear colourless liquid in a sealed plastic bottle Volume=50mL **Identification** identified). **Assay**: State: 20mg/mL Determined:**13.91mg/mL** Percentage:**69.56%** Limit: 95.0-105.0% DOES NOT COMPLY with specification **Sterility**: sterile. **Result**: sample is **Substandard** on the basis of Assay test performed

1. Miss Shahzadi Komal, Provincial Drugs Inspector, Tehsil Renala Khurd, Okara picked up the above-mentioned sample of the Product from M/s Al Hafiz Veterinary Tehsil Renala Khurd, Okara on 10-10-2023 and sent it to DTL Lahore for the purpose of test/analysis on

through memorandum No.178668 dated 14-10-2023.

2. We receive a form PDI through letter No 408/DI/RK/OK on dated 20th December 2023. Related Sale Stock of Sub-Standard Injection Ivovectin 50ml Batch No. 2223114 Mfg. By Vetz

Pharmaceutical (Pvt.) Ltd Kotri Sindh

3. As soon as we received yours letter the QA initiated investigations and took immediate action. Consequently, to your direction we have stopped sale and instructed our logistics and marketing department to initiate recovery from the market if any stock available.

4. There is No stock found in finished goods store of company.

5. We have comprehensively investigated the issue/case including BMR, Retention Samples and also analyzed the Warrantor portion on HPLC according BP Specification and the results of both samples found standard quality, the details of testing results are given as under; (Reports Attached- Annexure-1)

6. Our Analysis findings are as follows in the table

Product Name	Batch No	Results 95-105% (BP)	Remarks
Ivovectin Injection Warrantor Portion sample	2223114	19.54mg/m97068%	Standard
Ivovectin Injection QA Retention sample	2223114	19.81mg/ml 99.04%	Standard

7. n response company reply on dated 01-01-2024 & ask about re-test of sample in NIH. (Letter attached. Annexure -2)

8. In response letter Re-test request A letter received from Secretary PQCB Lahore dated 31-01-2024 with subject: Adduced Evidence under section 22(4) of the drugs act 1976 (letter copy attached Annexure-3)

9. Company reply through letter dated 15-02-2024 and submitted required document. (Letter copies attached annexure -4)

10. On dated 05-03-2024 company received Personal Hearing Notice from PQCB Lahore on Re-testing matter. Company reply through letter dated 14-03-2024 (letter Attached Annexure-5)

11. Mr. Javed Ahmed (Production Manager) appears in personal hearing on dated 14-03-2024 and explain the company position on this matter

12. Company received Order from PQCB Lahore on personal hearing proceedings and decision by the committee dated 09-05-2024 and Turn Down the company request for re-testing. (letter attached Annexure-6)

13. Although company used UV Spectrophotometer testing of product but company right to challenge in NIH Islamabad after confirming the re-testing result on HPLC according BP method. We much sure that if our request is not Turn Down the sample must be declared standard in NIH.

14. As example please read below

Ivovectin Injection Batch No 2323136 Sub-standard by DTL. Faisalahin (TRA 01-48024332 dated 8 July 2023. Company challenge is in Appellate laboratory (NIH) & NIH test report claims standard quality (Reports attached Annexure-7)

15. Ivonectin injection Batch No 2223114. nired in the month of July 2014

1. Company Corrective and Preventative measures on this matter

Good Manufacturing Practices:

We adhere to strict Good Manufacturing Practices (GMP) and quality control procedures in the production of pharmaceuticals. Our facilities have been inspected and certified as compliant with these GMP standards, ensuring that our products meet high-quality benchmarks.

Comprehensive Documentation:

We maintain comprehensive documentation of our manufacturing processes, quality control measures, and all relevant records, which can be made available for scrutiny. These documents provide a clear and transparent view of our commitment to product quality.

Audit Trail:

Our manufacturing and quality control processes are well documented with an extensive audit trail that allows for traceability of each batch of product. This traceability can verify that the Ivovectin Injection 50ml (Batch No. 2223114) was produced in full compliance with our established procedures.

iv. **Trend Analysis**: Company is established the mechanism for trend analysis of deviation & non-conformance through annual product review process (APR) for continual improvement of

process.

Employee Training: Company is conducting comprehensive training programs for all personnel involved in the manufacturing, packaging, and quality control Testing. This training emphasizes the importance of attention to detail and adherence to established protocols. With a lot of efforts and through counseling and training of respective staff Company is trying its level best.

vi**. Regulatory Compliance**:

We understand the gravity of the situation and the importance of compliance with regulatory standards. We take full responsibility for the oversight and are committed to preventing its recurrence. We assure you that we will continue to work diligently to uphold the highest standards of quality and safety in our manufacturing & testing processes.

2. We M/s Vetz Pharmaceutical (Pvt.) Ltd. Hereby verify the name of persons as given under,

a. Muhammad Ishaque Memon (Chief Executive Officer/ Warrantor)

b. Javed Ahmed Pitafi

(Production Incharge) (Quality Control Incharge) c. Muhammad Hanif Qureshi

3. As per your direction we are hereby submitting the requested documents the details as under; (Annexure-8)

a. Copy of Attested Valid Drug Manufacturing License (DML).

b. Copy of Attested Valid Drug Registration Letter.

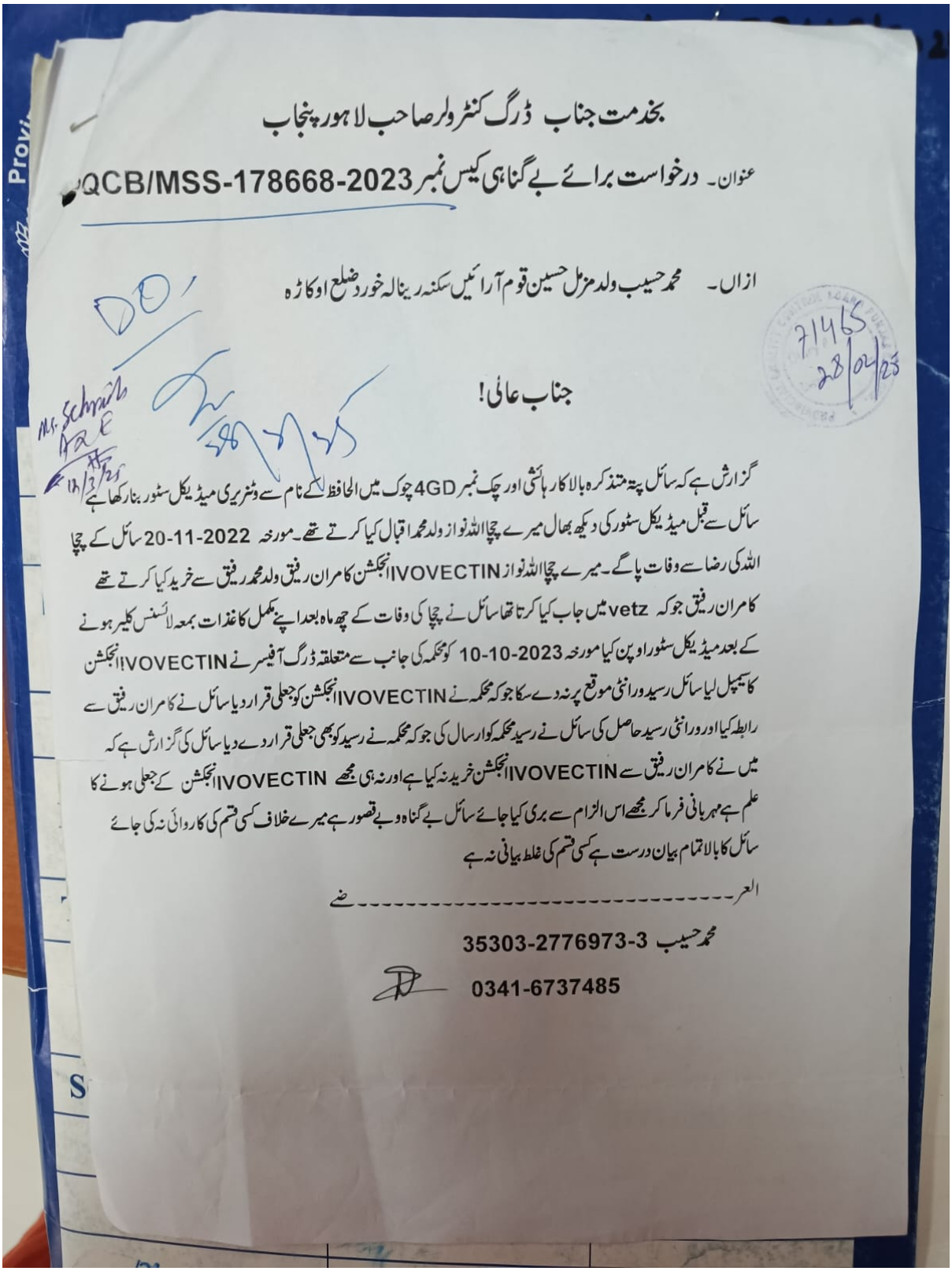
c. Copy of Attested Computerized National Identity Card (CNIC) of Technical Staff.

d. Copy of Attested Appointment Letter of Technical Staff.

e. Appointment letters of Technical Staff

We remain dedicated to maintaining a collaborative and transparent relationship with the Provincial Quality Control Board. We look forward to a fair and just resolution of this matter. Thank you for your attention to this response. We would also desire and seek personal hearing for clarification the case if required.

Reply of Muhammad Hasseb of Alhafiz vetinary store store



بخدمت جناب ڈرگ کنٹرولر صاحب لاہور پنجاب

عنوان۔ درخواست برائے بے گناہی کیس نمبر QCB/MSS-178668-2023

ازاں۔ محمد حسیب ولد مزمل حسین قوم آرائیں سکنہ رینالہ خورد ضلع اوکاڑہ

جناب عالی!

گزارش ہے کہ سائل پتہ متذکرہ بالا کا رہائشی اور چک نمبر 4GD چوک میں الحافظ کے نام سے وٹنریری میڈیکل سٹور بنا رکھا ہے سائل سے قبل میڈیکل سٹور کی دیکھ بھال میرے چچا اللہ نواز ولد محمد اقبال کیا کرتے تھے۔ مورخہ 20-11-2022 سائل کے چچا اللہ کی رضا سے وفات پا گے۔ میرے چچا اللہ نواز IVOVECTIN انجکشن کامران رفیق ولد محمد رفیق سے خرید کیا کرتے تھے کامران رفیق جو کہ vetz میں جاب کیا کرتا تھا سائل نے چچا کی وفات کے چھ ماہ بعد اپنے مکمل کاغذات بمعہ لائسنس کلیر ہونے کے بعد میڈیکل سٹور اوپن کیا مورخہ 10-10-2023 کو محکمہ کی جانب سے متعلقہ ڈرگ آفیسر نے IVOVECTIN انجکشن کا سیمپل لیا سائل رسید ورانٹی موقع پر نہ دے سکا جو کہ محکمہ نے IVOVECTIN انجکشن کو جعلی قرار دیا سائل نے کامران رفیق سے رابطہ کیا اور ورانٹی رسید حاصل کی سائل نے رسید محکمہ کو ارسال کی جو کہ محکمہ نے رسید کو بھی جعلی قرار دے دیا سائل کی گزارش ہے کہ میں نے کامران رفیق سے IVOVECTIN انجکشن خرید نہ کیا ہے اور نہ ہی مجھے IVOVECTIN انجکشن کے جعلی ہونے کا علم ہے مہربانی فرما کر مجھے اس الزام سے بری کیا جائے سائل بے گناہ و بے قصور ہے میرے خلاف کسی قسم کی کاروائی نہ کی جائے سائل کا بالا تمام بیان درست ہے کسی قسم کی غلط بیانی نہ ہے

العرض

محمد حسیب 35303-2776973-3

0341-6737485

4. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025
5. Case is placed before the Board for decision.

Summary	
Sampling Date (Form 4):	10-10-2023
Sent to DTL (Form 6):	14-10-2023
Date of receipt in DTL	18-10-2023
DTL Report Date (Form 7):	24-11-2023
Time Extension granted	N/A
1st DI Communication with firm dated	20-12-2023
Date of Retesting Request of Firm:	01-01-2024
Fate of Retesting request	**Turn down in 35th Committee Meeting Dated 14-03-2024**
Investigation Report Dated	19-09-2024
Firm History 3 years	**Firm: 09** **Product:03**

PROCEEDING & DECISION BY THE BOARD:

Case No. 28

PQCB/MSS-187882/2024
Tehsil Renala Kurd

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case**. 1. **M/s Webros Pharmaceuticals Plot 1 St 10, National Industrial Zone Rawat Islamabad Pakistan** through its Managing Director Anjum Ahmad 2. Anjum Ahmad Managing Director 3. Syed Mussarat Ali Production Incharge/ Warrantor 4. Shahid Hayat Quality Control Incharge of M/**s** Webros Pharmaceuticals Plot 1 St 10, National Industrial Zone Rawat Islamabad Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Renala Khurd, Okara reported that: -

i. She, on 01-01-2024 inspected the business premises of M/s Waseem Akram medical store Right side Al Madina Cloth home left side Al Madina Commission shop opposite all electronics near Sakhi Sarwar Chuchak Chowk Tehsil Renala Khurd, took following sample of the drug on Form No. 4 for the purpose of test/analysis and sent to Drug testing Laboratory, **Lahore** vide memo no. 187882 dated 02-01-2024.
ii. Following drug sample, after test/analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below:

Name of drug	**Batch no.**	**Name of manufacturer**	**DTL Test Report No. & Date**	**DTL Test Report Results**
Tablet Detamol Extra [Paracetamol 500mg, Caffeine 65mg] **Mfg date:**	323	M/s Webros Pharmaceuticals Plot 1 St 10, National Industrial Zone Rawat Islamabad	01-10194005959/DTL 18-03-2024	**Specification applied: BP 2023** **PHYSICAL CHARACTERISTICS** white color round tablet plain from both sides packed in Alu-PVC blister pack of 10 units. **IDENTIFICATION** Paracetamol & Caffeine are identified. **ASSAY of Paracetamol** **Stated** **Determined** **Percentage** 500mg/Tab 492mg/Tab 98.4% LIMIT: 95-105.0% of stated amount **ASSAY of Caffeine:**

2-2023

Exp date:

1-2025

Stated **Determined** **Percentage**

65mg/Tab 63.31mg/Tab 97.4%

LIMIT: 95-105.0% of stated amount

DISSOLUTION TEST: Does not comply with BP specifications as detailed below:

Tolerance limit*:* NLT 75% (Q) of the labelled amount of the Paracetamol after 45 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, NMT 2 units are less than 15% and no unit is less than Q-25%

LEVEL	**NUMBER TESTED**	**ACCEPTANCE CRITERIA**						**AVERAGE**	**REMARKS**
S1	6	Each individual unit should NLT Q+5% (80%)							
		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
Determined (%)		62	**51**	**57**	**57**	**53**	**52**	-	**Does not comply**

The sample fails to comply the release limits at S1 stage as release of 5 out of 6 units is less than Q-15 (60%)

Note: Time extension is granted via order no. PQCB/TEX-LHR-35/2024 dated 14-03-2024.

RESULT: The sample is declared **SUB-STANDARD** on the basis of **DISSOLUTION TEST** Paracetamol performed as per BP.

iii. M/s Waseem Akram medical store Right side Al Madina Cloth home left side Al Madina Commission shop opposite all electronics near Sakhi Sarwar Chuchak Chowk, Tehsil Renala Khurd provided invoice/bill warranty No. 48715 dated 03-07-2023 issued by M/s Maqbool Traders Depalpur Road Venus Chowk, Okara.

iv. Warrantor Portion and a copy of DTL report was sent to M/s Maqbool Traders Depalpur Road Venus Chowk, Okara who in turn provided invoice/bill warranty no. 22787 dated 09-03-2023 issued by M/s Webros Pharmaceuticals Plot 1 St 10, National Industrial Zone Rawat Islamabad Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Webros Pharmaceuticals Plot 1 St 10, National Industrial Zone Rawat Islamabad Pakistan and they were directed to provide requisite

information in this regard.

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

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

Show-cause notice(s) issued to the accused persons(s) dated 09-10-2024

Reply of show cause notice dated 26-10-2024

Webros Pharmaceuticals received a letter from provincial Quality Control Board, Lahore Le.. letter No. PQCB/MSS-187882/2024 dated 09-10-2024, receipt date 22/10/2024. We are hereby stated that.

We submit the following documents as mentioned in letter:

1. Name of Managing Director Anjum Ahmed.

2. Name of production Incharge

Syed Mussarat Ali

3. Name of Quality Control Incharge

Shahid Hayat

4. Name of Warranter

Syed Mussarat Ali

5- Drug Manufacturing License (ATTESTED)

Attached

6- Drug Registration Certificate. (ATTESTED)

Attached.

7- Copy of National ID Card of all above persons. (ATTESTED)

Attached.

8- Copy of job certificate. (ATTESTED)

Attached.

9. Appointment of technical staff. (ATTESTED) Attached. With the reference letter 560/DI/RK/OK

10- Recall Letter

2. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025
3. Case is placed before the Board for decision.

Summary	
Sampling Date (Form 4):	01-01-2024
Sent to DTL (Form 6):	02-01-2024
Date of receipt in DTL	06-01-2024
DTL Report Date (Form 7):	18-03-2024
Time Extension granted	**Time Extension granted in 35th Committee Meeting dated 14-03-2024**
1st DI Communication with firm dated	24-04-2024
Date of Retesting Request of Firm:	N/A
Fate of Retesting request	N/A
Investigation Report Dated	30-08-2024
Firm History 3 years	**Firm: 03** **Product:1**

PROCEEDING & DECISION BY THE BOARD:

Case No. 29

PQCB/ SM-06-04/2024

Tehsil Safdarabad, District Sheikhupura

ATTENDANCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S M/S Zafa Pharmaceutical Industries (Private) Limited, L-4/1, A & B, Block 21, Federal 'B' Industrial Area, Karachi** through its Chairman, M. Amin Khan. 2. M. Amin Khan — Chairman 3. Jawad Amin Khan — Managing Director 4. Zafar Amin — Director 5. Mrs Saba Ahmed — Director 6. Malik Azam Hussain — Production Incharge 7. M Abid Saeed — Quality Control Incharge 8. Dr. Shafiuddin — Manager Quality Assurance 9. Shehzad Ahmed Khan — Warrantor/ General Manager **of M/S Zafa Pharmaceutical Industries (Private) Limited, L-4/1, A & B, Block 21, Federal 'B' Industrial Area, Karachi.** 10. **M/S Martin Dow Marker Limited, 7, Jail Road, Quetta, Pakistan** through its Chief Executive Officer, Syed Anis Ahmad Shah. 11. Syed Anis Ahmad Shah — Chief Executive Officer & Director 12. Syed Dawood — Director 13. Ali Amir — Director 14. M Liaque — Production Incharge 15. Abid Fida — Quality Control Incharge 16. Syed Areeb Bin Tariq — Warrantor **of M/S Martin Dow Marker Limited, 7, Jail Road, Quetta, Pakistan.** 17. M Luqman Ahmad — Proprietor & Warrantor 18. Farman Ali — Qualified Person **of M/S Al Abad Medicine Company, Karamat Market, Off. DHQ Hopsital Sheikhupura.** 19. Tariq Mehmood — Proprietor & Warrantor 20. Irum Amara — Qualified Person **of M/S Sameel Enterprises, House # 2, Sadiquia Colony, Jamia Farooqia, Sharaqpur Roadm Sheikhupura.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Safdarabad, District, Sheikhpura reported that: -

i. The then Provincial Inspector of Drugs, 09.04.2019, inspected the business premises of M/s Ahmad Medicine Company situated at Murgha Chowk, Tehsil Safdarabad District Sheikhupura and seized following Drugs, Other Material and Articles on Form-5 for the reasons mentioned in last column.

Sr.	Name of Drug	Batch No.	Manufacturer	Quantity	Printed MRP	Reason for Seized
1	Xynosine Nasal Soray (15ml)	612	M/s Zafa Pharmaceutical Industries (Private) Limited	02	38.41	Sale/ Stock of Drugs having illegal price above the MRP approved by DRAP vide its SRO 34(1) 2019 Dated 10.01.2019 (Violation of Section 12 of Drugs Act 1976 and Schedule II of DRAP Act 2012)
2	Tablet Buscopan Plus	3279	M/s Martin Dow Markers Limited	100	390/100 Tablets	
3	Printed invoice No. 0075057 dated 19/03/19 issued from Al Abad Medicine Company, Karamat Market Sheikhupura in favour of M/s Ahmad Medicine Company Safdarabad					
4	Printed invoice No. 0142077 dated 02/04/19 issued from M/s Sameel Enterprises Sheikhupura in favour of Ahmad Medicine Company Safdarabad					

ii. M/s Ahmad Medicine Company situated at Murgha Chowk, Tehsil Safdarabad District Sheikhupura provided Invoices/warranties No. 0075057 dated 19.03.2019 and 0142077 dated 02.04.2019 issued by M/S Al Abad Medicine Company, Karamat Market, Off. DHQ Hopsital Sheikhupura and M/S Sameel Enterprises, House # 2, Sadiquia Colony, Jamia Farooqia, Sharaqpur Roadm Sheikhupura as a proof of its purchase.

iii. M/S Al Abad Medicine Company, Karamat Market, Off. DHQ Hopsital Sheikhupura provided invoice/ warranty No. 228690 dated 31.01.2019 issued by M/s Zafa Pharmaceutical Industries (Private) Limited, L-4/1, A & B, Block 21, Federal 'B' Industrial Area, Karachi as proof of its purchase.

iv. M/S Sameel Enterprises, House # 2, Sadiquia Colony, Jamia Farooqia, Sharaqpur Roadm Sheikhupura provided invoice/ warranty No. 9000012274 dated 21.03.2019 issued by M/s Martin Dow Marker Ltd., First Floor, Parveen Building, D-7, Shaheed-e-Millat Road, 75350, Karachi as proof of its purchase.

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. **Sale /stock or offer for sale of drugs in the finished form over and above the Maximum Retail Price (M.R.P) issued from DRAP in violation of Drug Pricing Policy-2018 read with S.R.O. 1610(1)/2018, dated 31.12.2018 and vide S.R.O. 34(1)/2019, dated 10.01.2019**
b. **Provision of false warranty**

3. Show-cause notice(s) issued to accused person(s) dated 31.12.2024.

Reply of Show cause Notices: (M/s Zafa Pharmaceutical Industries)

Please refer to your Letter No. PQCB/SM-06-04/2024 dated 31-12-2024 received on 27-01-2025 on the subject cited above. We would like to state that

1. The Provincial Inspector of Drugs, Tehsil Safdarabad, District Sheikhupura inspected the business premises of M/S Ahmad Medicine Company situated at Murgha Chowk, Tehsil Safdarabad, District Sheikhupura on 09-04-2019 and seized the drug Xynosine 0.1% Nasal Spray 15 ml, Batch No. 612, MRP Rs. 38.41 (Quantity: 02) on the basis of price which was observed above the MRP as approved by DRAP vide its SRO 34(1)/2019 dated 10-01-2019. In this regard we have to bring to your knowledge that

i. As per our record before the DRAP SRO 34(1)/2019 dated 10-01-2019 the MRP of Xynosine 0.1%

Nasal Spray 15 ml was Rs. 33.40 per Spray bottle.

ii. After receiving SRO 34(1)/2019, our Costing & Pricing Department increased the Maximum Retail Price of the drug Xynosine 0.1% Nasal Spray 15 ml (Registration No. 000865) in January 2019 as per clause 1(b) of the SRO. According to the SRO 34(1)/2019 clause 1 (b), Maximum Retail Prices of Drugs may be increased fifteen percent over and above existing maximum retail prices determined under the Drug Pricing Policy 2018 (Copy of SRO 34(1)/2019 enclosed)

iii. The MRP of seized drug Xynosine Nasal Spray 15 ml, Batch No. 612 were (Rs. 38.41 per Spray bottle) according to the DRAP SRO 34(1)/2019 dated 10-01-2019. Therefore, you are requested to please consider the above facts and close the case.

2. As per your direction, we are submitting the following information and documents:

i. Name of Managing Director (Non-Technical): Mr. Jawad Amin Khan

ii. Name of Production Incharge: Mr. Malik Azam Hussain

iii. Name of Quality Control Incharge: Mr. Muhammad Abid Saeed

iv. Name of Warrantor: Mr. Shehzad Ahmed Khan

v. Copy of CNIC of Managing Director, Production Incharge, Quality Control Incharge and Warrantor.

vi. Copy of Registration Letter with renewal document

vii. Copy of Drug Manufacturing License.

5. Personal hearing notice(s) issued to accused person(s) dated 20-05-2025

6. Case is placed before the Board for decision.

Sr. No.	**Summary of the Case**	
1	**Form-5 (Seizure date)**	09.04.2019
2	**Investigation Report by DI**	02.02.2024
3	**SCN Permission**	279-M (24.04.2024)
4	**Show Cause Notice Issued**	31.12.2024
5	**Reply of Firm to Show Cause Notice**	28.01.2025 (M/s Zafa Pharmaceutical Industries)
6	**History (3 years)**	Firm’s Reported: 71 Substandard Cases Reported
		Product’s Reported: Nil

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 30

PQCB/MSS-195096/2024

Government Teaching Hospital Shahdara, Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km Ferozepur Road, Lahore** through its Chief Executive Officer, Dr. Riaz Ahmed. 2. Dr. Riaz Ahmed — Chief Executive Officer/ Warrantor 3. Mushoraf Shahzad — Production Manager 4. Muhammad Tayyab — Quality Control Manager 5. Tayyaba Hassan — Quality Assurance Manager **of M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km Ferozepur Road, Lahore.**

BREIF FACTS OF THE CASE:

Provincial Inspector of Drugs, Government Teaching Hospital Shahdara, Lahore reported that: -

i. He, on 16.03.2024, inspected the premises of Main Medicine Store situated at 2nd floor, Government Teaching Hospital Shahdara, Lahore and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 195096 dated 16.03.2024.

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

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date
Tablet Safbon-D (Alendronate Sodium: 70mg, Vitamin D3: 5600 I.U.) **Mfg. Date Exp. Date**: **Reg. No**.: 02.2024 02.2026 088752	011	M/S Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km Ferozepur Road, Lahore	01-10194006997DTL Dated: 15.05.2024

DTL Test Report Result

Analysis with specifications applied: Innovator Specs

Physical Characteristics:

Stated as per MS: White round tablet having word **"SHROOQ"** engraved on one side and cut on other, packed in Alu-Alu blister and in a define shape unit carton along with leaflet.

Observed: White colored round biconvex tablet with line of bisection on one side and **plain on the other side** in blister packing of four units further packed in an outer carton along with leaflet. **(DOES NOT COMPLY)**

Weight Variation: Limit: 200mg+/-7.5%, Determined: All 20 units comply the limit., Average weight=200mg

Disintegration Test: All 6 units disintegrated within 15minutes.

Identification: Alendronate sodium and Vitamin D3 are identified.

Assay of Alendronate Sodium: Stated= 70mg/tab, Determined= 70.03mg/tab, Percentage= 100.04%, Limit= 90-110% of labelled amount.

Assay of Vitamin D3: Stated= 5600IU/tab, Determined= 5233.72IU/tab, Percentage= 93.46%, Limit= 90-140% of labelled amount.

Result: The above sample is **SUB-STANDARD**, on the basis of Physical description as per Manufacturer provided method of analysis.

iii. Store Keeper, Main Medicine Store situated at 2nd floor, Government Teaching Hospital Shahdara, Lahore provided Invoices/ warranties No. 2023-24-S001 dated nil issued by M/s Hi-Q Medicose, Office 312, 3rd Floor Capital PMA Centre Opp. Camp Jail Ferozepur Road, Lahore as proof of its purchase.
iv. Warrantor portion of drug sample was provided to M/s Hi-Q Medicose, Office 312, 3rd Floor Capital PMA Centre Opp. Camp Jail Ferozepur Road, Lahore.
v. M/s Hi-Q Medicose, Office 312, 3rd Floor Capital PMA Centre Opp. Camp Jail Ferozepur Road, Lahore provided Invoices/ warranties No. 03-00075 dated 11.03.2024 issued by M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km Ferozepur Road, Lahore as proof of its purchase.
vi. A copy of test/analysis report was provided to M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km Ferozepur Road, Lahore and they were asked to provide the requisite information in this regard. In response the firm submitted requested for retesting.
vii. The Committee of Provincial Quality Control Board, Punjab in its 45th meeting dated 23.10.2024 accepted the firm's request to withdraw its request for retesting.

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. **Manufacture for sale of/ sale of Substandard Drug**
b. **Issuance of False Warranty**

3. Show-cause notice issued to accused person(s) dated 12.05.2025.

4. Personal Hearing notice issued to the accused person(s) dated 20-05-2025

Sr.	**Summary of the case**	
1.	**Date of sampling**	16.03.2024
2.	**Sent to DTL**	16.03.2024
3.	**Date of receipt in DTL**	18.03.2024
4.	**Issuance of DTL Report**	15.05.2024

5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	27-05-2024
7.	**Retesting Request**	29.05.2024
8.	**Fate of retesting request**	Withdrawn by the Firm
9.	**Investigation Report of DI**	03.03.2025
10.	**Permission of SCN**	290th meeting dated 07.05.2025
11.	**SC Notice Issued**	12.05.2025
12.	**Reply of the firm**	
13	**History (3 years)**	03 cases of the firm including subject case 00 cases of the product

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 31

PQCB/MSS-179090/2023

Govt. Nawaz Sharif Teaching Hospital Yakki Gate, Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in subject case** 1. **M/s Hoover Pharmaceuticals Pvt. Ltd., Plot No.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan** through its Chief Executive Officer, Mir Anjum Ishaque 2. Mir Anjum Ishaque Chief Executive Officer 3. Azhar Mahmood Plant/ Production Manager 4. Muhammad Yaqub Quality Control Manager/ Warrantor of M/s Hoover Pharmaceuticals Pvt. Ltd., Plot No.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan.

BREIF FACTS OF THE CASE:

Provincial Inspector of Drugs, Government Muhammad Nawaz Sharif Teaching Hospital Yakki Gate, Lahore reported that: -

i. The then drug inspector, on 16-10-2023 inspected the premises of Main Medicine Store of Government Muhammad Nawaz Sharif Teaching Hospital Yakki Gate, Lahore, took different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Lahore vide memorandum no. 179090 dated 19-10-2023.
ii. The subject drug sample, after test/ analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below:

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report TRA No. & Date**
Capsule. GATOLIN [Each capsule contains Omeprazole Enteric coated pellets eq to Omeprazole…40mg) **Mfg date** **Exp date** **Regn No.** Oct-2023 Oct-2025 109342	H349	M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16 Zain Park Industrial Area Saggian Bypass Road, Lahore	01-10194004053/DTL dated 30-Nov-2023

Analysis with specifications applied: USP 2023

PHYSICAL CHARACTERISTICS: White coloured pellets enclosed in hard gelatin capsules shell having green cap and transparent body, in alu-alu packing of 7 units.

CONTENT UNIFORMITY BY WEIGHT VARIATION:

Limit: L1≤ 15 Determined: L1=4.2

IDENTIFICATION: The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (OMEPRAZOLE IDENTIFIED)

ASSAY OF OMEPRAZOLE:

Stated: 40mg/caps Determined: 40.52 mg/caps Percentage: 101.29% Limit: 90.0% - 110.0% of the labeled amount

DISSOLUTION TEST (Acid stage): The average of 6 units is NMT 15% of Omeprazole dissolved. (Complies)

DISSOLUTION TEST (Buffer stage): Does not comply with the USP Specifications as detailed below:

Tolerance Limit: NLT 70% (Q) of the labeled amount of omeprazole is dissolved.

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						AVERAGE (%)	REMARKS
S1	6	Each individual unit should NLT Q + 5% (75%)						-	Does not Comply
		UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6		
Determined (%)		8	8	8	9	9	8		

The sample fails to comply the release limit at S1 stage, as %release of all 6 units is below Q-25% (45%).

RESULT The above sample is **SUB-STANDARD**, on the basis of **DISSOLUTION TEST** performed as per **USP Test-1**.

iii. Storekeeper of Main Medicine Store of Government Muhammad Nawaz Sharif Teaching Hospital Yakki Gate, Lahore provided Invoice/ warranty No. 10-00036 dated 14-10-2023 issued by M/s Hoover Pharmaceuticals Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan as a proof of its purchase.

iv. Warrantor portion of the subject drug sample was sent to M/s Hoover Pharmaceuticals Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan.

v. A copy of test/ analysis report was sent to M/s Hoover Pharmaceuticals Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

vi. Pursuant to the request of M/s Hoover Pharmaceuticals Pvt. Ltd., Plot no.16 Zain Park Industrial Area, Saggian Bypass Road, Lahore Pakistan the retesting request of the subject drug sample was considered in the 33rd Committee Meeting of the Board held on 13-02-2024 and the subject drug sample was sent to NIH, Islamabad, from where the sample was declared **Sub-standard** as detailed below:

Name of drug	Batch	Name of manufacturer	Test Report No.	NIH Test Report Results

<table>
<tr><th></th><th>no.</th><th></th><th>& Date</th><th></th></tr>
<tr><td>Gatolin Capsules 40mg</td><td>H349</td><td>M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16, Zain Park Industrial Area, Saggian Bypass Road, Lahore-Pakistan</td><td>No. 018-P/2024 dated 14-06-2024</td><td>
<u>Reference:</u> United States Pharmacopoeia 2023

<u>DISSOLUTION TEST</u>:

<table>
<tr><td colspan="2">Determined</td></tr>
<tr><td>Acid Stage</td><td>All the six capsules within the limit</td></tr>
<tr><td>Buffer Stage</td><td>All the six capsules deviated from the limit</td></tr>
<tr><td colspan="2">Limit</td></tr>
<tr><td>Acid Stage</td><td>No individual value exceeds 15% of the omeprazole dissolved</td></tr>
<tr><td>Buffer Stage</td><td>Not less than 70% (Q) is dissolved</td></tr>
<tr><td colspan="2">Does not comply with USP-2023</td></tr>
</table>

<u>REMARKS:</u> Percentage release of drug among all six units tested at first stage is found less than 75% (Q+5%) of the stated amount of Omeprazole. Moreover, drug release in all six units found less than (Q-25%) at S1 level. Therefore, Dissolution test is stopped at first stage.

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

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

a. **Manufacturing/ stocking/ selling of Substandard Drug**
b. **Issuance of False Warranty**

3. Show-cause notice issued to accused person(s) dated 16.09.2024.

<u>Reply of Show Cause Notice:</u>

Kindly refer to your letter no. PQCB/MSS-179090/2023dated 16.09.2024 (Received on 23/09/2024) it is submitted that while we have challenged the test report of Government Analyst, we have adduced complete evidence u/s 22(4) of the Drugs Act 1976 with the attachment of following presented before this

honorable board.

A. Complete Batch Manufacturing Record.

B. Observations and calculations of QC analysis of the batch release.

C. Certificate of analysis of working standard.

D. Instrument calibration and verification record.

E. Test protocol and procedure in particular to dissolution test.

F. Observations and calculations of retained sample analysis.

As the same was justified, on the basis of such the honorable board has accepted it and forwarded the sample for retesting. The appellate lab given its report on Form 6 under rule 16, declared the sample sub-standard and at the end of the report on page 4 shown the results, which are surprisingly same digitally with the Government Analyst report as

Unit No.	DTL Report	Appellate Lab Report
1	8%	8.72%
2	8%	9.26%
3	8%	9.35%
4	9%	9.43%
5	9%	9.54%
6	8%	8.81%

The formula and protocols from USP 23 are shown in report but no observations/readings and calculations are given in protocols of the test report. Even the value of D (Dilution factor) used in preparing the appropriate sample solution is not mentioned. All the things render the test report non-conclusive and doubtful.

It is important to submit that the product in question contains omeprazole enteric coated pellets. The pellets have been purchased from the source "Vision Pharmaceuticals (Pvt.) Ltd" approved by DRAP vide registration letter no. F.5-1/2021-Reg-II (M-297) dated 30 July 2021 (Copy Attached). The supplier COA is also attached in which all the tests are well within limits. The facts have also been narrated to M/S Vision Pharmaceuticals for their comments.

The product was manufactured by just dosing the pellets in to the capsule shells on automatic capsule filling machine and there was no critical process as defined under rule 2(0) of DRUGS (LICENSING, REGISTRING AND ADVERTISING) RULES 1976.

The assay of the product as reflected in the report of Government Analyst is 101.29% and the product

also complies acid resistance stage of the dissolution test.

It is also important to mention that the complete Batch of Gatolin 40mg capsules Batch. No. H349 was supplied to GOVT. M. NAWAZ SHARIF TEACHING HOSPITAL YAKKI GATE LAHORE and as per practice of the Government hospitals the batch was not consumed by the public.

The above stated facts, our system, manufacturing process, and the documents speak the truth and can be verified at your convenience.

In the light of above, it is respectfully submitted that we may kindly be exonerated from the case of sub-standard Gatolin 40mg capsules Batch.No. H349

Your requisite information is as under

Designation	**Name**
Chief Executive Officer	Mir Anjum Ishaque
Production Manager	Azhar Mahmood
Quality Control Manager/Warrantor	Muhammad Yaqub

COA of Supplier	Attached **Annexure 1**
Drug Manufacturing License	Attached **Annexure 2**
Drug Registration Letter	Attached **Annexure 3**
Copies of CNIC's	Attached **Annexure 4**
Appointment Letters	Attached **Annexure 5**

Additional Reply Of The Show Cause Notice

In continuation to our Letter.No. HO-PQCB.09/24-001 Dated: 28th September. 2024, it is further submitted that we have approached to the manufacturer/supplier of the pellets "M/s Vision Pharmaceuticals (Pvt.) Ltd" for their comments on the report of appellate lab, whereby the Gatolin 40mg capsules Batch.No. H349 declared sub-standard.

On their response the supplier intimates that,

Vision Pharmaceuticals provide Omeprazole ECP, based on dissolution Test 02 specifications from USP monograph for Omeprazole Delayed Release Capsules. This statement clearly mention on our COA (COA attached)

Testing method provided is also in compliance with USP dissolution Test 02 specifications.

NIH shared a detailed report, explaining testing method used for dissolution test. They have used dissolution test 01(USP) that is not supported by our COA.

Testing method shared with DTL & NIH should be based on dissolution test 02 according to vision pharmaceuticals claim.

It is important to mention that the manufacturer/supplier had forwarded the COA at the time of supply to us in which the type of dissolution test was not mentioned/misprinted, due to this confusion it was not clear that it has to be mentioned on the outer carton of Gatolin 40mg capsules Batch.No. H349 that dissolution test 02 has to be applied.

In the light of above it is submitted that there is no issue in the quality of product and it has been declared sub-standard by DTL and appellate lab only because of technical mistake.

In view of that it is requested that a lenient view may kindly be taken in this regard

5. Personal Hearing notice issued to the accused person(s) dated 20-05-2025

Sr.	**Summary of the case**	
1.	**Date of sampling**	16.10.2023
2.	**Sent to DTL**	19.10.2023
3.	**Date of receipt in DTL**	19.10.2023
4.	**Issuance of DTL Report**	30.11.2023
5.	**Time Extension**	N/A
6.	**DI 1st communication with firm**	11.12.2023
7.	**Retesting Request**	22.12.2023
8.	**Fate of retesting request**	Substandard by NIH
9.	**Investigation Report of DI**	09.08.2024
10.	**Permission of SCN**	284th meeting dated 05.09.2024
11.	**SC Notice Issued**	16.09.2024

12.	**Reply of the firm**	28.09.2024, 25.10.2024
13	**History (3 years)**	04 cases of the firm including subject case 01 subject case of the product

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 32

PQCB/R-244/2022

(Chishtian)

ATTENDANCE:

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

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Chishtian, District Bahawalnagar reported that: -

i. His predecessor, on 21-02-2022, inspected the business premises of M/s Asif Medicose, Basti Ghulam Ali Near Pull Ashiq Muhammad, Tehsil Chishtian, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Bahawalpur vide memorandum no. 119251 dated 23-02-2022

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

Name of Drug	**Batch No.**	**Name of Manufacturer**	**DTL Report No. & Date**	**DTL Test Report Result**
Capsule. Opicap [Each capsule contains: Enteric-coated pellets of Omeprazole equivalent to Omeprazole …. 20mg] **Mfg Date:** 08-2021 **Expiry Date:** 08-2023	EH-21-019	M/S Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.	01-86001098/ DTL Dated 25-04-2022	**Analysis with specifications applied: USP 2021** **COMPOSITION:** Each capsule contains: Enteric coated pellets of omeprazole equivalent to Omeprazole…….20mg **DESCRIPTION:** Off-white, round and spherical pellets in hard gelatin capule of transparent yellow body and opaque yellow cap in blister of seven enclosed in outer carton. **IDENTIFICATION:** Omeprazole identified. **ASSAY:** Stated: 20 mg/ Capsule

Regn No. 028001				Determined: 9.51 mg/ Capsule Percentage: **45.76**% **(Does Not Comply)** Limit: 90–110 % **RESULT:** Given sample is **Sub-Standard**, with regards to Assay.

iii. M/s Asif Medicose, Basti Ghulam Ali Near Pull Ashiq Muhammad, Tehsil Chishtian, provided invoice/ warranty No. 12139 dated 06-02-2022 issued by M/s Javed Sons, Pharma Plus College Road Chishtian.

iv. Warrantor portion of drug sample was sent to M/S Javed Sons, Pharma Plus College Road Chishtian.

v. A copy of test/analysis report was sent to M/s Javed Sons, Pharma Plus College Road Chishtian who in-turn provided invoice/warranty no. 2108-19517 dated 31-08-2021 issued by M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan as a proof of its purchase.

vi. A copy of test/analysis report was sent to M/S Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

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

Name of Drug	**Batch No.**	**Name of Manufacturer**	**NIH Test Report No.**	**NIH Test Report Result**
Capsules OPICAP 20mg	EH-21-019	M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.	0231-P/2022 dated 06-10-2022	**ASSAY:** Stated: 20 mg/ capsule Determined: 9.032mg/ capsule Limit: 90-110% Percentage: 45.16**%** **Does not Comply with USP-39** **CONCLUSION:** The sample is of **Sub-Standard** quality on the basis of the tests performed.

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

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

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

REPLY OF SHOW CAUSE NOTICE BY FIRM:

1. We are in receipt of the Show Cause Notice No. PQCB/R-244/2022 dated 06-01-2023 whereunder you have directed M / s Don Valley Pharmaceuticals (Pvt.) Ltd. (the "Company") to show cause as to why any legal action may not be taken against the Company including but not limited to the initiation of prosecution before the Honorable Drug Court and cancellation of the Drug Manufacturing License and Drug Registration, for allegedly violating the provisions of the Drugs Act, 1976 and the DRAP Act, 2012 along with the rules framed thereunder.

2. In response to the Show Cause Notice under reply, we would like to submit as hereunder:

i. The Company is engaged in the manufacturing of high-quality and efficacious pharmaceutical products which are being manufactured at the state-of-the-art manufacturing site of the Company. Admittedly, no complaint with respect to the quality of the pharmaceutical products manufactured by the Company has been received from anywhere which not only affirms the excellent quality of the pharmaceutical products but also reflects the strict adherence of the Company with the Drug Laws and the rules made thereunder. In this backdrop, the Company seeks to refute the erroneous and inaccurate findings of the Government Analyst Drug Testing Laboratory Bahawalpur rendered vide TRA No. 01-86001098/DTL dated 25-04-2022 (the "DTL Report") and the Government Analyst National Institute of Health Islamabad rendered vide Test Report No. 0231-P/2022 dated 06-10-2022 (the "NIH Report") whereby Capsule Opicap Batch No. EH-21-19 (the "Product") has allegedly been declared as 'Substandard' on the basis of Assay.

ii. It is submitted that it is mandatory to ensure the compliance of the storage conditions specified on the outer unit carton of the Product. As per the label claim of the Product, it is essential to store it under 30 C and to protect the same from sunlight & moisture. The foregoing conditions have been listed on the label claim to ensure long-term efficacy of the Product as-well as to prevent the degradation of the API. Since, the results of all tests conducted at the time of the release of the Product were in compliance with the parameters set under USP, it is evident that the alleged deviation observed in the DTL. Report and the NIH Report has occurred only due to the inability of the third parties, including but not limited to the store keeper, to store and maintain the Product in accordance with the specified storage conditions.

    [Copies of the label claim of the Product along with the Certificate of Analysis is enclosed herewith as "Enclosures I-II"]

iii. The aforementioned submission is further substantiated by the results of the tests conducted upon the retention samples of the. Product which were kept in an appropriate storage environment. In view thereof, it shall be against the dictates of justice to penalize the Company and its officials on the basis of the negligence exhibited by third parties to store the Product in a proper manner.

    [Copy of the results conducted on the retention samples is enclosed herewith as "Enclosure III"]

iv. Without prejudice to the foregoing and despite the absolute innocence of the Company and its officials, please find the following information as per your requirement:

    Production In-charge (Shabana kashif)

    Quality control In-charge (Muhammad Tariq Mahmood)

v. Accordingly, it is reiterated that the entire manner in which the sample of the Product has been obtained and tested is riddled with glaring infirmities and illegalities. The Government Analysts have clearly and visibly failed to adhere with the ordinary testing protocols employed to test a pharmaceutical product and as a result of the same has rendered erroneous findings vis-à-vis the quality of the Product.

vi. In view thereof, it shall be against the dictates of justice to penalize the Company and its officials on the basis of a flawed and faulty investigation. In view of the foregoing, it is affirmed that the Company and its officials have not violated the provisions of the drug laws and the rules made thereunder. Therefore, it is respectfully requested that the titled show cause notice and any subsequent proceedings may kindly be withdrawn in the interest of justice, equity and fair- play.

4. Personal hearing notice(s) issued to the accused persons(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 **275th Special Meeting** held on **31.01.2024** under the Chairpersonship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice Chairperson. Taiba Aslam, Secretary DQCB District Bahawalnagar attended the meeting online via Zoom Link along with original case record. No one among nominated accused appeared before the Board, However, Fatima Zahid (Advocate) appeared before the Board on the behalf of M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.

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

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

7. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its 276th meeting held on 29.02.2024 under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson). Taiba Aslam, Secretary DQCB District Bahawalnagar attended the meeting via zoom link and Rao Sajod, Drug Inspector, Chishtian was present along with original case record. No one among nominated accused appeared before the Board, However, M Ishfaq (Warrantor) along with Fatima Zahid (Advocate) and Ghana Sajid (Lawyer) appeared before the Board on the behalf of M/s Don Valley Pharmaceuticals (Pvt.) Ltd., 31-Km Main Ferozepur Road, Lahore, Pakistan.
8. The Board decided to **Pend** the case.
9. Personal hearing notice(s) issued to the accused persons(s)

Summary:

Manufacturing Date: 08.2021

Expiry Date: 08.2023

Sampling Date (Form 4): 21.02.2022

Sent to DTL (Form 6): 23.02.2022

Date of receipt in DTL: 25.02.2022

DTL Report Date (Form 7): 25.04.2022

Time Extension: N/A

1ST DI Communication with firm on dated: 13.05.2022

Date of Retesting Request of Firm: 24.05.2022

Fate of Retesting Request: Allowed in 248th meeting dated 04.08.2022 (NIH Substandard)

Investigation Report Dated: 10.12.2022

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD: