

**Health & Population Department
PROVINCIAL QUALITY CONTROL BOARD, PUNJAB.**

297 PQCB Meeting

Date: 12-02-2026

Time: 11:00 AM

Venue

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

TABLE OF CONTENTS

- **Item No. 1**
- **ADULTERATED DRUG CASES**
 - **Case No. 1**
 - MSS-238355/2025 (Case Id: 0000214826)
 - **Case No. 2**
 - PQCB/MSS-240904/ 2025 (Case Id: 0000217179)
 - **Case No. 3**
 - PQCB/MSS-239921/ 2025 (Case Id: 0000216515)
 - **Case No. 4**
 - MSS-238356/ 2025 (Case Id: 0000214827)
 - **Case No. 5**
 - PQCB/MSS-238993, 238994/ 2025 (Case Id: 0000215529)
 - **Case No. 6**
 - PQCB/MSS-240858, 240859, 240860/ 2025 (Case Id: 0000217167)

- **Case No. 7**
- PQCB/MSS-238817, 238818/ 2025 (Case Id: 0000215386)
- **Case No. 8**
- PQCB/MSS-235919, 235921, 235918, 235920/ 2025 (Case Id: 0000212072)
- **Item No. 2**
- **SPURIOUS DRUG CASES**
- **Item No. 3**
- **FIR CASES**
- **Item No. 4**
- **SUBSTANDARD CASES**
 - **Case No. 1**
 - R-944/2021 (Case Id: 0000066427)
 - **Case No. 2**
 - MSS-199328/2024 (Case Id: 0000154316)
 - **Case No. 3**
 - R-850/ 2021 (Case Id: 0000065215)
 - **Case No. 4**
 - R-843/2021 (Case Id: 0000059610)
 - **Case No. 5**
 - MSS-200985/2024 (Case Id: 0000157351)
 - **Case No. 6**
 - MSS-215525/ 2025 (Case Id: 0000176858)
 - **Case No. 7**
 - R-923/2021 (Case Id: 0000062838)
 - **Case No. 8**
 - R-754/ 2021 (Case Id: 0000055974)

- **Case No. 9**
- R-647/ 2021 (Case Id: 0000059615)
- **Case No. 10**
- R-848/2021 (Case Id: 0000066702)
- **Case No. 11**
- MSS-198611/2024 (Case Id: 0000154315)

- **Item No. 5**

- **PSI CASES**

- **Case No. 1**
- R-302/ 2023 (Case Id: 0000102957)
- **Case No. 2**
- R-687/ 2022 (Case Id: 0000087910)
- **Case No. 3**
- R-551/2022 (Case Id: 0000093263)

- **Item No. 6**

- **MISBRANDED CASES (RECTIFIED LABEL)**

ITEM No. 1

ADULTERATED DRUG CASES

Case No. 1

PQCB/MSS-238355, 238356/ 2025

Drug Inspector CEO DHA Bahawalpur

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore through its Director Muhammad Bilal Javed 2. Muhammad Bilal Javed Director 3. Muhammad Faheem Production Manager 4. Abdul Rauf Khan Quality Control Incharge/ Warrantor of M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore.
Drug Inspector	

Summary of the case:

- Sampling date (Form 4): 02-10-2025
- Sent to DTL (Form 6): 02-10-2025
- Date of receipt in DTL: 03-10-2025
- DTL Report Date (Form 7): 26-11-2025
- DTL Time Extension: DTL report not time barred
- DI intimation to firm: 01-12-2025
- Retesting request if any: Yes dated 16-12-2025
- Fate of retesting request: Turn Down in 296th meeting dated 15-01-2026
- Investigation report Dated: 31-12-2025
- Permission for issuance of SCN: 296th meeting dated 15-01-2026
- SCN Issued: 21-01-2026
- History (2023 onwards): Firm: 67
- Product: 56

Following Drug samples after test/analysis was declared as **Adulterated** by Government Analyst Drug Testing Laboratory, Bahawalpur, as detailed below:

Sr.	Drug Sample	Batch	Manufacturer	TRA No. and Date
1.	Injection Neudex	DX037	M/S Neutro Pharma Pvt. Ltd., 9.5 Km,	01-

[Dexamethasone Sodium Phosphate eq. to
Dexamethasone Phosphate 4mg/ml]

Sheikhupura Road, Lahore

10096005393/DTL

26-11-2025

Mfg. date: Aug-2025

Exp. date: Aug-2027

Reg.no. 042943

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains: **Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphat... 4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit: 7.0-8.5 Determined: 7.6 at 25.8°C

CONTAINER CONTENT: Limit: Not less than Nominal Determined: 1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 3.99 mg/ml (99.64%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined **0.058 mg/ml** **(Does NOT Comply)**

STERILITY TEST: The sample is sterile

RESULT: The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

2.	Drug Sample	Batch	Manufacturer	TRA No. and Date
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Injection Neudex

DX038

M/S Neutro Pharma Pvt. Ltd., 9.5 Km,
Sheikhupura Road, Lahore

01-

10096005394/DTL

[Dexamethasone Sodium Phosphate eq. to
Dexamethasone Phosphate 4mg/ml]

26-11-2025

Mfg. date: Aug-2025

Exp. date: Aug-2027

Reg.no. 042943

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains: **Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate...4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit: 7.0-8.5 Determined:7.5 at 25.0°C

CONTAINER CONTENT: Limit: Not less than Nominal Determined: 1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.

Dexamethasone Sodium Phosphate is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 4.21 mg/ml (105.32%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.041 mg/ml (Does NOT Comply)

STERILITY TEST: The sample is sterile

RESULT: The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, o/o CEO DHA Bahawalpur reported that: -

- i. She, on 02.10.2025, inspected the premises of Medicine Store CEO DHA Bahawalpur, took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 0000238355 & 0000238356 dated 02.10.2025.
- ii. Store Keeper Medicine Store CEO DHA Bahawalpur provided the Invoice/Bill/Warranty No. 111860 Dated 24-09-2025 issued by M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore as a proof of purchase of the said drug.
- iii. Warrantor portions of drug samples were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
- iv. Copies of test/analysis reports were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
- v. In response the firm submitted retesting request which was **Turned Down** by the Board in its 296th meeting dated 15-01-2026.
- vi. The Provincial Inspector of Drugs requested for grant of permission for prosecution against above-mentioned accused, 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:-
 - a. **Manufacturing for sale/ sale of Adulterated Drugs**
 - b. **Issuance of False Warranty**

3. Show cause notice(s) issued to accused persons dated 21-01-2026.

4. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 2

PQCB/MSS-240904/ 2025

Tehsil Bahawalpur City District Bahawalpur

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore through its Director Muhammad Bilal Javed 2. Muhammad Bilal Javed (CNIC#35201-5070788-7) Director 3. Muhammad Faheem (CNIC# 35404-7608209-5) Production Incharge 4. Abdul Rauf Khan (CNIC#61101-1959062-3) Quality Control Incharge/ Warrantor of M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore.
Drug Inspector	

Summary of the case:

- Sampling date (Form 4): 22-10-2025
- Sent to DTL (Form 6): 23-10-2025
- Date of receipt in DTL: 25-10-2025
- DTL Report Date (Form 7): 06-12-2025
- DTL Time Extension: DTL report not time barred
- DI intimation to firm: 13-12-2025
- Retesting request if any: Yes dated 31-12-2025
- Fate of retesting request: Turn Down in 296th meeting dated 15-01-2026
- Investigation report Dated: 03-01-2026
- Permission for issuance of SCN: 296th meeting dated 15-01-2026
- SCN Issued: 20-01-2026
- History (2023 onwards): Firm: 67
- Product: 56

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

Drug Sample	Batch	Manufacturer	TRA No. and Date
Injection Neudex [Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg/ml] Mfg. date:Sep-2025 Exp. date:Sep-2027	DX050	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore	01-10096005896/DTL 06-12-2025

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains: **Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate.. 4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit:7.0-8.5 Determined:7.6 at 24.9°C

CONTAINER CONTENT: Limit:Not less than Nominal_Determined:1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated	4 mg/ml
Determined	4.18 mg/ml (104.51%)
Limit	90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined **0.073 mg/ml** **(Does NOT Comply)**

STERILITY TEST: The sample is sterile

RESULT: The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

Note: Drugs Testing Laboratory Faisalabad vide letter no. 0307/DS/DTL/FSD dated 29-12-2025 reported that, same batch no. DX050 of the same drug sample is sent by Provincial Inspector of Drugs, Toba Tek Singh and is reported in the light of decision of PQCB orders no. PQCB/ISSU-01/M-292/2025 dated 20-08-2025 and informed to Provincial Inspector of Drugs Toba Tek Singh that this batch is already declared Adulterated by DTL Punjab, Bahawalpur vide test/analysis report no. 01-10096005896/DTL dated 06-12-2025.

BRIEF FACTS OF THE CASE:

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

- i. She, on 22.10.2025, inspected the premises of Central Pharmacy Bahawal Victoria Hospital Bahawalpur, took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 0000240904 dated 23.10.2025.
- ii. Store Keeper Central Pharmacy Bahawal Victoria Hospital Bahawalpur provided the Invoice/Bill/Warranty No. 111876 Dated 09-10-2025 issued by M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore as a proof of purchase of the said drug.
- iii. Warrantor portion of drug sample was sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
- iv. A copy of test/analysis report were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
- v. In response the firm submitted retesting request which was **Turned Down** by the Board in its 296th meeting dated 15-01-2026.
- vi. 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:-

a. Manufacturing/ Selling/ Stocking of Adulterated Drug

b. Issuance of False Warranty

3. Show cause notice(s) issued to accused persons dated 20-01-2026.

4. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 3

PQCB/MSS-239921/ 2025

Tehsil Bahawalpur City District Bahawalpur

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore through its Director Muhammad Bilal Javed 2. Muhammad Bilal Javed Director 3. Muhammad Faheem Production Incharge 4. Abdul Rauf Khan Quality Control Incharge/ Warrantor of M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore.
Drug Inspector	

Summary of the case:

- Sampling date (Form 4): 17-10-2025
- Sent to DTL (Form 6): 18-10-2025
- Date of receipt in DTL: 20-10-2025
- DTL Report Date (Form 7): 06-12-2025
- DTL Time Extension: DTL report not time barred
- DI intimation to firm: 13-12-2025
- Retesting request if any: Yes dated 31-12-2025
- Fate of retesting request: Turn Down in 296th meeting dated 15-01-2026
- Investigation report Dated: 03-01-2026
- Permission for issuance of SCN: 296th meeting dated 15-01-2026
- SCN Issued: 20-01-2026
- History (2023 onwards): Firm: 67
- Product: 56

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

Drug Sample	Batch	Manufacturer	TRA No. and Date
Injection Neudex [Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg/ml] Mfg. date: Sep-2025	DX049	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore	01- 10096005753/DTL 06-12-2025

Exp. date: Sep-2027

Reg.no.042943

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains:**Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphat.. 4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH:Limit:7.0-8.5_Determined:7.5 at 23.5 °C

CONTAINER CONTENT:Limit:Not less than Nominal_Determined: 1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated	4 mg/ml
Determined	4.03 mg/ml (100.77%)
Limit	90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.154 mg/ml (Does NOT Comply)

STERILITY TEST: The sample is sterile

RESULT: The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

BRIEF FACTS OF THE CASE:

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

- i. She, on 17.10.2025, inspected the premises of Central Pharmacy Bahawal Victoria Hospital Bahawalpur, took below mentioned drug sample on Form No.04 for the

purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 0000239921 dated 18.10.2025.

- ii. Store Keeper Central Pharmacy Bahawal Victoria Hospital Bahawalpur provided the Invoice/Bill/Warranty No. 111876 Dated 09-10-2025 issued by M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore as a proof of purchase of the said drug.
 - iii. Warrantor portion of drug sample was sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
 - iv. A copy of test/analysis report was sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
 - v. In response the firm submitted retesting request which was **Turned Down** by the Board in its 296th meeting dated 15-01-2026.
2. 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:-

- a. **Manufacturing/ Selling/ Stocking of Adulterated Drug**
- b. **Issuance of False Warranty**

3. Show cause notice(s) issued to accused persons dated 20-01-2026.
4. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 4

PQCB/MSS-238355, 238356/ 2025

Drug Inspector CEO DHA Bahawalpur

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore through its Director Muhammad Bilal Javed 2. Muhammad Bilal Javed Director 3. Muhammad Faheem Production Manager 4. Abdul Rauf Khan Quality Control Incharge/ Warrantor of M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore.
Drug Inspector	

Summary of the case:

- **Sampling date (Form 4): 02-10-2025**
- **Sent to DTL (Form 6): 02-10-2025**
- **Date of receipt in DTL: 03-10-2025**
- **DTL Report Date (Form 7): 26-11-2025**
- **DTL Time Extension: DTL report not time barred**
- **DI intimation to firm: 01-12-2025**
- **Retesting request if any: Yes dated 16-12-2025**
- **Fate of retesting request: Turn Down in 296th meeting dated 15-01-2026**
- **Investigation report Dated: 31-12-2025**
- **Permission for issuance of SCN: 296th meeting dated 15-01-2026**
- **SCN Issued: 21-01-2026**
- **History (2023 onwards): Firm: 67**
- **Product: 56**

Following Drug samples after test/analysis was declared as **Adulterated** by Government Analyst Drug Testing Laboratory, Bahawalpur, as detailed below:

Sr.	Drug Sample	Batch	Manufacturer	TRA No. and Date
1.	Injection Neudex [Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg/ml] Mfg. date: Aug-2025	DX037	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore	01- 10096005393/DTL 26-11-2025

Exp. date: Aug-2027

Reg.no. 042943

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains: **Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphat... 4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit: 7.0-8.5 Determined: 7.6 at 25.8°C

CONTAINER CONTENT: Limit: Not less than Nominal Determined: 1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 3.99 mg/ml (99.64%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.058 mg/ml (Does NOT Comply)

STERILITY TEST: The sample is sterile

RESULT: The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

2.	Drug Sample	Batch	Manufacturer	TRA No. and Date
	Injection Neudex [Dexamethasone Sodium Phosphate eq. to	DX038	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhupura Road, Lahore	01- 10096005394/DTL

Dexamethasone Phosphate 4mg/ml]

26-11-2025

Mfg. date: Aug-2025

Exp. date: Aug-2027

Reg.no. 042943

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains: **Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate...4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit: 7.0-8.5 Determined:7.5 at 25.0°C

CONTAINER CONTENT: Limit: Not less than Nominal Determined: 1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.

Dexamethasone Sodium Phosphate is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 4.21 mg/ml (105.32%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined **0.041 mg/ml** **(Does NOT Comply)**

STERILITY TEST: The sample is sterile

RESULT: The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, o/o CEO DHA Bahawalpur reported that: -

- i. She, on 02.10.2025, inspected the premises of Medicine Store CEO DHA Bahawalpur, took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 0000238355 & 0000238356 dated 02.10.2025.
- ii. Store Keeper Medicine Store CEO DHA Bahawalpur provided the Invoice/Bill/Warranty No. 111860 Dated 24-09-2025 issued by M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore as a proof of purchase of the said drug.
- iii. Warrantor portions of drug samples were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
- iv. Copies of test/analysis reports were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
- v. In response the firm submitted retesting request which was **Turned Down** by the Board in its 296th meeting dated 15-01-2026.
- vi. The Provincial Inspector of Drugs requested for grant of permission for prosecution against above-mentioned accused, 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:-
 - a. **Manufacturing for sale/ sale of Adulterated Drugs**
 - b. **Issuance of False Warranty**

3. Show cause notice(s) issued to accused persons dated 21-01-2026.

4. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 5

PQCB/MSS-238993, 238994/ 2025

Tehsil & District Jhelum

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore through its Director Muhammad Bilal Javed 2. Muhammad Bilal Javed Director 3. Muhammad Faheem Production Incharge 4. Abdul Rauf Khan Quality Control Incharge/ Warrantor
Drug Inspector	
of M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore.	

Summary of the case:

- **Sampling date (Form 4): 08-10-2025**
- **Sent to DTL (Form 6): 08-10-2025**
- **Date of receipt in DTL: 13-10-2025**
- **DTL Report Date (Form 7): 19-11-2025**
- **DTL Time Extension: DTL report not time barred**
- **DI intimation to firm: 28-11-2025**
- **Retesting request if any: Yes dated 04-12-2025**
- **Fate of retesting request: Turn Down in 296th meeting dated 15-01-2026**
- **Investigation report Dated: 12-01-2026**
- **Permission for issuance of SCN: 296th meeting dated 15-01-2026**
- **SCN Issued: 20-01-2026**
- **History (2023 onwards): Firm: 67**
- **Product: 56**

Following Drug samples after test/analysis were declared as **Adulterated** by Government Analyst Drug Testing Laboratory, Rawalpindi, as detailed below:

Sr	Drug Sample	Batch	Manufacturer	TRA No. and Date
1.	Injection Neudex 1ml [Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg/ml] Mfg. date: Exp. date: Reg.no.	DX043	M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore	TRA # 01-74015063/DTL dated 19-11-2025

Sep-2025 Sep-2027 042943

Specs Applied: USP 2025/Others/In House

PHYSICAL DESCRIPTION:

Transparent liquid filled in labelled transparent glass ampoule, further packed in outer labelled carton containing 25 ampoules. (1*25 ampoules).

pH TEST: Limit: 7.0-8.5, Result: 7.4 @ 23.6°C (USP-2025) (Complies the test)

IDENTIFICATION:

Dexamethasone Sodium Phosphate Identified (Test-B) (HPLC)(USP-2025) (Complies the test)

Dexamethasone (Base) is Identified (HPLC) (In-House) (DOES NOT COMPLY)

ASSAY:

Dexamethasone Phosphate:

Stated: 4mg/ml, Determined: 4.239mg/ml (HPLC)(USP-2025), Percentage: 105.98 % (Complies the test),
Rounded Off (As per USP): 106.0%, Limit: 90.0% - 115.0%

Dexamethasone (Base): Determined: 0.084 mg/ml (HPLC) (In-House) (DOES NOT COMPLY)

STERILITY: No visible microbial growth observed. (Direct Inoculation), Sample is sterile (USP-2025)
(Complies the test)

ENDOTOXIN TEST: Observed: No Gel formed, Limit: NMT 31.3 Eu/mg of dexamethasone phosphate_(USP-2025) (Complies the test)

RESULT: The above sample is "Adulterated" as defined under clause (iv) of sub-section (a) of section 3 of The Drugs Act, 1976 as it contains Dexamethasone (Base) as an ingredient a substance other than the prescribed substance.

2.	Drug Sample	Batch	Manufacturer	TRA No. and Date
	<p>Injection Neudex 1ml</p> <p>[Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg/ml]</p> <p>Mfg. date: Exp. date: Reg.no.</p> <p>Sep-2025 Sep-2027 042943</p>	DX044	M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore	TRA # 01-74015064/DTL dated 19-11-2025

Specs Applied: USP 2025/Others/In House

PHYSICAL DESCRIPTION:

Transparent liquid filled in labelled transparent glass ampoule, further packed in outer labelled carton containing 25 ampoules. (1*25 ampoules).

pH TEST: Limit: 7.0-8.5, Result: 7.4 @ 23.6°C (USP-2025) (Complies the test)

IDENTIFICATION: Dexamethasone Sodium Phosphate Identified (Test-B) (HPLC)(USP-2025) (Complies the test)

Dexamethasone (Base) is Identified (HPLC) (In-House) (DOES NOT COMPLY)

ASSAY:

Dexamethasone Phosphate:

Stated: 4 mg/ml, Determined: 4.279mg/ml (HPLC)(USP-2025), Percentage: 106.94% (Complies the test)

Rounded Off (As per USP): 107.0%, Limit: 90.0% - 115.0%

Dexamethasone (Base): Determined: **0.067 mg/ml** (HPLC) (In-House) **(DOES NOT COMPLY)**

STERILITY: No visible microbial growth observed. (Direct Inoculation), Sample is sterile (USP-2025) (Complies the test)

ENDOTOXIN TEST: Observed: No Gel-clot formed, Limit: NMT 31.3 Eu/mg of dexamethasone phosphate

(USP-2025) (Complies the test)

RESULT: The above sample is "Adulterated" as defined under clause (iv) of sub-section (a) of section 3 of The Drugs Act, 1976 as it contains Dexamethasone (Base) as an ingredient a substance other than the prescribed substance.

BRIEF FACTS OF THE CASE:

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

- i. He, on 08.10.2025, inspected the premises of Main Medicine Store CEO Office DHA Jhelum, took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide memorandum no. 0000238993 & 0000238994 dated 08.10.2025.
- ii. Store Keeper Main Medicine Store CEO Office DHA Jhelum provided the Invoice/Bill/Warranty No. 111876 Dated 30-09-2025 issued by M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore as a proof of purchase of the said drug.
- iii. Warrantor portion of drug samples was sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
- iv. Copies of test/analysis reports were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.

- v. In response the firm submitted retesting request which was **Turned Down** by the Board in its 296th meeting dated 15-01-2026.
- vi. 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:-
 - vii. **Manufacture for sale of/ sale of Adulterated Drugs**
 - viii. **Issuance of False Warranty**
- 3. Show cause notice(s) issued to accused persons dated 20-01-2026.
- 4. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 6

PQCB/MSS-240858, 240859, 240860/ 2025

Tehsil Bahawalpur City District Bahawalpur

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore through its Director Muhammad Bilal Javed 2. Muhammad Bilal Javed Director 3. Muhammad Faheem Production Incharge 4. Abdul Rauf Khan Quality Control Incharge/ Warrantor of M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore.
Drug Inspector	

Summary of the case:

- **Sampling date (Form 4): 22-10-2025**
- **Sent to DTL (Form 6): 23-10-2025**
- **Date of receipt in DTL: 25-10-2025**
- **DTL Report Date (Form 7): 06-12-2025**
- **DTL Time Extension: DTL report not time barred**
- **DI intimation to firm: 13-12-2025**
- **Retesting request if any: Yes dated 31-12-2025**
- **Fate of retesting request: Turn Down in 296th meeting dated 15-01-2026**
- **Investigation report Dated: 03-01-2026**
- **Permission for issuance of SCN: 296th meeting dated 15-01-2026**
- **SCN Issued: 20-01-2026**
- **History (2023 onwards): Firm: 67**
- **Product: 56**

Following Drug samples after test/analysis were declared as **Adulterated** by Government Analyst Drug Testing Laboratory, Bahawalpur, as detailed below:

Sr.	Drug Sample	Batch	Manufacturer	TRA No. and Date
1.	Injection Neudex [Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg/ml] Mfg. date: Sep-2025	DX046	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore	01- 10096005893/DTL 06-12-2025

Exp. date: Sep-2027

Reg.no.042943

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains: **Dexamethasone Sodium Phosphate eq.to Dexamethasone Phosphate.. 4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit:7.0-8.5 Determined: 7.6 at 24.5 °C

CONTAINER CONTENT: Limit:Not less than Nominal Determined: 1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 4.23 mg/ml (105.71%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.059 mg/ml (Does NOT Comply)

STERILITY TEST:The sample is sterile

RESULT:The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

2.	Drug Sample	Batch	Manufacturer	TRA No. and Date
	Injection Neudex [Dexamethasone Sodium Phosphate eq. to	DX047	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhupura Road, Lahore	01-10096005894/DTL 06-12-2025

Dexamethasone Phosphate 4mg/ml]

Mfg. date: Sep-2025

Exp. date: Sep-2027

Reg.no.042943

Specs Applied: USP 2025

COMPOSITION:Each 1ml contains:**Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate..... 4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit:7.0-8.5 Determined:7.5 at 24.1 °C

CONTAINER CONTENT:Limit: Not less than Nominal Determined: 1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 4.13 mg/ml (103.28%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.097 mg/ml (Does NOT Comply)

STERILITY TEST: The sample is sterile

RESULT:The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

3.	Drug Sample	Batch	Manufacturer	TRA No. and Date
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Injection Neudex

DX048

M/S Neutro Pharma Pvt. Ltd., 9.5 Km,
Sheikhupura Road, Lahore

01-10096005895/DTL

[Dexamethasone Sodium Phosphate eq. to
Dexamethasone Phosphate 4mg/ml]

06-12-2025

Mfg. date: Sep-2025

Exp. date: Sep-2027

Reg.no.042943

Specs Applied: USP 2025

COMPOSITION:Each 1ml contains:**Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate..... 4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit:7.0-8.5 Determined:7.5 at 24.7°C

CONTAINER CONTENT: Limit:Not less than Nominal Determined:1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 4.19 mg/ml (104.70%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.082 mg/ml (Does NOT Comply)

STERILITY TEST:The sample is sterile

RESULT:The sample is declared as "ADULTERATED" as per section 3 (a) (iv) of The Drugs Act 1976.

BRIEF FACTS OF THE CASE:

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

- i. She, on 22.10.2025, inspected the premises of Accident and Emergency Department Bahawal Victoria Hospital Bahawalpur, took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 0000240858, 0000240859 & 0000240860 dated 23.10.2025.
 - ii. Store Keeper Accident and Emergency Department Bahawal Victoria Hospital Bahawalpur provided the Invoice/Bill/Warranty No. 111878 Dated 09-10-2025 issued by M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore as a proof of purchase of the said drug.
 - iii. Warrantor portions of drug samples were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
 - iv. Copies of test/analysis reports were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
 - v. In response the firm submitted retesting request which was **Turned Down** by the Board in its 296th meeting dated 15-01-2026.
2. 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:-

a. Manufacturing/ Selling/ Stocking of Adulterated Drugs

b. Issuance of False Warranty

3. Show cause notice(s) issued to accused persons dated 20-01-2026.
4. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 7

PQCB/MSS-238817, 238818/ 2025

Tehsil & District Lodhran

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore through its Director Muhammad Bilal Javed 2. Muhammad Bilal Javed Director 3. Muhammad Faheem Production In-charge 4. Abdul Rauf Khan Quality Control In-charge/ Warrantor of M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore.
Drug Inspector	

Summary of the case:

- **Sampling date (Form 4): 07-10-2025**
- **Sent to DTL (Form 6): 07-10-2025**
- **Date of receipt in DTL: 08-10-2025**
- **DTL Report Date (Form 7): 02-12-2025**
- **DTL Time Extension: DTL report not time barred**
- **DI intimation to firm: 08-12-2025**
- **Retesting request if any: Yes dated 18-12-2025**
- **Fate of retesting request: Turn Down in 296th meeting dated 15-01-2026**
- **Investigation report Dated: 31-12-2025**
- **Permission for issuance of SCN: 296th meeting dated 15-01-2026**
- **SCN Issued: 21-01-2026**
- **History (2023 onwards): Firm: 67**
- **Product: 56**

Following Drug samples after test/analysis was declared as **Adulterated** by Government Analyst Drug Testing Laboratory, Multan, as detailed below:

Sr.	Drug Sample	Batch	Manufacturer	TRA No. and Date
1.	Injection Neudex [Each 1 ml contains: Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg] 1 ml Mfg. date: Aug-2025	DX039	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore	01-105012828/DTL 02-12-2025

Exp. date: Aug-2027

Reg.no. 042943

Specs Applied: USP 2025

DESCRIPTION: Clear colorless to light straw-colored solution in transparent Glass ampoule, sealed and labelled, further packed in labelled outer carton.

pH:

Limit: 7.0-8.5

Determined: 7.5 at 25.2°C (COMPLIES)

CONTAINER CONTENT:

Limit: Not less than Nominal

Determined: 1 mL (COMPLIES)

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/mL

Determined 3.92 mg/mL (98.0%)

Limit 90.0-115.0% (COMPLIES)

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.055 mg/mL (Does NOT Comply)

Sterility It conforms to sterility test (COMPLIES)

RESULT:The sample is declared as "**ADULTERATED**" as per section 3(a)(iv) of The Drugs Act 1976.

2.	Drug Sample	Batch	Manufacturer	TRA No. and Date
	<p>Injection Neudex</p> <p>[Each 1 ml contains: Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg] 1 ml</p> <p>Mfg. date: Sep-2025</p> <p>Exp. date: Sep-2027</p> <p>Reg.no. 042943</p>	DX041	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhupura Road, Lahore	01-105012829/DTL 02-12-2025
<p>Specs Applied: USP 2025</p> <p>DESCRIPTION: Clear colorless to light straw-colored solution in transparent Glass ampoule, sealed and labelled, further packed in labelled outer carton.</p> <p>pH:</p> <p style="text-align: center;">Limit: 7.0-8.5</p> <p>Determined: 7.6 at 25.7°C (COMPLIES)</p> <p>CONTAINER CONTENT:</p> <p style="text-align: center;">Limit: Not less than Nominal</p> <p>Determined: 1 mL (COMPLIES)</p> <p>IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:</p> <p>The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. Dexamethasone Sodium Phosphate is identified.</p> <p>Further extra peak observed in sample chromatogram.</p> <p>ASSAY OF DEXAMETHASONE PHOSPHATE:</p> <p style="text-align: center;">Stated 4 mg/mL</p> <p style="text-align: center;">Determined 4.104 mg/mL (102.6%)</p> <p style="text-align: center;">Limit 90.0-115.0% (COMPLIES)</p>				

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.045 mg/mL (Does NOT Comply)

Sterility It conforms to sterility test (COMPLIES)

RESULT: The sample is declared as "ADULTERATED" as per section 3(a)(iv) of The Drugs Act 1976.

Note: Drugs Testing Laboratory Punjab, Lahore vide letter no. DPN/29270/DTL dated 11-12-2025 reported that, same batch no. DX039 of the same drug sample is sent by Provincial Inspector of Drugs, Tehsil & District Narowal and is reported in the light of decision of PQCB orders no. PQCB/ISSU-01/M-292/2025 dated 20-08-2025 and informed to Provincial Inspector of Drugs Tehsil & District Narowal that this batch is already declared Adulterated by DTL Punjab, Multan vide test/analysis report no. 01-105012828/DTL dated 02-12-2025.

BRIEF FACTS OF THE CASE:

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

- i. He, on 07.10.2025, inspected the premises of Main Medicine Store District Health Authority, Near BHU Rukanpur Lodhran, took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Multan vide memorandum no. 0000238817 & 0000238818 dated 07.10.2025.
 - ii. Manufacturer portions of drug samples were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore.
 - iii. Store Keeper Main Medicine Store District Health Authority, Near BHU Rukanpur Lodhran provided the Invoice/Bill/Warranty No. 111872 Dated 29-09-2025 issued by M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore as a proof of purchase of the said drug.
 - iv. Warrantor portions of drug samples were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
 - v. Copies of test/analysis reports were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
 - vi. In response the firm submitted retesting request which was **Turned Down** by the Board in its 296th meeting dated 15-01-2026.
2. 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:-

- a. **Manufacturing for sale/ sale of Adulterated Drugs**
- b. **Issuance of False Warranty**

3. Show cause notice(s) issued to accused persons dated 21-01-2026.
4. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 8

PQCB/MSS-235919, 235921, 235918, 235920/ 2025

Tehsil & District Bahawalnagar

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore through its Director Muhammad Bilal Javed 2. Muhammad Bilal Javed Director 3. Muhammad Faheem Production Incharge 4. Abdul Rauf Khan Quality Control Incharge/ Warrantor of M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore.
Drug Inspector	

Summary of the case:

- **Sampling date (Form 4): 12-09-2025**
- **Sent to DTL (Form 6): 12-09-2025**
- **Date of receipt in DTL: 15-09-2025**
- **DTL Report Date (Form 7): 26-11-2025**
- **DTL Time Extension: Granted in 294th meeting dated 20-11-2025**
- **DI intimation to firm: 03-12-2025**
- **Retesting request if any: Yes dated 22-12-2025**
- **Fate of retesting request: Turn Down in 296th meeting dated 15-01-2026**
- **Investigation report Dated: 13-01-2026**
- **Permission for issuance of SCN: 296th meeting dated 15-01-2026**
- **SCN Issued: 20-01-2026**
- **History (2023 onwards): Firm: 67**
- **Product: 56**

Following Drug samples after test/analysis were declared as **Adulterated** by Government Analyst Drug Testing Laboratory, Bahawalpur, as detailed below:

Sr.	Drug Sample	Batch	Manufacturer	TRA No. and Date
1.	Injection Neudex [Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg/ml] Mfg. date: Aug-2025	DX035	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore	01- 10096004959/DTL 26-11-2025

Exp. date: Aug-2027

Reg.no. 042943

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains: **Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate.....4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit: 7.0-8.5 Determined:7.6 at 24.5°C

CONTAINER CONTENT: Limit: Not less than Nominal Determined:1.04 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 4.16 mg/ml (104.06%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.074 mg/ml (Does NOT Comply)

STERILITY TEST: The sample is sterile.

Note: The extension is granted via PQCB order no. **PQCB/TEX-BHW-294/2025** Dated 20-11-2025.

RESULT: The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

2.	Drug Sample	Batch	Manufacturer	TRA No. and Date
	Injection Neudex	DX036	M/S Neutro Pharma Pvt. Ltd., 9.5 Km,	01-

[Dexamethasone Sodium Phosphate eq. to
Dexamethasone Phosphate 4mg/ml]

Sheikhupura Road, Lahore

10096004960/DTL

26-11-2025

Mfg. date: Aug-2025

Exp. date: Aug-2027

Reg.no. 042943

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains: **Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate.... 4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit:7.0-8.5 Determined:7.6 at 23.8°C

CONTAINER CONTENT: Limit: Not less than Nominal Determined:1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 4.06 mg/ml (101.59%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.067 mg/ml (Does NOT Comply)

STERILITY TEST: The sample is sterile.

Note: The extension is granted via PQCB order no. **PQCB/TEX-BHW-294/2025** Dated 20-11-2025.

RESULT:The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

3. Drug Sample	Batch	Manufacturer	TRA No. and Date						
<p>Injection Neudex</p> <p>[Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg/ml]</p> <p>Mfg. date: Aug-2025</p> <p>Exp. date: Aug-2027</p> <p>Reg.no. 042943</p>	DX032	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhupura Road, Lahore	01-10096004957/DTL 26-11-2025						
<p>Specs Applied: USP 2025</p> <p>COMPOSITION: Each 1ml contains: Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate..... 4mg</p> <p>DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml</p> <p>pH: Limit:7.0-8.5_Determined:7.6 at 24.7°C</p> <p>CONTAINER CONTENT: Limit: Not less than Nominal Determined:1 ml</p> <p>IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:</p> <p>The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. Dexamethasone Sodium Phosphate is identified.</p> <p>Further extra peak observed in sample chromatogram.</p> <p>ASSAY OF DEXAMETHASONE PHOSPHATE:</p> <table style="margin-left: auto; margin-right: auto;"> <tr> <td style="padding-right: 20px;">Stated</td> <td>4 mg/ml</td> </tr> <tr> <td style="padding-right: 20px;">Determined</td> <td>4.11 mg/ml (102.83%)</td> </tr> <tr> <td style="padding-right: 20px;">Limit</td> <td>90.0-115.0%</td> </tr> </table> <p>Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):</p> <p>The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).</p> <p>Dexamethasone (Base) is Identified.</p> <p>Determined 0.051 mg/ml (Does NOT Comply)</p> <p>STERILITY TEST: The sample is sterile.</p>				Stated	4 mg/ml	Determined	4.11 mg/ml (102.83%)	Limit	90.0-115.0%
Stated	4 mg/ml								
Determined	4.11 mg/ml (102.83%)								
Limit	90.0-115.0%								

Note: The extension is granted via POCB order no. **PQCB/TEX-BHW-294/2025** Dated 20-11-2025.

RESULT: The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

4.	Drug Sample	Batch	Manufacturer	TRA No. and Date
	Injection Neudex [Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg/ml] Mfg. date: Aug-2025 Exp. date: Aug-2027 Reg.no. 042943	DX034	M/S Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhupura Road, Lahore	01-10096004958/DTL 26-11-2025

Specs Applied: USP 2025

COMPOSITION: Each 1ml contains: **Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate..... 4mg**

DESCRIPTION: Clear colorless to light straw-colored solution in transparent glass

ampoule, sealed and labelled, further packed in labelled outer carton. Stated volume =1ml

pH: Limit:7.0-8.5 Determined:7.6 at 24.9°C

CONTAINER CONTENT: Limit:Not less than Nominal Determined:1 ml

IDENTIFICATION OF DEXAMETHASONE SODIUM PHOSPHATE:

The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. **Dexamethasone Sodium Phosphate** is identified.

Further extra peak observed in sample chromatogram.

ASSAY OF DEXAMETHASONE PHOSPHATE:

Stated 4 mg/ml

Determined 4.11 mg/ml (102.68%)

Limit 90.0-115.0%

Identification & Quantification of Adulteration of DEXAMETHASONE (Base) (HPLC-PDA, USP):

The retention time/PDA spectrum of the extra peak of the Sample solution corresponds to that of the Standard solution of Dexamethasone (Base).

Dexamethasone (Base) is Identified.

Determined 0.067 mg/ml (Does NOT Comply)

STERILITY TEST:The sample is sterile.

Note: The extension is granted via PQCB order no. **PQCB/TEX-BHW-294/2025** Dated 20-11-2025.

RESULT: The sample is declared as "**ADULTERATED**" as per section 3 (a) (iv) of The Drugs Act 1976.

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs Tehsil & District Bahawalnagar reported that:-

- i. He, on 12.09.2025, inspected the premises of Main Medicine Store CEO DHA Bahawalnagar, took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 0000235919, 0000235921, 0000235918, & 0000235920 dated 12.09.2025.
 - ii. Store Keeper Main Medicine Store CEO DHA Bahawalnagar provided the Invoice/Bill/Warranty No. 111850 Dated 09-09-2025 issued by M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore as a proof of purchase of the said drug.
 - iii. Warrantor portions of drug samples were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
 - iv. Copies of test/analysis reports were sent to M/s Neutro Pharma Pvt. Ltd., 9.5 Km, Sheikhpura Road, Lahore and they were asked to provide the requisite information in this regard.
 - v. In response the firm submitted retesting request which was **Turned Down** by the Board in its 296th meeting dated 15-01-2026.
2. 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:-

a. Manufacture for sale of/ sale of Adulterated Drugs

b. Issuance of False Warranty

3. Show cause notice(s) issued to accused persons dated 20-01-2026.
4. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD

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ITEM No. 2

SPURIOUS DRUG CASES

ITEM No. 3

FIR CASES

ITEM No. 4
SUBSTANDARD CASES

Case No. 1

PQCB/R-944/2021

DHQ/THQ Khushab

ATTENDANCE:

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">1. M/s Macter international Limited, F-216, S.I.T.E Karachi through Chief Operating Officer, Mujeeb Ur Rehman2. Mujeeb Ur Rehman Chief Operating Officer3. Zeeshan Khan Production Incharge4. Khalid Irfan Quality Control Incharge5. Muzammil Siddique Warrantor <p>of M/s Macter international Limited, F-216, S.I.T.E Karachi</p>
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SUMMARY OF THE CASE

1	Sampling Date: (Form 4)	22-07-2021
2	Sent to DTL (Form 6):	31-07-2021
3	Mfg. date	04-2021
	Exp date	03-2023
4	Date of receipt in DTL	04-08-2021
5	DTL Report date	02-10-2021
7	1ST DI Communication with firm	11-10-2021

8	Retesting Request of Firm	N/A
9	Investigation Report of DI	03-10-2024
10	SCN permission	286-M dated 30-10-2024
11	Show cause issued	06-11-2024
12	Reply of the firm	13-11-2024
13	Firm History: (2021-25)	Firm: 29 Product: 24

i. Following drug sample, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Powder for Suspension. ULTIMA 60ml [Clarithromycin125mg/5ml] Mfg date: 04-2021 Exp date: 03-2023	1009	M/s Macter international Limited, F-216, S.I.T.E Karachi-Pakistan.	01-75001923/DTL dated 02-10-2021	Results of test/analysis with specifications applied: USP 2021 <u>PHYSICAL DESCRIPTION:</u> WHITE to off white coored powder contained in multidose amber colored glass bottle with affixed label, sealed with aluminum screw cap on which company logo is printed further packed in outer labeled carton. On reconstitution, off white colored slightly viscous suspension formed. <u>pH:</u> Observed: 6.17 at 25.1°C (DOES NOT COMPLY) Limit: 4.0 - 5.4 <u>DELIVERABLE VOLUME:</u> <u>Observed:</u> 60ml

				<p>Limit: Average of 10 units is NLT the nominal volume</p> <p>IDENTIFICATION: Clarithromycin identified.</p> <p>ASSAY:</p> <p>Stated: 125 mg/ 5mL</p> <p>Determined: 124.075 mg/ 5mL</p> <p>Percentage: 99.26 %</p> <p>Limit: 90.0 – 115.0 %</p> <p>RESULT: The above sample is SUB-STANDARD, with respect to pH test performed.</p>
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, DHQ Hospital Khushab reported that: -

- i. She, on 02-07-2021 inspected the Medicine Store of THQ Hospital Khushab, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 100055 dated 03-07-2021.
- ii. Storekeeper of Main Medicine Store of THQ Hospital Khushab provided invoice/warranty No. 90364074 dated 26-05-2021 issued by M/s Macter international Limited, F-216, S.I.T.E Karachi.
- iii. Warrantor Portion of the drug sample was sent to M/s Macter international Limited, F-216, S.I.T.E Karachi.
- iv. A copy of Test/ Analysis reports was sent to M/s Macter international Limited, F-216, S.I.T.E Karachi with directions to provide the requisite information and 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: -

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

3. Show cause Notice (s) issued to the accused person(s) Dated 06-11-2024

Reply of showcause notice

We M/s. Macter International Limited (the "Company") acknowledge to receipt of your Letter No. PQCB/R-944/2021 Dated November 6th, 2024 (the "Letter"), which is received to us on November 12th, 2024. In this connection we would like to state that Batch No. 1009 of Ultima has already been decided/warned by the Provincial Quality Control Board (PQCB) reference no.PQCB/R-463,464/2021.

In this context we are also enclosing the required information as directed in your letter, i.e. copies of CNICS of technical staff, copy of Drug Manufacturing License, copy of Drug Registration etc.

Personal details of concern persons given below;

<i>Sr,No.</i>	<i>Names</i>	<i>Designation</i>	<i>CNIC</i>
1.	<i>Mujeeb Ur Rehman</i>	<i>Chief Operating Officer</i>	<i>421011-636923-5</i>
2	<i>Khalid Irfan</i>	<i>Quality Control</i>	<i>42301-6283542-3</i>
3	<i>Zeeshan khan</i>	<i>Production In-charge</i>	<i>41304-2308759-3</i>
4	<i>Muzammil Siddique</i>	<i>Warrantor</i>	<i>42401-0728133-0</i>

Pray: Provincial Quality Control Board has deliberated the case in detail and has done product specific inspection (PSI) of our facility w.r.t Ultima Dry Suspension pH related issues and have shared the recommendations. Under the guidance of PQCB team a CAPA has been developed and case has been resolved. Please find attached detailed CAPA, now we request that this case may be closed.

Truly yours,

4. Personal Hearing Notice (s) issued to the accused person(s) Dated 28-01-2026

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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9	Investigation Report of DI	22-08-2025 & 23-08-2025
10	SCN permission	293-M dated 25-09-2025
11	Show cause issued	05-01-2026
12	Reply of the firm	12-01-2026
13	Firm History: (2023-25)	<p>Firm: 19</p> <p>Product: 05</p> <p>01 is Standard from NIH (24AT002)(CEO Office Attock)</p> <p>01 Warning in 290 M dated 07-05-2025 (24AT061 FIC Hospital Faisalabad</p>

i. Following drug sample, after test/analysis were declared as Substandard by Government Analyst Drug Testing Laboratory **Bahawalpur** as detailed below

Sr,No	Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
1	<p>Tablet Askprol</p> <p>[Each Uncoated Tablet contains Paracetamol 500mg]</p> <p>Mfg Date: 03-2024</p> <p>Expiry Date: 02-2027</p> <p>Reg No.030726</p>	24AT063	<p>M/S Citi Pharma Ltd., (Formerly Askari Pharmaceuticals)</p> <p>3 Km, Head Baloki Road, Phool Nagar, Kasur</p>	<p>01-1009708716/DTL</p> <p>19-07-2024</p>	<p>Specification applied: BP 2024</p> <p>COMPOSITION: Each Uncoated tablet contains: Paracetamol BP 500mg</p> <p>DESCRIPTION:</p> <p>As per MS: "White to almost white colored round beveled edges tablets, having both sides plain."</p> <p>Observed: White to almost white colored, round shaped, slightly biconvex tablets without beveled edges, plain at both sides.</p> <p>Hence the sample is not complying the Physical Appearance as per MS. SUB-STANDARD.</p> <p>WEIGHT VARIATION:</p> <p>Limit: Average Weight ± 5%</p> <p>Results: Complies</p>

DISSOLUTION TEST:

Tolerance limit: NLT 70% (Q) in 45 Minutes.

ACCEPTANCE CRITERIA					
Each unit is not less than 70% in 45 minutes.					
1	2	3	4	5	6
99.44%	100.95%	101.45%	102.71%	100.83%	101.96%

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 500 mg/Tab
Determined 487.65 mg/Tab (97.53%)
Limit 95.0-105.0%

RESULT: The Sample is declared as "Sub-Standard" on basis of Physical Appearance.

2	Tablet Askprol [Each Uncoated Tablet contains Paracetamol 500mg] Mfg Date: 03-2024 Expiry Date: 02-2027 Reg	24AT064	M/S Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur	TRA No. 01-10097008717/ DTL dated 19-07-2024	Specification applied: BP 2024 <u>COMPOSITION:</u> Each Uncoated tablet contains: Paracetamol BP 500mg <u>DESCRIPTION:</u> As per MS: "White to almost white colored round beveled edges tablets, having both sides plain." Observed: White to almost white colored, round shaped, slightly biconvex tablets without beveled edges , plain at both sides. Hence the sample is not complying the Physical Appearance as per MS. SUB-STANDARD. <u>WEIGHT VARIATION:</u> Limit: Average Weight ± 5%
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No.030726

Results: Complies

DISSOLUTION TEST:

Tolerance limit: NLT 70% (Q) in 45 Minutes.

ACCEPTANCE CRITERIA

Each unit is not less than 70% in 45 minutes.

1	2	3	4	5	6
99.57%	98.43%	99.82%	96.29%	99.82%	99.44%

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 500 mg/Tab

Determined 498.65 mg/Tab (99.73%)

Limit 95.0-105.0%

RESULT: The Sample is declared as "Sub-Standard" on basis of Physical Appearance

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Govt Hajji Abdul Qayyum Teaching Hospital Sahiwal submitted that: -

- i. She, on 11-05-2024 inspected, the premises of Main Medicine store of Govt Hajji Abdul Qayyum Teaching Hospital Sahiwal took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memorandum no 198611 & 199328 dated 22-05-2024
- ii. The Medicine store keeper, provided invoice warranty No.GP/776/2024& GP/777/2024 dated 30-04-2024 by M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur
- iii. Warrantor portion of drug sample was sent to M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur
- iv. A copy of test/analysis report was sent to M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur
- v. Pursuant to the request of manufacturer, the retesting request was considered in 46nd Committee meeting dated 17-12-2024 which was withdrawn by firm

i. Manufacture for sale/ Sale of Substandard Drug

ii. Issuance of false warranty

2. Show cause Notice (s) issued to the accused person(s) Dated 05-01-2026

Reply of showcause notice

Respected Sir,

We Citi Pharma Limited located at 3.0 KM Head Balloki Road Kasur-Pakistan respectfully submits this response in reply to your letter No. PQCB/MSS-198611/2024,199328/2024 dated 05 January 2026

Kind reference is made to the earlier decision letter No. PQCB/MSS-200223/2024 dated 07 May 2025, issued in response to our challenge letter CP/PQCB/2024/013 concerning Askprol 500 mg Tablet, Batch No. 24AT061 (TRA: 01-97000207/DTL), which was declared substandard solely on the basis of physical appearance. The Board subsequently issued a warning, referred the sample to PDTRC for testing and closed the case upon the batch being declared passed. The present batch, cited on identical grounds, has also been challenged by us through a challenge letter CP/PQCB/2024/010 submitted in the same manner.

Sr.No.	Product Name	Batch #	TRA # & Date	Decision by PQCB	Current status
1	Askprol 500 mg Tablet (Paracetamol BP 500mg)	24AT061	01-97000207	Warning Issued & Sample send to PDTRC for testing	PASSED and closed
2	Askprol 500 mg Tablet (Paracetamol BP 500mg)	24AT063	01-10097008716 /DTL	Show cause Notice	
3	Askprol 500 mg Tablet (Paracetamol BP 500mg)	24AT064	01-10097008717 /DTL	Show cause Notice	

We therefore request that the present case of Askprol 500 mg Tablet, Batch No. 24AT063 24AT064M ,(TRA: 01-10097008716/DTL, 01-10097008716/DTL), be resolved by referring the sample to PDTRC for testing, in line with the previously closed case.

Citi Pharma Limited remains committed to full regulatory compliance and assures its complete cooperation. We shall promptly provide any further clarification or documentation required by your esteemed office.

Thanking you in anticipation.

3. Personal Hearing Notice (s) issued to the accused person(s) Dated 28-01-2026

4. Case is placed before Board for Descion

PROCEEDINGS AND DECISION BY THE BOARD:

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Case No. 3

PQCB/R-850/ 2021

Tehsil & District Bahawalnagar

ATTENDANCE:

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">1. M/S Macter International Limited, F-216, S.I.T.E., Karachi, Pakistan through its Chief Operating Officer, Mujeeb Ur Rehman,2. Mujeeb Ur Rehman Chief Operating Officer3. Khalid Irfan Quality Control Incharge4. Zeeshan Khan Production Incharge5. Muzammil Siddiqui Warrantor <p>of M/S Macter International Limited, F-216, S.I.T.E., Karachi, Pakistan.</p>
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Summary of the case:

- Sampling date (Form 4): 14-06-2021
- Sent to DTL (Form 6): 14-06-2021
- Date of receipt in DTL: 15-06-2021
- DTL Report Date (Form 7): 15-07-2021
- DTL Time Extension: DTL report not time barred
- DI intimation to firm: 13-11-2021
- Retesting request if any: Yes dated 16-08-2021 (directly in the o/o PQCB)
- Fate of retesting request: Substandard from NIH vide report no. 059-P/ 2022 dated 06.05.2022
- Investigation report Dated: 21-06-2023
- Permission for issuance of SCN: 264th meeting dated 14-07-2023
- SCN Issued: 11-10-2023
- Reply of the firm to show cause notice: Yes dated 24-10-2023
- History (2021-2025): Firm: 29
- Product: 24

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
Powder for Reconstitution Ultima 60ml (Clarithromycin:	1013	M/s Macter International Limited, F-216, S.I.T.E.,	01-77004608/ DTL dated: 15.07.2021	Specifications applied: USP 2020 Description: When reconstituted as directed each 5ml contains: Clarithromycin USP: 125mg (as coated granules 27.5%)

125mg/5ml)		Karachi, Pakistan		<p>Description: White coated granules when reconstituted gives white to off white colored suspension. (Stated Volume: 60ml)</p> <p>Dissolution (USP 2002): Limit: 4.0-5.4, Determined: 5.8 (Does not comply with specs.)</p> <p>Identification: Clarithromycin is identified.</p> <p>ASSAY: Complies</p> <p>RESULT: The sample is declared Substandard on the basis of pH Test.</p>
Mfg Date:				
05.2021				
Expiry Date:				
04.2023				
Regn No.				
029793				

Pursuant to the request of M/s Macter International Limited, F-216, S.I.T.E., Karachi, Pakistan the retesting request of the subject drug samples was considered in the 240th Meeting of the Board held on 15.03.2022 and the subject drug samples were sent to NIH, Islamabad, from where the samples was declared **Sub-standard** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result
Suspension Ultima (Clarithromycin: 125mg/5ml)	1013	M/s Macter International Limited, F-216, S.I.T.E., Karachi, Pakistan	059-P/ 2022 dated 06.05.2022	<p>Analysis with specifications applied: USP-39</p> <p>pH:</p> <p>Limit: 4.0-5.4</p> <p>Found: 5.9 ± 0.06 at 20-25°C (Does not comply)</p> <p>Result: The sample is of Sub-Standard quality on the basis of test performed.</p>

BRIEF FACTS OF THE CASE:

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

- i. The then Provincial Inspector of Drugs, on 14.06.2021, inspected the premises of MSD Bahawalnagar, O/o CEO (DHA), Bahawalnagar and took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 97405 dated 14.06.2021.
- ii. Store Keeper of MSD Bahawalnagar, O/o CEO (DHA), Bahawalnagar provided Invoice/warranty 90365406, Dated 31.05.2021 issued by M/S Macter International Limited, F-216, S.I.T.E., Karachi, Pakistan as a proof of its purchase.
- iii. Warrantor portion of drug sample was sent to M/S Macter International Limited, F-216, S.I.T.E.,

Karachi, Pakistan and they were asked to explain their position in this regard.

iv. A copy of test/analysis report was sent to M/ Macter International Limited, F-216, S.I.T.E., Karachi, Pakistan and they were asked to provide the requisite information in this regard. In response, the firm challenged the test/analysis reports of the drug samples and requested to re-test the above-mentioned drug samples from Appellate Laboratory, National Institute of Health, Islamabad.

2. Drug Inspector requested to grant permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP 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 persons dated 11-10-2023.

Reply of firm to show cause notice vide letter no. 1926 dated 24-10-2023:

Dear Sir,

We M/s. Macter International Limited (the "Company") acknowledge to receipt of your Letter No PQCB/R-850/2021 Dated October 11, 2023 (the "Letter"), which is received to us on October 23, 2023.

In this connection we would like to bring in your knowledge, that PQCB has already issued the warning with aspect to assay result & slight pH difference for the same batch no. 1013 of Ultima powder for reconstitution 60 ml with TRA No. 01-89004482 & TRA No. 01-89005124. Please find enclosed copy of PQCB decision.

Please note that the DTL test report limits (4.0-5.4) mentioned in your letter, indicates the pH instead of dissolution parameter therefore we are submitting our answer on the basis of pH results only.

We hope that this will meet your requirement. We are looking forward to your utmost support in the subject matter from your good office.

4. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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10	SCN permission	267-M dated 07-09-2023
11	Show cause issued	03-10-2023
12	Reply of the firm	13-10-2023
13	Firm History: (2021-25)	Firm: 18 Product: 13

Following drug sample, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below

Name of drug	Batch No.	Name of manufacturer	DTL Report No. & Date	Results of DTL Report
Syrup Speczine 120 ml [Promethazine HCl...5mg/ 5ml] Mfg. Date: 09- 2020 Expiry Date: 03- 2022 Reg. no.: 012597	510	M/s Spectrum Laboratories Pvt. Ltd. 8 km Raiwind Road, Lahore.	TRA No. 01- 75000559/DTL Dated: 01-07- 2021	Specifications of Test Applied: USP 2020 Physical Description: Pink coloured, slightly viscous liquid, filled in translucent white coloured plastic bottle, with affixed label closed with white coloured plastic screw cap on which "S L" is embossed, further packed in outer labelled unit carton. Identification: Promethazine HCl identified. Assay: <u>Stated:</u> 5 mg /5 ml <u>Determined:</u> 3.839 mg/5ml <u>Percentage:</u> 76.78 % (Does not Comply) <u>Limit:</u> 90.0 -110.0% Result: The above sample is Substandard as assay of Promethazine hydrochloride is less than the label claim.

BRIEF FACTS OF THE CASE

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

- i. His Predecessor, on 27-02-2021, inspected the business premises of M/s Abdullah Medical Store, Moh Lohan Khel, Market Kamar Mushani, Tehsil Isakhel, District Mianwali and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject sample of the drug-to-Drug Testing Laboratory, Rawalpindi vide memo number 86218 dated 28-02-2021.
- ii. M/s Abdullah Medical Store, Moh Lohan Khel, Market Kamar Mushani, Tehsil Isakhel, District Mianwali provided invoice/ warranty no. B 36484 dated 14-01-2021 issued by M/s Faheem Medicine Company Mahala Khenke Khel Ballokhel Road Mianwali as a proof of its purchase of the said drug.
- iii. Warrantor portion of the drug sample was sent to M/s Faheem Medicine Company Mahala Khenke Khel Ballokhel Road Mianwali.
- iv. M/s Faheem Medicine Company Mahala Khenke Khel Ballokhel Road Mianwali provided invoice/ warranty no. 1885 dated 07-11-2020 issued by M/s Spectrum Laboratories Pvt. Ltd. 8 km Raiwind Road, Lahore.
- v. A copy of test report of the drug sample was sent to M/s Spectrum Laboratories Pvt. Ltd. 8 km Raiwind Road, Lahore with directions to provide the requisite information and 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: -

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

Reply of showcause Notice

Kindly refer to your letter No: PQCB/R-843/2021 dated: 03-10-2023 received on 11-10-2023 on the above referred subject.

Respectfully submitted that:

1. The drug inspector took the above referred sample on 27-02-2021 from M/S Abdullah Medical Store Kamar Mushani Tehsil Esa Khel District Mianwali.
2. Besides others the following mandatory provisions of the Drugs act 1976 have not been complied with in this case.
3. Section 19 (3) (iii). Instead of 7 days the warrantor portion was sent to M/S Fahcem Medicine Company Mianwali vide your letter No: 151/Di-Esk/2021 dated 14-12-2021 (that is after 11 month).
4. Section 19 (3) (iv) the fourth portion ment for the manufacturer has never been received.
5. Section 22 (2) has not been complied with-regarding submission of test report.
6. Section 32 (3) (b) (i) has not been complied with-regarding submission of warranty.

Furthermore, we checked our control sample and it has been found to be of standard quality.

We challenged the test report of the Govt. Analyst.

The requisite information is as under:

Sr.No	Name	Designation
1	Irfan Maqbool Baig	Chief Executive
2	Mr. Muhammad Abdul Rehman	Production Incharge
3	Miss Fauzia Anjum	Quality Control Incharge
4	Mr. Nauman Haider	Warrantor

Copies of the valid DML, Reg. letter of Speczine Syrup, CNICs, appointment letters of the technical staff are enclosed herewith.

We challenged the test report No: TRA-01-7500559 dated 01-07-2021 of the Govt. Analyst DTL Rawalpindi. we do not know the fate of our request till today.

You are Therefore requested to kindly take a lenient view in the matter

3. Personal Hearing Notice (s) issued to the accused person(s) Dated 28-01-2026
4. Case is placed before the Board for Descion

PROCEEDINGS & DECISION BY THE BOARD

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Case No. 5

PQCB/MSS-200985/2024

Sahiwal Teaching Hospital Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur through its director Zameer -ul -Hassan 2. Zameer -ul -Hassan Director 3. Mushoraf Shahzad Production Manager 4. Muhammad Jameel Quality Control Incharge 5. Khansa Omer Warrantor
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SUMMARY OF THE CASE

1	Sampling Date: (Form 4)	12-06-2024
2	Sent to DTL (Form 6):	13-06-2024
3	Mfg. date 04-2021 Exp date 03-2023	03-2024 02-2027
4	Date of receipt in DTL	14-06-2024
5	DTL Report date	22-07-2024
6	Time extension	N/A
7	1ST DI Communication with firm	30-08-2024
8	Retesting Request of Firm	Placed in 46th Committee Meeting dated 17-12-2024 withdrawn by firm
9	Investigation Report of DI	24-12-2025

11	Show cause/personal hearing issued	28-01-2026
13	Firm History: (2023-25)	<p>Firm: 19</p> <p>Product: 05</p> <p>01 is Standard from NIH (24AT002) (CEO Office Attock)</p> <p>01 Warning in 290 M dated 07-05-2025 (24AT061 (FIC Hospital Faisalabad)</p>

i. Following drug sample, after test/analysis were declared as Substandard by Government Analyst Drug Testing Laboratory **Bahawalpur** as detailed below

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
<p>Tablet Askprol</p> <p>[Each Uncoated Tablet contains Paracetamol 500mg]</p> <p>Mfg Date: 03-2024</p> <p>Expiry Date: 02-2027</p> <p>Reg No.030726</p>	24AT063	<p>M/S Citi Pharma Ltd., (Formerly Askari Pharmaceuticals)</p> <p>3 Km, Head Baloki Road, Phool Nagar, Kasur</p>	<p>TRA No. 01-10097008976/DTL dated 22-07-2024</p>	<p>Specification applied: BP 2024</p> <p>COMPOSITION: Each Uncoated tablet contains:</p> <p style="text-align: center;">Paracetamol BP 500mg</p> <p>DESCRIPTION:</p> <p>As per MS: "White to almost white colored round beveled edges tablets, having both sides plain."</p> <p>Observed: White to almost white colored, round shaped, slightly biconvex tablets without beveled edges, plain at both sides.</p> <p>Hence the sample is not complying the Physical Appearance as per MS. SUB-STANDARD.</p> <p>WEIGHT VARIATION:</p> <p style="text-align: center;">Limit: Average Weight ± 5%</p> <p style="text-align: center;">Results: Complies</p> <p>DISSOLUTION TEST:</p> <p style="text-align: center;"><i>Tolerance limit: NLT 70% (Q) in 45 Minutes.</i></p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;">ACCEPTANCE CRITERIA</div>

				Each unit is not less than 70% in 45 minutes.	
				1	2
				3	4
				5	6
				93.27%	94.03%
				95.03%	95.79%
				94.03%	94.78%
				IDENTIFICATION: Paracetamol is identified.	
				ASSAY OF PARACETAMOL:	
				Stated	500 mg/Tab
				Determined	503.05 mg/Tab (100.61%)
				Limit	95.0-105.0%
				RESULT: The Sample is declared as "Sub-Standard" on the basis of Physical Appearance.	

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Sahiwal Teaching Hospital Sahiwal submitted that: -

- i. The then drug inspector, on 12-06-2024 inspected, Medicine store of Sahiwal Teaching Hospital Sahiwal took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, **Bahawalpur** vide memorandum no. 200985 dated 13-06-2024.
 - ii. The Medicine store keeper, provided invoice warranty No.GP/775/2024 dated 30-04-2024 by M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur
 - iii. Warrantor portion of drug sample was sent to M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur
 - iv. A copy of test/analysis report was sent to M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur
 - v. Pursuant to the request of manufacturer, the retesting request was considered in **46nd** Committee meeting dated 17-12-2024 which was withdrawn by firm
 - i. **Manufacture for sale/ Sale of Substandard Drug**
 - ii. **Issuance of false warranty**
2. Show cause Notice/Personal Hearing (s) issued to the accused person(s) Dated 28-01-2026.

Reply of Firm

Respected Sir,

We Citi Pharma Limited located at 3.0 KM Head Balloki Road Kasur-Pakistan respectfully submits this response in reply

to your letter No. 315/DI/STH

Kind reference is made to the earlier decision letter No. PQCB/MSS-200223/2024 dated 07 May 2025, issued in response to our challenge letter CP/PQCB/2024/013 concerning Askprol 500 mg Tablet, Batch No. 24AT061 (TRA: 01-97000207/DTL), which was declared substandard solely on the basis of physical appearance. The Board subsequently issued a warning, referred the sample to PDTRC for testing and closed the case upon the batch being declared passed. The present batch, cited on identical grounds, has also been challenged by us through a challenge letter CP/PQCB/2024/010 submitted in the same manner.

<i>Sr.No.</i>	<i>Product Name</i>	<i>Batch #</i>	<i>TRA # & Date</i>	<i>Decision by PQCB</i>	<i>Current status</i>
1	Askprol 500 mg Tablet (Paracetamol BP 500mg)	24AT061	01-97000207	Warning Issued & Sample send to PDTRC for testing	PASSED and closed
2	Askprol 500 mg Tablet (Paracetamol BP 500mg)	24AT063	01-10097008976 /DTL		

We therefore request that the present case of Askprol 500 mg Tablet, Batch No. 24AT063 ,(TRA: 01-10097008976/DTL), be resolved by referring the sample to PDTRC for testing, in line with the previously closed case.

Citi Pharma Limited remains committed to full regulatory compliance and assures its complete cooperation. We shall promptly provide any further clarification or documentation required by your esteemed office.

Thanking you in anticipation.

3. Case is placed before Board for Descion

PROCEEDINGS AND DECISION BY THE BOARD:

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Case No. 6

PQCB/MSS-215525/ 2025

Punjab Institute of Mental Health, Lahore

ATTENDANCE

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad, Pakistan through its Managing Director, Ch. Ayaz Munawar 2. Ch. Ayaz Munawar Managing Director 3. Imran Aslam Production Incharge/ Warrantor 4. Asif Iqbal Quality Control Incharge Of M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad, Pakistan
Drug Inspector	

SUMMARY OF THE CASE:

1	Sampling Date: (Form 4)	02-01-2025
2	Sent to DTL (Form 6):	02-01-2025
3	Date of receipt in DTL	02-01-2025
4	DTL Report date	01-03-2025
5	Time extension	Not Time Barred
6	1ST DI Communication with firm	08-03-2025
7	Retesting Request of Firm	Yes (13-03-2025)
8	Fate of Retesting Request	Withdrawn in 47-CM dated 30-05-2025
9	Sample Received by NIH	30-03-2022

10	NIH Report	16-05-2022 (Substandard)
11	Investigation Report of DI	09-08-2025
12	Show cause issued	19-01-2026
13	Reply of the firm	Not yet
14	Firm History (2022-25):	Firm: 4 Product: 2

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 No. & Date	DTL Test Report Result
Solution. Raze ORAL SOLUTION [Each ml of oral solution contains: Risperidone USP.....1mg] Mfg Date: Dec-2024 Expiry Date: Nov-2026 Regn No. 089564	RO-14	M/S Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad, Pakistan	01- 141001619/DTL dated 01-03-2025	Analysis with specifications applied: USP 2024 PHYSICAL DESCRIPTION: Colorless solution in amber color glass bottle having label pasted on it and sealed with aluminium screw cap, further packed in an outer carton containing leaflet and 2mL plastic dropper. Claimed volume=60 mL Determined volume=61mL pH: Determined: 2.81 at 24.1° C Limit: 2.0-4.0 IDENTIFICATION OF RISPERIDONE: Test A: The retention time of the major peak of the <i>Sample solution</i> corresponds to that of the <i>Standard</i> <i>solution</i> , as obtained in the <i>Assay</i> (Risperidone is identified). ASSAY OF RISPERIDONE:

				<p>Stated= 1 mg/mL</p> <p>Determined= 0.814 mg/mL</p> <p>Percentage= 81.4%</p> <p>Limits = 90.0% to 110.0% of the labelled amount</p> <p>(DOES NOT COMPLY)</p> <p><u>IDENTIFICATION OF ETHYLENE GLYCOL AND DIETHYLENE GLYCOL:</u> There are no peaks in chromatograms obtained with sample solutions similar to that of the peaks in the chromatogram obtained with standard solutions.</p> <p>(Ethylene Glycol and Diethylene Glycol not identified)</p> <p>RESULT: The above sample is <u>SUB-STANDARD</u> on the basis of assay of Risperidone performed as per USP.</p>
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BRIEF FACTS OF THE CASE

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

- i. She, on 02-01-2025, inspected the premises of Central Pharmacy, Punjab Institute of Mental Health Lahore, took following drug sample on Form No. 04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide memorandum no. 215525 dated 02-01-2025.
- ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed above.
- iii. Storekeeper, Central Pharmacy, Punjab Institute of Mental Health Lahore provided invoice/ warranty bearing No. 9339 dated 28-12-2024 issued by M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad, Pakistan as a proof of its purchase of subject drug sample.
- iv. Warrantor & Manufacturer portions of subject drug sample were sent to M/S Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad, Pakistan.
- v. A copy of test/analysis report was sent to M/S Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, 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 subject drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad. Later on, firm submitted written request for withdrawal of the retesting request vide letter Ref. No GP/PQCB/LHR/05/2025-1 Dated 30-05-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE COMMITTEE:

47th meeting held on 30-05-2025

The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **47th meeting held on 30-05-2025** under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. No one from Glitz Pharma attended the meeting.

The Secretary PQCB apprised the committee that Drug Testing Laboratory report conveyed by the Provincial inspector of Drugs to manufacturer vide letter no 257/DI/PIMH dated 08-03-2025 Manufacturer requested for retesting Ref No.GP/RO/PIMH/03/2025-01 dated 13-03-2025.The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. MSS 215525/2025 dated 07-04-2025 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard) and firm provided evidence.

The firm's representative submitted a written request for withdrawal of the retesting request vide letter Ref. No GP/PQCB/LHR/05/2025-1 Dated 30-05-2025.

The Committee after due deliberation and discussion unanimously decided to accept the firm's request for **withdrawal** of the retesting request of the drug sample and the Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board

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

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

3. Show-cause notice(s) issued to accused person(s) dated 19-01-2026

4. Personal hearing notice(s) issued to accused person(s) dated 02-02-2026

5. Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 7

PQCB/ R-923/2021

Tehsil & District Nankana Sahib

ATTENDANCE

Secretary DQCB	<u>Accused Persons involved in subject case</u>
	<ol style="list-style-type: none">1. M/s Macter international Limited, F-216, S.I.T.E Karachi through Chief Operating Officer, Mujeeb Ur Rehman2. Mujeeb Ur Rehman Chief Operating Officer3. Zeeshan Khan Production Incharge4. Khalid Irfan Quality Control Incharge5. Muzammil Siddiqui Warrantor <p>of M/s Macter international Limited, F-216, S.I.T.E Karachi</p>
Drug Inspector	

SUMMARY OF THE CASE:

1	Sampling Date: (Form 4)	05-05-2021
2	Sent to DTL (Form 6):	05-05-2021
3	Date of receipt in DTL	07-05-2021
4	DTL Report date	02-07-2021
5	Time extension	Not Time Barred
6	1ST DI Communication with firm	31-07-2021
7	Retesting Request of Firm	Yes (09-08-2021)
8	Fate of Retesting Request	Allowed in 240-M dated 15-03-2022
9	Sample Received by NIH	30-03-2022

10	NIH Report	16-05-2022 (Substandard)
11	Investigation Report of DI	06-11-2023
12	Show cause issued	31-07-2024
13	Reply of the firm	20-08-2024
14	Firm History:	Firm: 29 (2021-25) Product: 24 (2021-25)

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
ULTIMA 60ml [Clarithromycin 125mg/5ml] Powder for Suspension Mfg Date: 04-2021 Exp. Date: 03-2023 Regn No. 029793	1007	M/s Macter international Limited, F-216, S.I.T.E Karachi- Pakistan.	01- 166000896/DTL dated 02-07- 2021	Results of test/analysis with specifications applied: USP 2021 <u>PHYSICAL DESCRIPTION:</u> WHITE COLOURED GRANULAR POWDER FOR SUSPENSION IN AMBER GLASS BOTTLE WITH A SEALED SCREW CAP AND STOPPER. UPON RECONSTITUTION WITH WATER FORMS WHITE UNIFORM SUSPENSION. <u>pH:</u> Limit: 4.0 - 5.4 Determined: 5.76 at 24.9°C (DOES NOT COMPLY) <u>IDENTIFICATION:</u> The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (CLARITHROMYCIN IDENTIFIED) <u>ASSAY OF CLARITHROMYCIN:</u> Stated: 125.0 mg/ 5mL

				<p>Determined: 139.95 mg/ 5mL</p> <p>Percentage: 111.96 %</p> <p>Limit: 90.0 – 115.0 % of stated amount</p> <p>RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of the pH test performed as per USP.</p>
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The sample was declared as Sub-standard by NIH as detailed below:

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Suspension Ultima 60ml [Clarithromycin 125mg/5ml]	1007	M/s Macter international Limited, F-216, S.I.T.E Karachi	No. 061-P/2022 dated 16 th May, 2022	<p>pH:</p> <p>Determined: 5.7 ± 0.06</p> <p>Limit: 4.0-5.4</p> <p>Does not Comply with USP-39</p> <p>CONCLUSION: The sample is <u>Sub-standard</u> quality on the basis of tests performed.</p>

BRIEF FACTS OF THE CASE

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

- i. Her predecessor, on 05-05-2021 inspected the Main Medicine Store of CEO (DHA) Nankana Sahib, took subject drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Lahore via memo no. 91593 dated 05-05-2021.
- ii. Following drug sample, after test/analysis were declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed above.
- iii. Storekeeper of Main Medicine Store of CEO (DHA) Nankana Sahib provided Invoice/ warranty No. 90361535 dated 29-04-2021 issued by M/s Macter international Limited, F-216, S.I.T.E Karachi.
- iv. Warrantor Portion of the drug sample was sent to 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 provide the requisite information and to explain their position in this regard. In response, the firm challenged both of the test/analysis reports and requested to re-test the above-mentioned drug samples from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to the request of M/s Macter international Limited, F-216, S.I.T.E Karachi the subject drug sample was sent to NIH, Islamabad, from where the sample was declared as Sub-standard as detailed above.

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

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

3. Show-cause notice(s) issued to accused person(s) dated 31-07-2024

Firm submitted written reply to the Show Cause Notice vide letter no. 2042 dated 20-08-2024

We M/s. Macter International Limited (the "Company") acknowledge to receipt of your Letter No. PQCB /R-923/2021 Dated July 31, 2024 (the "Letter"), which is received to us on August 16th 2024. We would like to bring in your knowledge that Batch No. 1007 of Ultima has already been decided/ warned by the Provincial Quality Control Board (PQCB) reference no. PQCB/R-438,537,473,696,231,454,771,770,769,624/2021, R-329/2022.

As PQCB has deliberated the case in detail and has done product specific inspection of our facility. Under the guidance of PQCB team a CAPA has been developed and case has been resolved. In this context, we also would like to highlight the following legal principles:

- 1. **Constitutional Provision:** Article 13 of the Constitution of Pakistan states that no person shall be prosecuted or punished for the same offense more than once. This provision upholds the principle of "double jeopardy" which prevents an individual from being tried twice for the same charges.*
- 2. **Legal Safeguard:** Section 403 of the Code of Criminal Procedure (Cr. P.C.) also provides protection against being tried twice for the same offense. This safeguard is crucial in ensuring that no individual or entity is subjected to repeated legal proceedings for the same charges.*

Given that Batch No. 1007 has already been reviewed and decided by the PQCB, we respectfully request that this matter be considered resolved in accordance with the above legal principles.

4. Personal hearing notice(s) issued to accused person(s) dated 27-01-2026

5. Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 8

PQCB/R-754/ 2021

Tehsil Dina District Jhelum

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Spectrum Laboratories (Pvt.) Ltd, 8 km, Raiwind Road, Lahore-Pakistan through its Chief Executive Officer Irfan Maqbool Baig 2. Irfan Maqbool Baig Chief Executive Officer 3. Fozia Anjum Quality Control Incharge 4. Muhammad Abdul Rehman Production Incharge 5. Nouman Haider Warrantor
Drug Inspector	
of M/s Spectrum Laboratories (Pvt.) Ltd, 8 km, Raiwind Road, Lahore-Pakistan.	

Summary of the case:

- **Sampling date (Form 4): 23-12-2020**
- **Sent to DTL (Form 6): 23-12-2020**
- **Date of receipt in DTL: 01-01-2021**
- **DTL Report Date (Form 7): 02-03-2021**
- **DTL Time Extension: 61 days**
- **DI intimation to firm: 16-03-2021**
- **Retesting request if any: Nil**
- **Fate of retesting request: NA**
- **Investigation report Dated: 25-02-2023**
- **Permission for issuance of SCN: 259th meeting dated 18-04-2023**
- **SCN Issued: 27-06-2023**
- **Reply of the firm to show cause notice: Yes dated 06-07-2023**
- **History (2021-2025): Firm: 18**
- **Product: 13**

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Syrup Speczine 120ml	513	M/s Spectrum Laboratories (Pvt.) Ltd, 8 Km,	01- 74000403/ DTL dated:	Result of test/ analysis with specifications applied USP 2020 <u>PHYSICAL DESCRIPTION:</u>

<p>[Promethazine HCl 5mg/5ml]</p> <p>Mfg. Date:09-2020</p> <p>Exp. Date:03-2022</p> <p>Reg# 012597</p>		<p>Raiwind Road, Lahore-Pakistan</p>	<p>02 Mar 2021</p>	<p>Pink coloured visibly clear liquid of medicinal odour, filled in translucent plastic bottle with affixed label, closed with white plastic screw cap engraved with "SL", further packed in outer labelled unit carton.</p> <p><u>IDENTIFICATION</u></p> <p>Promethazine HCl Identified.</p> <p><u>ASSAY:</u></p> <p>Stated: 5mg/5ml</p> <p>Determined: 4.140mg/5ml</p> <p>Percentage 82.80%</p> <p>Limit: 90-110%</p> <p><u>RESULT:</u></p> <p><u>The above sample is Substandard on the basis of Assay test performed.</u></p>
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BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Dina, District Jhelum reported that:-

- i. His predecessor, on 23-12-2020 inspected the premises of M/S Subhan medical Store, opposite PTCL Office, Mangla Road, Dina and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 0000080769 dated 23-12-2020.
 - ii. Proprietor, M/S Subhan medical Store, opposite PTCL Office, Mangla Road, Dina provided invoice/warranty No. 429 dated 16-12-2020 issued by M/S Khan Medical Store, GT Road, GT Road, Sohawa.
 - iii. Warrantor Portion was sent to M/S Khan Medical Store, GT Road, GT Road, Sohawa.
 - iv. M/S Khan Medical Store, GT Road, Sohawa provided invoice/warranty No. 16362 dated 07-12-2020 issued by M/S Tariq Drug Agencies, Muhammad Ali Amin Medicine Market Chowk, Urdu Bazar, Lahore, who in turn provided invoice/warranty No. 2196 dated 30-11-2020 issued by M/S Spectrum Laboratories (Pvt.) Ltd, 8 Km, Raiwind Road, Lahore.
 - v. A copy of Test/ Analysis report was sent to M/s Spectrum Laboratories (Pvt.) Ltd, 8 Km, Raiwind Road, Lahore and they were directed to provide requisite information in this regard.
2. Drug Inspector requested to grant permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP and Rules framed there under by the way of: -

i. Manufacture for Sale /Sale of Substandard Drug

ii. Issuance of false warranty

2. Show cause notice(s) issued to accused persons dated 27-06-2023.

Reply of firm to show cause notice vide letter no. SL/PQCB dated 06-07-2023:

Kindly refer to your letter No: PQCB/R754/2021 dated 27-06-2023 received on 04-07-2023 on the above referred subject. The information is as under:

- | | |
|------------------------------|---------------------|
| 1. Irfan Maqbool Baig | Chief Executive |
| 2. Mr. Muhammad Abdul Rehman | Production Incharge |
| 3. Miss Fauzia Anjum | Q.C Incharge |
| 4. Mr. Nauman Haider | Warrantor |

All the requisite documents are enclosed herewith as directed.

The test report of the Government analyst states:

Assay of Promethazine HCL is 82.80% (limit 90%-110%).

Respectfully, submitted that serial No: 2 and 3 of test report No: TRA-01-74000403/DTL dated 02-03-2021 of DTL Rawalpindi in respect of Speczine Syrup 120ml, shows that the sample was not sent to D'TL within 7 days as required under section 19(3)(i) of the drug Act 1976.

As the mandatory provision of the drugs Act 1976 have not been complied with therefore the test report under reference have no legal value.

We have checked our control sample and it has been found to be of standard quality.

As the mandatory provision of section 19(3)(i) of the drug Act 1976 have not been complied with It is therefore prayed that lenient view, may kindly be taken Please.

3. Personal hearing notice(s) issued to accused person(s) dated 27-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 9

PQCB/R-647/ 2021

Tehsil Kahuta District Rawalpindi

ATTENDANCE:

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">1. M/s Medera Pharmaceuticals (Pvt.) Ltd., 249/A Industrial Triangle, Kahuta Road, Islamabad-Pakistan through its Chief Executive Officer Hamayun Kabir2. Hamayun Kabir Chief Executive Officer3. Muhammad Siraj Production In-charge/ Manager4. Abdul Wajid Quality Control Manager/ Warrantor <p>of M/s Medera Pharmaceuticals (Pvt.) Ltd., 249/A Industrial Triangle, Kahuta Road, Islamabad-Pakistan.</p>
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Summary of the case:

- Sampling date (Form 4): 27-02-2021
- Sent to DTL (Form 6): 01-03-2021
- Date of receipt in DTL: 02-03-2021
- DTL Report Date (Form 7): 29-06-2021
- DTL Time Extension: Granted in 232nd meeting dated 24-06-2021
- DI intimation to firm: 07-08-2021
- Retesting request if any: Yes (received in o/o drug inspector dated 31-08-2021)
- Fate of retesting request: Turn Down in 246th meeting dated 05-07-2022
- Investigation report Dated: 11-10-2022
- SCN Issued: 21-02-2023
- Reply of the firm to show cause notice: Nil
- History (2021-2025): Firm: 08
- Product: 03

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

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Alerzine Tablet [Cetirizine (Dihydrochloride) 10mg]	018	M/s Medera Pharmaceuticals (Pvt.) Ltd.,249/A Industrial Triangle, Kahuta	01- 74001022/DTL dated	Analysis with specifications applied: USP 2020 <u>PHYSICAL DESCRIPTION:</u> White coloured, round shaped, biconvex tablets,

Mfg Date 12-2020	Road, Islamabad-Pakistan	29-06-2021	packed in Alu/Alu blister of 1x10's, further packed in labelled outer carton.																								
Expiry Date 11-2023																											
Regn. No. 028856																											
			<table border="1"> <thead> <tr> <th>Tablet No.</th> <th>Percent Drug Release</th> <th>Tablet No.</th> <th>Percent Drug Release</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>117.07</td> <td>4</td> <td>127.06</td> </tr> <tr> <td>2</td> <td>123.35</td> <td>5</td> <td>127.86</td> </tr> <tr> <td>3</td> <td>124.60</td> <td>6</td> <td>127.50</td> </tr> </tbody> </table> <p>Tolerance: NLT 80% (Q) of labelled amount of Cetirizine HCl dissolved.</p> <p>Result: all six units comply dissolution testing.</p> <p><u>IDENTIFICATION:</u></p> <p>Cetirizine HCl identified</p> <p><u>ASSAY:</u></p> <table border="1"> <tbody> <tr> <td>Stated:</td> <td>10mg/Tablet</td> </tr> <tr> <td>Determined:</td> <td>11.859mg/Tablet</td> </tr> <tr> <td>Percentage:</td> <td>118.59%</td> </tr> <tr> <td>Limit:</td> <td>90%–110%</td> </tr> </tbody> </table> <p><u>RESULT:</u> The above sample is <u>SUBSTANDARD</u>, on the basis of the Assay test performed.</p>	Tablet No.	Percent Drug Release	Tablet No.	Percent Drug Release	1	117.07	4	127.06	2	123.35	5	127.86	3	124.60	6	127.50	Stated:	10mg/Tablet	Determined:	11.859mg/Tablet	Percentage:	118.59%	Limit:	90%–110%
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Determined:	11.859mg/Tablet																										
Percentage:	118.59%																										
Limit:	90%–110%																										

BRIEF FACTS OF THE CASE:

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

- i. He, on 27-02-2021, inspected the premises of M/S Mr. Chemist Pharmacy opposite THQ Hospital Kahuta,

Tehsil Kahuta, District Rawalpindi, took 2 different drug samples, including Tablet Alerzine 10mg, Batch No. 018 manufactured by M/s Medera Pharmaceuticals (Pvt.) Ltd., 249/A Industrial Triangle, Kahuta Road, Islamabad, on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide memorandum no. 0000086223 dated 01-03-2021.

- ii. M/S Mr. Chemist Pharmacy opposite THQ Hospital Kahuta, Tehsil Kahuta, District Rawalpindi provided invoice/warranty bearing No. 0137434 dated 07-01-2021 issued by M/S Care Distributors, Plot no. 83, Street 7 I-10/3, Islamabad, who in turn provided invoice/warranty bearing No.773 dated 15-12-2020 issued by M/s Medera Pharmaceuticals (Pvt.) Ltd., 249/A Industrial Triangle, Kahuta Road, Islamabad-Pakistan
- iii. Warrantor portion of drug sample was sent to M/S Care Distributors, Plot no. 83, Street & I-10/3, Islamabad.
- iv. A copy of test/analysis report was sent to M/S Medera Pharmaceuticals (Pvt.) Ltd., 249/A Industrial Triangle, Kahuta Road, Islamabad-Pakistan with directions to explain their position and provide requisite information in this regard.
- v. The firm requested re-testing of the sample. The Re-testing request of the Firm was forwarded to Secretary, Provincial Quality Control Board, Lahore vide Letter No. 80 DDC/ Kahuta dated 04-09-2021.
- vi. The re-testing request of the firm was turned down by Provincial Quality Control Board, Punjab in its 246th meeting dated 05-07-2022

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

- i. **Manufacture for sale/ Sale of Sub-standard drug**
- ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused persons dated 21-02-2023.
4. Personal hearing notice(s) issued to accused person(s) dated 27-01-2026.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 10

PQCB/ R-848/2021

Sher Shah Town, District Multan

ATTENDANCE

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/S Siza International, Pvt, 18-Km, Ferozpur Road, Lahore , through its Director, Muhammad Ghalib Raazee 2. Muhammad Ghalib Raazee Director 3. Muhammad Imran Khalil Production Manager 4. Riasat Ali QualityControl Incharge/Warrantor of M/S Siza International, Pvt, 18-Km, Ferozpur Road, Lahore
Drug Inspector	

SUMMARY OF THE CASE:

1	Sampling Date: (Form 4)	08-07-2021
2	Sent to DTL (Form 6):	08-07-2021
3	Date of receipt in DTL	08-07-2021
4	DTL Report date	02-07-2021
5	Time extension	Not Time Barred
6	1ST DI Communication with firm	10-09-2021
7	Retesting Request of Firm	NA
8	Investigation Report of DI	05-07-2023
9	Show cause issued	11-06-2024
10	Reply of the firm	Nill

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Capsule Lomper [Omeprazole:20mg] Mfg. date: 06-2020 Exp. date: 05-2022 Reg # 011618	08-21	M/S Siza International, Pvt, 18-Km, Ferozepur Road, Lahore.	01-89005536 /DTL, Dated 06-09-2021
<p>Specification applied: USP 2020</p> <p>Description: White to off-white color pellets in a hard gelatin capsule of yellow body and dark green cap packed in a ALU-ALU blister of 14 units in a labelled outer carton. Each outer contains 1 blister of 14 units i.e., 1*14=14 Capsules.</p> <p>Identification Omeprazole Identified.</p> <p>Assay:</p> <p>Omeprazole</p> <p>Stated: 20 mg/ Capsule</p> <p>Determined: 23.492 mg/ Capsule</p> <p>Percentage: 117.46 %</p> <p>Limit: 90-110% (Does not Comply)</p> <p>Result: The above sample is Sub-Standard on the basis of test performed.</p>			

BRIEF FACTS OF THE CASE

- i. M/S Madina Medical Store, Basti Talab, Sher Shah Bypass, Multan, provided invoice/ warranty No. 244418 dated: 07-07-2021 issued by M/S Premier sales (Pvt) Ltd., 66-A, Sultanabad, Near Al Janat Home, Gulgasht Colony, Multan as a proof of its purchase.
- ii. Warrantor portion of drug sample was sent to M/S Premier sales (Pvt) Ltd., 66-A, Sultanabad, Near Al Janat Home, Gulgasht Colony, Multan.
- iii. M/S Premier sales (Pvt) Ltd., 66-A, Sultanabad, Near Al Janat Home, Gulgasht Colony, Multan in turn provided invoice/warranty no. 21-10222, dated: 22-05-2021 issued by M/S Siza International, Pvt, 18-Km, Ferozepur Road, Lahore as a proof of purchase.
- iv. A copy of test/analysis report was sent to M/S Siza International, Pvt, 18-Km, Ferozepur Road, Lahore, and

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

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

a. Manufacture for sale /Sale of Substandard drug

b. Issuance of false warranty

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

4. Personal hearing notice(s) issued to accused persons(s) dated 28-01-2026.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 11

PQCB/MSS-198611,199328/2024

Government Haji Abdul Qayyum Teaching Hospital Lahore

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur through its director Zameer -ul -Hassan 2. Zameer -ul -Hassan Director 3. Mushoraf Shahzad Production Manager 4. Muhammad Jameel Quality Control Incharge 5. Khansa Omer Warrantor
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SUMMARY OF THE CASE		
1	Sampling Date: (Form 4)	11-05-2024
2	Sent to DTL (Form 6):	22-05-2024
3	Mfg. date 04-2021	03-2024
	Exp date 03-2023	02-2027
4	Date of receipt in DTL	23-05-2024
5	DTL Report date	19-07-2024
6	Time extension	N/A
7	1ST DI Communication with firm	30-07-2024
8	Retesting Request of Firm	Placed in 46 th Committee Meeting dated 17-12-2024 withdrawn by firm

9	Investigation Report of DI	22-08-2025 & 23-08-2025
10	SCN permission	293-M dated 25-09-2025
11	Show cause issued	05-01-2026
12	Reply of the firm	12-01-2026
13	Firm History: (2023-25)	<p>Firm: 19</p> <p>Product: 05</p> <p>01 is Standard from NIH (24AT002)(CEO Office Attock)</p> <p>01 Warning in 290 M dated 07-05-2025 (24AT061 FIC Hospital Faisalabad</p>

i. Following drug sample, after test/analysis were declared as Substandard by Government Analyst Drug Testing Laboratory **Bahawalpur** as detailed below

Sr,No	Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
1	<p>Tablet Askprol</p> <p>[Each Uncoated Tablet contains Paracetamol 500mg]</p> <p>Mfg Date: 03-2024</p> <p>Expiry Date: 02-2027</p> <p>Reg No.030726</p>	24AT063	<p>M/S Citi Pharma Ltd., (Formerly Askari Pharmaceuticals)</p> <p>3 Km, Head Baloki Road, Phool Nagar, Kasur</p>	<p>01-1009708716/DTL</p> <p>19-07-2024</p>	<p>Specification applied: BP 2024</p> <p>COMPOSITION: Each Uncoated tablet contains: Paracetamol BP 500mg</p> <p>DESCRIPTION: As per MS: "White to almost white colored round beveled edges tablets, having both sides plain." Observed: White to almost white colored, round shaped, slightly biconvex tablets without beveled edges, plain at both sides.</p> <p>Hence the sample is not complying the Physical Appearance as per MS. SUB-STANDARD.</p> <p>WEIGHT VARIATION: Limit: Average Weight ± 5% Results: Complies</p>

DISSOLUTION TEST:

Tolerance limit: NLT 70% (Q) in 45 Minutes.

ACCEPTANCE CRITERIA					
Each unit is not less than 70% in 45 minutes.					
1	2	3	4	5	6
99.44%	100.95%	101.45%	102.71%	100.83%	101.96%

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 500 mg/Tab
Determined 487.65 mg/Tab (97.53%)
Limit 95.0-105.0%

RESULT: The Sample is declared as "Sub-Standard" on basis of Physical Appearance.

2	Tablet Askprol [Each Uncoated Tablet contains Paracetamol 500mg] Mfg Date: 03-2024 Expiry Date: 02-2027 Reg	24AT064	M/S Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur	TRA No. 01-10097008717/ DTL dated 19-07-2024	Specification applied: BP 2024 <u>COMPOSITION:</u> Each Uncoated tablet contains: Paracetamol BP 500mg <u>DESCRIPTION:</u> As per MS: "White to almost white colored round beveled edges tablets, having both sides plain." Observed: White to almost white colored, round shaped, slightly biconvex tablets without beveled edges , plain at both sides. Hence the sample is not complying the Physical Appearance as per MS. SUB-STANDARD. <u>WEIGHT VARIATION:</u> Limit: Average Weight ± 5%
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No.030726

Results: Complies

DISSOLUTION TEST:

Tolerance limit: NLT 70% (Q) in 45 Minutes.

ACCEPTANCE CRITERIA

Each unit is not less than 70% in 45 minutes.

1	2	3	4	5	6
99.57%	98.43%	99.82%	96.29%	99.82%	99.44%

IDENTIFICATION: Paracetamol is identified.

ASSAY OF PARACETAMOL:

Stated 500 mg/Tab

Determined 498.65 mg/Tab (99.73%)

Limit 95.0-105.0%

RESULT: The Sample is declared as "Sub-Standard" on basis of Physical Appearance

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Govt Hajji Abdul Qayyum Teaching Hospital Sahiwal submitted that: -

- i. She, on 11-05-2024 inspected, the premises of Main Medicine store of Govt Hajji Abdul Qayyum Teaching Hospital Sahiwal took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memorandum no 198611 & 199328 dated 22-05-2024
- ii. The Medicine store keeper, provided invoice warranty No.GP/776/2024& GP/777/2024 dated 30-04-2024 by M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur
- iii. Warrantor portion of drug sample was sent to M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur
- iv. A copy of test/analysis report was sent to M/s Citi Pharma Ltd., (Formerly Askari Pharmaceuticals) 3 Km, Head Baloki Road, Phool Nagar, Kasur
- v. Pursuant to the request of manufacturer, the retesting request was considered in 46nd Committee meeting dated 17-12-2024 which was withdrawn by firm

i. Manufacture for sale/ Sale of Substandard Drug

ii. Issuance of false warranty

2. Show cause Notice (s) issued to the accused person(s) Dated 05-01-2026

Reply of showcause notice

Respected Sir,

We Citi Pharma Limited located at 3.0 KM Head Balloki Road Kasur-Pakistan respectfully submits this response in reply to your letter No. PQCB/MSS-198611/2024,199328/2024 dated 05 January 2026

Kind reference is made to the earlier decision letter No. PQCB/MSS-200223/2024 dated 07 May 2025, issued in response to our challenge letter CP/PQCB/2024/013 concerning Askprol 500 mg Tablet, Batch No. 24AT061 (TRA: 01-97000207/DTL), which was declared substandard solely on the basis of physical appearance. The Board subsequently issued a warning, referred the sample to PDTRC for testing and closed the case upon the batch being declared passed. The present batch, cited on identical grounds, has also been challenged by us through a challenge letter CP/PQCB/2024/010 submitted in the same manner.

Sr.No.	Product Name	Batch #	TRA # & Date	Decision by PQCB	Current status
1	Askprol 500 mg Tablet (Paracetamol BP 500mg)	24AT061	01-97000207	Warning Issued & Sample send to PDTRC for testing	PASSED and closed
2	Askprol 500 mg Tablet (Paracetamol BP 500mg)	24AT063	01-10097008716 /DTL	Show cause Notice	
3	Askprol 500 mg Tablet (Paracetamol BP 500mg)	24AT064	01-10097008717 /DTL	Show cause Notice	

We therefore request that the present case of Askprol 500 mg Tablet, Batch No. 24AT063 24AT064M ,(TRA: 01-10097008716/DTL, 01-10097008716/DTL), be resolved by referring the sample to PDTRC for testing, in line with the previously closed case.

Citi Pharma Limited remains committed to full regulatory compliance and assures its complete cooperation. We shall promptly provide any further clarification or documentation required by your esteemed office.

Thanking you in anticipation.

3. Personal Hearing Notice (s) issued to the accused person(s) Dated 28-01-2026

4. Case is placed before Board for Descion

PROCEEDINGS AND DECISION BY THE BOARD:

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ITEM No. 5

PSI CASES

Case No. 1

PQCB/R-302/ 2023

DHQ Hospital Gujranwala

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Medisave Pharmaceuticals, 578-579 Sundar Industrial Area, Raiwind Road, Lahore through its Chief Executive Officer/ Warrantor Imtiaz Ahmad 2. Imtiaz Ahmad Chief Executive Officer/ Warrantor 3. Tariq Mehmood Head of Quality Operations 4. Abdul Rasheed Bhatti Production Incharge 5. Zahid Sarfraz Quality Assurance Manager of M/s Medisave Pharmaceuticals, 578-579 Sundar Industrial Area, Raiwind Road, Lahore.
Drug Inspector	

BRIEF FACTS OF THE CASE:

No.	Product	Batch #	Mfg/ Exp Date	DTL Result	NIH	PSI Marked in
1	Injection Rapir (Each 5 ml ampoule contains Iron Sucrose Complex equivalent to elemental iron 100 mg)	22J325	09-2022 08-2024	pH and Turbidity Test	pH (Turbidity Test was not performed due to non-availability of facility)	278-M dated 28-03-2024

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INSPECTION:

Inspection Date: 24-04-2025

Inspection Committee Members:

1	Additional Secretary Drugs Control	Dr. Qalandar Khan
2	GMP Auditor, Sundar Industrial Estate,	Sara Yasien

Inspection Committee submitted its report which was duly conveyed to firm vide letter no. SY/1-7/2025 dated 23-05-2025, pursuant to which M/s Medisave Pharmaceuticals submitted its response in terms of Corrective & Preventive Actions vide letter no. NIL dated 25-08-2025.

Sr.#	Findings/ Product Specific NCs	Recommendations	Answer/Action Taken: Corrective actions & Preventive measures
1	USP 2022 limits for pH were 10.5-11.1 at 20°C but firm had not taken pH reading in consideration of temperature.	Firm is advised to get calibration of available pH meter done from accredited lab.	USP limits for pH are being followed and pH reading is being taken in consideration of temp. at 20 °C.
2	Log book of in house calibration data of pH meter (2022) showed that it was not verified with pH buffer 10 throughout the year.	Firm should authorize its trained personnel's only to perform finished product analysis.	As per record this product Rapir 5ml Injection being manufacturer one or two time in year whenever this product is testing for pH, PH meter is calibrated with pH buffer 10 limits (10.5-11.1) attached.
3	In Nov 2022 (manufacturing month of concerned batch), daily in house verification of pH meter showed that pH buffer 7.01 reading was noted considering only one digit after decimal point. Hence, USP criteria of ± 0.05 could not be satisfactorily determined.	Firm should maintain good manufacturing, good laboratory and good documentation practices.	We have replaced the pH meter and using Hanna pH meter only.
4	Firm had produced calibration certificates of HANNA pH meter whereas one Phoenix PH meter and one WTW pH meter were available in lab.		We have stop using phoenix pH meter further more and discontinued.
5	In 2020-21, daily in house verification of pH meter, pH buffer 7.01 showed value of 7.08 dated 16/10/2020, 27/10/2020, 02/11/2020, 13/11/2020, 30/11/2020, 09/12/2021, 7.09 dated 28/10/2020 and 29/10/2020.		Phoenix pH meter has been discontinued permanently.

6	In 2025, same practices seen, in daily in house verification of pH meter. pH buffer 7.01 showed value 7.11 dated 06/02/2025 but no deviations were raised.		Discrepancies have been removed and log book maintained.
7	Electrode of pH meter was covered fully in white deposits. No history of preventive maintenance was there.		Phoenix pH meter has been discontinued and only Hanna pH meter is in working.
8	Turbidity test of concerned product had been witnessed and it was observed that no properly designed facility to perform this test was available in firm.	Firm should arrange its own facility of Liquid Particle counter	Turbidity test has been performed in present of auditor as per pharmacopeia and verified by auditor results were within specified limits.
9	Firm had not produced any documented CAPA done in respect of this batch.	Firm should maintain good manufacturing, good laboratory and good documentation practices.	Documented CAPA, In this product we are using sodium hydroxide for pH adjustment we make solution of sodium hydroxide and transfer this solution drop by drop with the pipette by constant stirring the solution to make homogeneous solution and to keep the pH within specified limits.
10	Manufacturing process was not validated till 2024. A retrospective validation report was compiled on 10/04/2025.	In house analytical methods including titration methods should be validated.	Retrospective validation report has already been provided, which shows that our product manufacturing process is smooth and consistent.
11	USP 2022 recommends assay of sucrose through HPLC-RI and of iron through Atomic absorption spectroscopy. Firm did not possess both of these facilities.	As per LRA Rules, 1976, Section General of Schedule G. Contract production and analysis shall be correctly defined, agreed and controlled in order to avoid misunderstandings that could result in a drug or work or analysis of unsatisfactory quality. A written contract between the contract giver and the contract acceptor shall clearly establish the duties of each party had state	We have purchased new HPLC. RI system and this product is being tested as per pharmacopeia. (Test Report attached)

		<p>the way in which the authorized person shall exercise his full responsibility in releasing each batch of product for sale or issuing the certificate of analysis and a copy of such a contract shall be supplied to the Central Licensing Board also.</p> <p>Firm is recommended to produce CLB intimation and DRAP approval in case of Inj. Rapir (finished product) analysis.</p>	
12	Firm had not performed analytical method validation for in house titration method used to release finished product for marketing.	<p>Final product testing should be done completely as per official pharmacopoeia.</p> <p>In house analytical methods including titration methods should be validated.</p>	Validation report is attached for finished product for conformation.
13	Analytical report of filled ampoule was considered as finished product analysis and it was not reviewed by Quality Assurance manager.	<p>SOPs to review the process of analytical and quality assurance data/documents should be stringent.</p> <p>Microbiological monitoring in sterile and non-sterile area should be in accordance to ISO 14644-1:2015.</p> <p>Firm should maintain good manufacturing, good laboratory and good documentation practices.</p>	Analytical report is present in our BMR which is duly verified by QA dept.

Sr.#	Observations/ General NCs	Recommendations	Answer/Action Taken: Corrective actions & Preventive measures
1	No primary or secondary standards were available. Firm was using in-house working standards standardized with	Firm should use primary or secondary standards where possible or working standards	Few Primary and secondary reference standards available, however working standard are validated against the

	manufacturers' working standards.	should be used with complete traceability. Internal and external audits should be conducted.	manufacturers working standard.
2	FTIR was out of order at time of inspection.	FTIR should be made available in good working condition as early as possible	New FTIR purchase is under process as old FTIR is out of order.
3	No record of failed or reprocessed samples was maintained in firm.	Internal and external audits should be conducted.	SOP and format for failed product are attached.
4	Ketosave injection 30mg/ml, Batch 25C136, ready for packing was stacked in corridors.		Ketosave injection 30mg/ml batch No. 25C136 was in process which was stacked in corridors packed and sent to finished goods store
5	Flaps of filling machine were torn out and not over lapping each other		Torn flaps of filling machine have been replaced and over lapping each other
6	Door closures were out of order.		New Door closer have been fixed.
7	No signs of emergency exit were displayed in premises.		Emergency sign of exit already been displayed in premises but few more are added.
8	Area under maintenance and out of order equipment were not labeled accordingly.	Microbiological monitoring in sterile and non-sterile area should be in accordance to ISO 14644-1:2015.	Area under maintenance and out of order equipments have been labeled.

PDTRC Report:

30 ampoules of Injection Rapir Batch# 25C126 Mfg. 03-25, Expiry 02-27 were collected for pH testing at PDTRC. It was declared **Standard Quality** vide PDTRC test report no. PDTRC/TR-Pharma/0117/2025 dated: 14-05-2025, complying the pH test with 10.79 @ 20.1°C (Limit =10.5 – 11.1 @20.0°C).

2. Personal Hearing Notice(s) issued to accused person(s) dated 11-11-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

3. The subject case was considered by the Provincial Quality Control Board under Section 11 of the Drugs Act 1976 in its 294th meeting held on 20.11.2025 under the chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB. Ms. Sonia Secretary DQCB Gujranwala attended the meeting online via Zoom and Drug Inspector Ms. Arsalan Rasool attended the meeting along with original case record. Among the nominated accused Abdul Rasheed Bhatti Production Incharge appeared before the Board. The firm reiterated that PSI was marked in 278th Board Meeting held on 28-03-2024 and they have already submitted its response in terms of Corrective & Preventive Actions taken which are evident of the fact that firm has taken all measures in accordance with the PSI Committee's recommendations in order to avoid any such occurrences in the future. They further requested the Board to consider their actions taken in lieu of committee's recommendations.

4. The Board after careful perusal of the case record observed that the subject case has been discussed at length in its 278th meeting in which Product Specific Inspection (PSI) was directed by the Board. Pursuant to which the committee members conducted inspection of the firm on 24-04-2025. The Board considered the PSI Committee's report in detail and firm's submitted Corrective & Preventive measures taken in accordance with committee's recommendations. The Board further advised GMP Auditor to verify the CAPA submitted by the firm that whether the firm has taken necessary corrective & preventive measures in accordance with the observations and corresponding recommendations by the PSI committee members to submit its report in this regard. Keeping in view, the Board, after due deliberation and detailed discussion, unanimously decided to **Adjourn** the case of **M/s Medisave Pharmaceuticals, 578-579 Sundar Industrial Area, Raiwind Road, Lahore** till verification of CAPA submitted by the firm especially purchase of FTIR and submission of the report by concerned GMP Auditor.

GMP Auditor submitted CAPA Verification of M/s Medisave Pharmaceuticals as follows:

Subject: CAPA VERIFICATION OF M/S MEDISAVE PHARMACEUTICALS

Respected Sir,

With respect to the 294th meeting of PQCB held on 20/11/2025, the undersigned along with Mr. Muddasir Munir, GMP Auditor, Quaid-e-Azam Industrial Estate, Lahore, visited M/S Medisave Pharmaceuticals on 20/01/2026, in the presence of Production In-Charge (Mr. Abdul Rasheed Bhatti) and QCM (Mr. Tariq Mahmood), in investigation of the following case:

PQCB Case No.	Drug Product	B. No.	Offense	DTL Concerned	Reference Book(s)
PQCB R-302/2023	Injection Rapir (Each 5 ml ampoule contains Iron Sucrose Complex equivalent to elemental iron 100 mg)	22J325	Sub-standard on the basis of pH (11.58 at 20°C) and turbidity (3.10)	DTL Faisalabad	USP 2022 Limits: pH (10.5–11.1 at 20°C) and turbidity (4.4–5.3)

Observations:

1. FTIR was available and functional.
2. HPLC-RI was available and functional.
3. Firm had purchased ten (10) primary standards.

4. Microbiologist was available.
5. Karl Fischer was available and functional.
6. Calibration of pH meter was done.

Non-Conformances:

1. Stability samples of Injection Rapir (Each 5 ml ampoule contains Iron Sucrose Complex equivalent to elemental iron 100 mg) were found in QC lab; however, no record of testing of product on HPLC-RI was available.
2. Finished products, ready for packing, were found stacked in corridors.

Recommendations:

1. Testing of finished products should be done strictly in compliance with compendia.
2. Firm should enhance the capacity of in-process quarantine and finished goods store.

5. Personal hearing notice(s) issued to accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 2

PQCB/R-687/ 2022

Tehsil Yazman District Bahawalpur

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<ol style="list-style-type: none">1. M/s Adamjee Pharmaceuticals (pvt.) Ltd., Plot # 39, Sector 15, Korangi Industrial Area, Karachi through its Managing Director Farooq Hamirani2. Farooq Hamirani Managing Director3. Shahid ahmed Khan Production Manager4. Asim Kamal Ansari Quality Control Manager5. M. Ali Warrantor
	of M/s Adamjee Pharmaceuticals (pvt.) Ltd., Plot # 39, Sector 15, Korangi Industrial Area, Karachi.

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 No.
Suspension Perilium (5ml contains: Domperidone: 5mg) Mfg. Date: Exp. Date: Reg. No. 05.2022 05.2024 026102	347	M/s Adamjee Pharmaceuticals (Pvt.) Ltd., Plot # 39, Sector 15, Korangi Industrial Area, Karachi	01-10094000377/DTL dated: 30.09.2022

DTL Test Report Result

Specifications applied: MS

Composition: Each 5ml contains: Domperidone BP: 5mg

Description: White colored suspension in sealed amber color glass bottle. Stated Volume: 60ml

pH (MS): Limit: 5.0-6.5, **Determined: 4.267 (Does not comply with the specifications)**

Identification (MS): Domperidone is identified.

Assay (MS): (Domperidone) Stated: 5mg/5ml, Determined: 4.71mg/5ml, Percentage: 94.21%, Limit: 90.0-110.0%

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

Pursuant to the request of M/s Adamjee Pharmaceuticals (Pvt.) Ltd., Plot # 39, Sector 15, Korangi Industrial Area, Karachi the retesting request of the subject drug samples was considered in the 20th Meeting of Committee of the Board held on 17.05.2023 and the subject drug sample was sent to NIH, Islamabad, from where the samples was declared **Sub-standard** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result
Oral Suspension Perilium 60ml	347	M/s Adamjee Pharmaceuticals (Pvt.) Ltd., Plot # 39, Sector 15, Korangi Industrial Area, Karachi	0107-P/ 2023 dated 31.07.2023	<p>Analysis with specifications applied: MS</p> <p>pH: Determined: 3.9 ± 0.06 Limit:5.0-6.5 (Does not comply with manufacturer specification)</p> <p>Result: The sample is of Sub-Standard quality on the basis of test performed.</p>

3. Show cause notice issued to the accused person(s) dated 31-12-2024.
4. Showcause/ Personal hearing notice issued to the accused person mentioned at Sr. No. 5 dated 07-08-2025.
5. Personal hearing notice issued to the accused person(s) mentioned at Serial No 1-4 dated 07-08-2025.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

6. The subject case was considered by the Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **292nd** meeting held on **20-08-2025** under the Chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB, Health & Population Department. Mr. Jahangir Khan, Secretary DQCB Bahawalpur attended the meeting online via zoom link. No one among the nominated accused persons of M/s Adamjee Pharmaceuticals (Pvt.) Ltd., Plot # 39, Sector 15, Korangi Industrial Area, Karachi was present, however, Counsel of the firm Abdul Majid (Advocate) appeared before the Board on behalf of the firm and submitted that all other quality parameters except pH are within limits. Also we have checked the retention sample and warrantor portion and the results show these are of standard quality. He asked the Board for a lenient view.
7. The Board after careful perusal of case record observed that subject drug sample Oral Suspension Perilium 60ml, Batch # 347 has been declared substandard on the basis of pH from DTL Bahawalpur as well as from NIH, Islamabad with pH determined to be 4.267 and 3.9, respectively, whereas the limit as per MS is 5.0-6.5. The Board was considerate that the fluctuations in pH of any formulation raise questions over the product stability, efficacy and its Production. Furthermore, the Board was of the opinion that the product must meet the quality standards and, in order to dig out the root cause of the defects in the Production, Quality Control & Quality Assurance of the firm, there is a dire need of product specific inspection. Therefore, the Board decided to **pend the case** and constitute a committee comprising of the followings to conduct **PSI** of the firm **M/s Adamjee Pharmaceuticals (Pvt.) Ltd., Plot # 39, Sector 15, Korangi Industrial Area, Karachi** and submit report for consideration by the Board.
8. Furthermore, the Board directed the committee to submit its report in this regard within 90 days otherwise Secretary PQCB would be authorized to change the committee members.

1.	Dr. Muhammad Munawar Hayat (Secretary PQCB)	Convener
2.	Prof. Rtd. Muhammad Uzair	Member

Pharmaceutical Expert (Member PQCB)

PRODUCT SPECIFIC INSPECTION REPORT OF M/S ADAMJEE PHARMACEUTICALS (PVT) LTD, KARACHI

Panel Members:

Dr. Muhammad Munawar Hayat, Secretary, Punjab (CONVENOR).

Mr. Waseem Mahmood, director operation, PQCB.

Date of Inspection of Unit: 24-10-2025

- Inspection of unit was conducted with reference to sample detail given below.

No.	Case No. with year	Product	Batch #	Mfg. Date	Detail result
1	PQCB/R-687/2022	SUSPENSION PERILIUM	347	05-2022	Substandard on pH

- The sample was declared substandard by on MS specifications.
 - Drug Testing laboratory Bahawalpur on pH (Determined: 4.267) Limit: 5.0-6.5
 - Appellate Lab NIH, Islamabad on pH (Determined: 3.9) Limit: 5.0-6.5

Introduction of firm

- Unit Established in 1986.
- Covered area 8800 square feet (Two Acares) of total 2 floors.
- Production areas are totally on ground floor.
- Administration offices on second floor
- Currently, Seven (07) sections of different pharmaceutical units.

Technical Staff

1. Mr. Farooq Hamirani, Managing Director.
2. Mr. Asim Kamal Ansari, Quality Control Manager.
3. Mr. Shahid Ahmed Khan, Senior Production Manager.

Certifications of M/S Adamjee Pharma

- V. ISO 9001:2015 (IAF), Valid until 11-12-2026 (Anex-A).
- V. ISO 45001:2015 (IAF), Valid until 11-12-2026 (Anex-B).
- V. ISO 14001:2015 (IAF), Valid until 11-12-2026 (Anex-C).

Detail of some important aspects of Unit

- The mater formula of formulation contains sugar, Glycerin, Methyl Paraben, Propyl Paraben, Xanthan Gum, Sodium Banzoate,

Sodium Saccharine, Polysorbate 80 and Titanium dioxide.

- In QC lab, Five (05) HPLC system, having IR detector, PDA detector and UV visible detectors.
- For data safety and storage, firm is having Chromatographic CDS system and backup facility.
- FTIR is available and functional.
- Two Dissolution apparatuses are present in functional state.
- Two pH meter without printer are present.
- Spill Kit and Emergency shower is installed in wet Chemistry Lab.
- Two Large size Stability Chambers are available in Lab.
- Epoxy flooring is installed in about whole area of manufacturing.
- Microbiological testing lab is present.

Findings / NCs

1. The pH meter are without printer. The firm is advise to purchase pH meter with printer.
2. The firm is advised to obtain external calibration from PNAC certified company.
3. The firm is advised to increase the sample size at time of final release of suspension Perillum.
4. Spill Kit for chemical Emergency is not installed in wet Chemistry Lab.
5. The firm is advise daily calibration of QC equipment especially pH meter and balances.
6. The firm is advised to Participate in PT testing in pH parameter.

Measures Taken by Firms

1. The Firm improved the analysis standard and firm purchased new HPLC and pH meter.
2. Firm having new HPLC system.
3. The firm having ISO certifications: 9001:2015, 45001:2015, and 14001:2015.

Sample for PDTRC

The panel / inspection team collected two samples of Suspension Perillum, Batch Number 382 and 364 for testing from the Pakistan Drug testing & Research Centre, Lahore, which were tested and declared standard quality (reports enclosed).

Conclusion

After careful evaluation of record and panel inspection, is of opinion that the cause of deviation in pH of suspension is may be due to change of one ingredient citric acid monohydrate, which shows deviation in buffering system to maintain pH of suspension. After that change, now pH of different batches is in limit 5.0-6.5.

9. Firm submitted CAPA against PSI report vide letter dated 13-01-2026 as follows:

SUB: "CAPA" against Product Specific Inspection Report of Perillum Suspension By: 347

Dear Sir,

With reference to your letter dated 06-01-2026, ref. No. PQCB/R-687/2022, please find herewith the attached copy of "CAPA" against Product Specific Inspection Report of Perillum Suspension B#: 347

Corrective Action and PREVENTIVE Action

S.No.	OBSERVATION	CORRECTIVE	PREVENTIVE
1	<i>Perilium suspension B#347 was declared substandard on the basis of pH.</i>	<i>Since Perilium suspension B#347 expired on 05-2024, no corrective action is possible.</i>	<i>Accelerated Stability Testing: Three pilot batches of the revised formulation must complete 3 months of accelerated stability at Temp. 40°C ±2°C, R.H. 75% ±5% with no pH deviation exceeding ±0.2 units.</i>

10. Personal hearing notice issued to the accused person(s) dated 28-01-2026.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 3

PQCB/R-551/2022

Lahore General Hospital, District Lahore

ATTENDANCE:

Secretary DQCB	1. M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore, Pakistan through its CEO/warrantor Hamid Bukhtiar,
Drugs Inspector	2. Hamid Bukhtiar CEO/ Warrantor 3. M. Hayat Hussain Production Manager 4. Amar Mureed Quality Control Manager
	of M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.

BRIEF FACTS OF THE CASE:

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

- i. She, on 16-09-2022 inspected the Main Medicine Store of Lahore General Hospital, District Lahore, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Lahore vide memorandum no 140227 dated 16-09-2022.
- ii. Following product sample, after test/ analysis was declared as **Standard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below: -

Name of product	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Bandages. MEDI LAP SPONGES [OPEN WOVEN BANDAGES CLOTH 30cm* 30cm (4ply) with X-RAY DETECTABLE THREAD, STERILE]	016	M/s Karim Industries, 1/2Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.	01- 183001375/DTL Dated: 19-11-2022	Result of test/ analysis with specifications applied BP 2022 DESCRIPTION: Lap sponge of open wove white cotton cloth, folded into rectangles or squares, in such a manner that no cut edges are exposed, and stitched round the open sides. The X-ray detectable strip of blue colour is securely sewn into one corner of the pad. Claimed size=30cm x 30cm x 4ply WARPS: Limit: 135-163/10cm Determined: 155/10cm WEFTS:
Mfg. Date: Aug-2022				

<p>Exp. Date: Aug-2027</p> <p>Regn. No. MDMR-000067</p>				<p>Limit: 84-96/10cm</p> <p>Determined: 93/10cm</p> <p><u>WEIGHT PER UNIT AREA:</u></p> <p>Limit: NLT 33g/m²</p> <p>Determined: 55.30g/m²</p> <p><u>LENGTH:</u></p> <p>Limit: 30cm (NLT 5%)</p> <p>Determined: 31.2cm</p> <p><u>WIDTH:</u></p> <p>Limit: 30cm (NLT 5%)</p> <p>Determined: 30.4 cm</p> <p><u>STERILITY TEST:</u> The sample is non-sterile</p> <p style="text-align: center;">(DOES NOT COMPLY)</p> <p>RESULT: The above sample is <u>SUB-STANDARD</u> on the basis of STERILITY TEST performed as per BP.</p>
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- iii. The store keeper Main Medicine store, Lahore General Hospital, District Lahore, provided invoice/warranty No. 1244 dated 12-09-2022 issued by M/S Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan.
- v. The Drug Inspector, Lahore General Hospital, District Lahore took the subject drug sample on Form-3 dated 22-12-2022 with directions of not to dispose of stock.
- vi. A copy of test/analysis report was sent to M/S Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

Previous Proceedings of the Board: (Regarding Retesting Request)

20th Committee Meeting of the Board held on 17-05-2023

2. The subject request for retesting of the drug sample was placed before the Committee Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **20th meeting** held on **17-05-2023** under the Convenorship of Director General, Drugs Control. The Secretary PQCB apprised that Drug Testing Laboratory report conveyed by the Provincial inspector of Drugs to

manufacturer vide letter No. DI /693/LGH dated 03-12-2022 Manufacturer requested for retesting vide letter No. Ki/22-1366 Dated:10-12-2022

3. The office of the Secretary Provincial Quality Control Board asked the firm to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. PQCB/P-123-2/2023 dated 05-04-2023 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above -mentioned batch) and firm provided relevant data.

4. The firm vide letter no. Ref no. Ki/23-1432 Dated 11.02.2023 requested to **withdraw** their re-testing request. The Committee after due deliberation and discussion unanimously decided to accept the firm's request for **withdrawal** of the retesting requests of the subject drug samples and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Committee.

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

- i. **Manufacture for sale/sale of Substandard Therapeutic goods (Drug/Medical device)**
- ii. **Issuance of false warranty**

6. Show-cause notice(s) issued to accused person(s) dated 29-08-2023

Firm replied to the show cause notice vide letter no. Ref No. Ki/23-1714 dated 15-09-2023

Reference to your Letter No. PjCB/R-551/2022 dated 29-08-2023 concerning Medi Lap Sponges 30cm x 30cm bearing Batch No. 016, which DTL report declared of substandard quality under report No. TRA 01-183001375/DTL Dated 19-11-2022, citing the reason of non-sterility.

*We wish to inform you that we have conducted a thorough examination of the retained samples of above said batch through our Technical Experts at our testing lab. The results of our analysis indicate that the products meet of **standard quality as per requirements**, including the sterility test.*

*Further, as we received the sample portion from concern Hospital which **physical condition of packing was not in good form**. Ultimately, the result of that sample sterility does not comply as our experts examine because it is **already leaked** and could not comply the standard quality of **leakage test**.*

*Because sometimes due to **mishandling & transportation the issue of leakage** can be occurs as a single pin hole in blister packaging can disturb its sterility.*

*It is also submitted that all parameters regarding testing of our sample of Medi Lap Sponges are complies except Sterility Test which we understand it's **happened due to leakage of said samples**.*

*We have **already replaced the stock** of Medi Lap Sponges 30em x 30cm with fresh batches which declared of standard quality. Further we request you to **please allow us to get the stock re-sterilized from PARAS (Gama Radiation)**. So that the conformity of Sterility Test may comply in accordance and **give direction to the concern Hospital for consume the stock**.*

*In this regard, we are **ready to bear all the expenses**.*

*In view of the submissions made above, it is humbly prayed that **the case maybe dropped** in best interest of justice.*

7. Personal hearing notice(s) issued to accused person(s) dated 22-01-2024

Previous Proceedings & Decision by The Board:

275th Special meeting held on 31-01-2024

8. 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 chairmanship of Vice chairperson, PQCB. Mr. Hassan Saeed Secretary DQCB Lahore and Ms Sadia Rana Drug Inspector Lahore General Hospital were present along with original case record. No-one appeared before the Board on behalf of M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore, Pakistan. Secretary PQCB apprised the Board that the firm has submitted written request for adjournment vide reference no. Ki-24437 dated 29-01-2024.

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

10. Personal hearing notice(s) issued to accused person(s) dated 20-02-2024

Previous Proceedings & Decision by The Board:

276th meeting held on 29-02-2024

11. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **276th meeting** held on **29-02-2024** under the Chairmanship of Special Secretary, Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Mr. Hassan Saeed, Secretary DQCB, District Lahore and Ms. Sadia Rana, Drug Inspector, Lahore General Hospital District Lahore was present along with the original case record. Among the nominated accused persons, Hamid Bukhtiar (Chief Executive Officer) of M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan appeared before the Board and submitted that the retention portion of the sample when tested was found complying all parameters as opposed to the observation of deviation of a single parameter of sterility as per the DTL report. The breach in packing due to poor storage conditions at the sampling premises or mishandling during transportation might be a contributing factor in non-compliance of sterility test. He further stated that the firm has replaced the stock at the hospital which has been declared of standard quality. Firm further requested the Board for ignoring the non-compliance of a single parameter due to inappropriate handling, as all other tested parameters such as warps, wefts, weight per unit area, length & width of the sponges are complying the limits.

12. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject sample Medi Lap sponges [Open woven bandages cloth 30cm* 30cm (4ply) with X-Ray Detectable Thread, Sterile] Batch No. 016 has been declared substandard by the Drugs Testing Laboratory, Lahore on the basis of observation of the sample as non-sterile. The Board was perturbed over failure of the key parameter of a sterile Medi Lap sponge as non-sterility would destroy the basic purpose of using a sterile sponge. The Board was of the view that such non-sterile Medi Lap sponge would fail to keep the wound microbe-free and might become the reason of super-infections when used on an open wound directly. The Board was affirmative that failure of sterility to comply might be a single but being a key parameter of a Medi Lap sponge, it would be unable to provide aseptic wound care and might render the whole process of exudative wound care, contaminated.

13. Keeping in view all observed facts of the case, the Board, after due deliberation and detailed discussion, unanimously decided to grant **permission for prosecution** against the following accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under

1. **M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore, Pakistan** through its CEO/warrantor Hamid Bukhtiar,
2. Hamid Bukhtiar CEO/ Warrantor

3. M. Hayat Hussain Production Manager
4. Amar Mureed Quality Control Manager

of M/s Karim Industries, ½ Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan

For the offences of:

a. Manufacture for sale/sale of Substandard Therapeutic goods (Drug/Medical device)

b. Issuance of false warranty

14. Furthermore, the Board directed the Drug Inspector to launch the complaint against the above-mentioned accused persons in the concerned Drug Court.

REVIEW PETITION

1. That Karim Industries is a leading and trusted name in the medical field, offering diverse array of surgical dressing products that are essential for medical practices ensuring the patients receive the best possible care. We are fully compliant with the Drugs Act 1976 and rules framed thereunder

2. That the petitioner's long-standing reputation for quality and regulatory compliance, as evidenced by numerous reports and certifications, should be taken into consideration. Our products have consistently been declared of standard quality. Moreover, DRAP panel of inspectors have also conducted many inspections of our premises and issued GMP certificates. The isolated nature of this alleged issue further suggests a procedural error in handling before testing rather than a systemic quality failure.

3. That we have been supplying our products to various hospitals nationwide without any complaint. Our products have consistently been declared standard quality. Moreover, DRAP panel of inspectors have also conducted many inspections of our premises and issued GMP certificates.

4. That our product meets all parameters except for the alleged so-called sterility test. We have conducted a thorough examination and repeatedly tested the retention sample of above- mentioned batch in our state-of-the-art laboratory. The results confirmed that our product met all the standard quality parameters according to our own specifications kept intact in proper storage conditions.

5. Our QC experts believe that analyst at the Drug Testing Laboratory (DTL) did not perform the vacuum leakage test (VLT) before conducting the sterility test which is a pre-requisite. This test is integral part of the Manufacturer's specifications/method of testing submitted to DRAP at the time of registration. Even Drug Testing Laboratory did not ask us to provide the method of analysis. The Sterility test cannot be performed if the sample is not intact, which could only be confirmed through a simple Vacuum leakage test. The DTL report does not indicate whether this test was performed, rendering the report questionable. It is worth mentioning that our product is so delicate that minor mishandling of the drug sample can affect its sterility, and even a minor prick of needle can compromise its quality.

6. It is worth mentioning that we manufacture quality products strictly following SOPs on the principle of Quality by Design (QbD) and frequent inspections of DRAP inspectors are testament to this claim. However, chances of any mechanical damage to our products during transportation and mishandling at the time of loading /unloading and shifting within hospital cannot be ruled out as our instant product is highly delicate. That was the reason we emphasized the Vacuum leakage test to check the intactness of packaging before sterility test.

7. That the alleged sterility issue could also be attributed to transportation and subsequent mishandling of our product at the store of the hospital. These factors are beyond the control of the manufacturer and can compromise the sterility of the product. Few samples of warrantor portion sent to us were also found physically in bad conditions which corroborate our stance and could not pass Vacuum leakage test.

8. According to section 18(1)(f) of the Drugs Act 1976, if the contravention can be remedied, the stocks shall not be seized upon an undertaking in writing not to sell the drug without remedying the defect, under intimation to the Board. Without conceding, it is respectfully submitted that if there is sterility issue with our product the same is a remediable contravention and can be removed on re-sterilizing the entire stock, voluntarily, without any risk to patients.

9. That the petitioner's willingness to voluntarily re-sterilize the entire stock demonstrates a commitment to patient safety and adherence to regulatory standards, underscoring the company's dedication to maintaining high-quality products.

10. That in the instant case allegedly substandard stock was not used on patients and still lying in the hospital which can be presumed as not sold, therefore no offence was committed by the petitioner's company.

11. Moreover, the company has already replaced the whole stock with fresh stock as a goodwill gesture. Replacement of the stock itself is a punishment causing huge financial loss without any fault of the company. Under article 13 of the constitution after one punishment for the same fault second punishment is prohibited. There are ample precedents that PQCB dropped / warned cases if replacement was given by the firm.

12. That without prejudice to foregoing, the Government Analyst failed to apply complete protocols while conducting tests on the sample. The mandatory vacuum leakage test was not performed as drug analysis data of DTL was not confronted to us in the last meeting of PQCB. Without following the manufacturer's method / protocols, the test report is inconclusive and cannot be used as evidence against us.

13. Additionally, the report of the Government Analyst is time barred in violation of section 22(2) of the Drugs Act 1976 with no extension granted by the PQCB.

14. That procedural lapses by the PQCB in issuing a non-speaking order and failing to address the petitioner's raised points violated principles of natural justice, warranting a thorough review and reconsideration of the impugned order.

15. That it is the duty and obligation of public functionaries to act justly, fairly, equitably without any element of discrimination and pass order with reasons. But the impugned order was passed by PQCB without reasons, without adverting to points raised by the petitioner during hearing, in violation of Rule 5(3) of Punjab Drug Rules 2007, hence liable to be recalled/reviewed.

16. The rule of consistency be observed and we may please be exonerated from the charge based on previous practice of this Honorable Board as many similar cases where replacement was given by the company were dropped/warning issued. We are legitimate expectant of similar treatment.

PRAYER:

In the light of the above it is respectfully submitted that:

The review petition may kindly be accepted, the impugned orders dated 29-02-2024 be set aside, and case against the petitioner be dropped.

II. All the stock may be returned to the company for re-sterilization as it is remediable under section 18(1) (f) of the Drugs Act 1976 on the undertaking that it will not be used by patients without remedying the defect after test/analysis by the DTL. Punjab

III. Or alternatively, all the stock may be returned to the company on the undertaking on stamp paper that it will not be used for medical purposes.

IV. The concerned drug Inspector may kindly be directed not to put up the case before concerned Drug Court till the final disposal of this review petition.

Previous Proceedings and Decision by The Board:

15. The subject review petition was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **283rd Special meeting** held on **20.08.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab /Vice-Chairperson PQCB. Mr. Hassan Saeed Secretary DQCB Lahore attended the meeting via zoom link and Ms. Sadia Rana Drugs Inspector Lahore General Hospital, Lahore attended the meeting along with original case file. Mr. Hamid (CEO) along with counsel of M/s Karim Industries, 1/2Km, Raiwind Lahore Road, Raiwind, Lahore-Pakistan before the Board to plead the case.

16. The counsel of the firm agitated the same arguments mentioned in review petition focusing on the point that our product was declared substandard on the basis of sterility test but when we performed test/analysis of retention samples, it was up to the mark so there is handling or transportation problem due to which physical pressure may be exerted and product may

not have remained intact as when we checked the warrantor portion through vaccum leakage test, 02 out of 03 didn't pass this test so we believe that it was a handling/transportation problems. The counsel further stated that in last year, about 100 reports of the same product declared of standard Quality. The Board after careful perusal of case record, due deliberation and discussion unanimously decided to **pend** the case till inspection report is received from GMP Auditor.

GMP Inspection Report of M/s Karim Industries

Overall Assessment – Report Rating

This summary indicates the compliance results against the guidance outlined in Schedule B-II under The Drugs (Licensing, Registering and Advertising) Rules 1976, framed under The Drugs Act, 1976, and opportunities for improvement. The assessment included a review of procedures, records, and quality control systems established by **M/S Karim Industries**. Based on our methodology and the risk categorization criteria agreed upon with the Primary and Secondary Healthcare Department (P&SHD), we have rated M/S Karim Industries, 1/2 Km, Lahore Raiwind Road, Lahore, onside Rohi Nala, Near Petrol Pump, Raiwind, Distt. Lahore. **Medium-Risk Unit (Needs Improvement)**.

Our findings, as mentioned in this report have been discussed with the management of M/s Karim Industries. Our conclusion is based on the issues given below:

Summary of Identified Issues:

Non-Compliances	Critical
Critical	0
Major	07
Minor	04
Total	11

3.1 GENERAL INFORMATION

Name of Manufacturer	M/S Karim Industries	
Physical Address	1/2-Km, Lahore Raiwind Road, Onside Rohi Nala, Near Petrol Pump, Raiwind, Distt. Lahore.	
Medical Devices Manufacturing	ELM-0014	

License No.	
Contact Address	Sheikh Shahzad Nabi 0321-9453166
Date of inspection	20-08-2024
Purpose of inspection	GMP Inspection
Name of inspectors	1. Mr. Muhammad Muddasir Munir 2. Mr. Suhail Ahmad
Name of Firm Representatives accompanying during the inspection	1. Mr. Hamid Bukhtiar (Owner/Partner) 2. Mr. Akmal Mehmood (Production Incharge) 3. Mr. Muhamad Sarfraz Akhtar (Quality Control Incharge)

3.2 Detail of manufacturing section (s)

1. Absorbent Cotton Wool Section
2. Crepe & Cotton Bandage Section
3. Gauze Section (Sterile & Non-Sterile)
4. Plaster of Paris (POP) and Tulle Dressing Section

3.3 Focus of the inspection

The inspection was focused on a thorough cGMP evaluation of the firm. The inspection covered the sections of the GMP as per schedule B-II of the Drug Act 1976 including premises, equipment, documentation, materials, personnel, validation, sanitation and hygiene, production, quality control, quality assurance, and utilities.

3.4 Inspected areas

1. Quality Assurance
2. Calibration and Validation
3. Quality Control
4. Personnel
5. Premises
6. Equipment

7. Production Operations

8. Warehouse Management

9. Utilities (Water Treatment System, Air Handling System, Compressed Air System, etc.)

Critical/ major/ minor findings/ observations are tabulated as follows along with firm's response.

M/s Karim Industries submitted following response in terms of CAPA (Corrective Action & Preventive Action) to the GMP Inspection Report vide letter no. ki-25283 dated 19-02-2025:

1. Critical Findings / Observations	No critical findings and observation found during inspection
4.2 Major findings and observations.	
4.2.1 Issues related to vendor qualifications a) No approved vendor list b) No backend workup was available for any of the approved vendor	4.2.1 a) Copy of approved vendor list attached. b) vendor list is attached
4.2.2 Issues related to personnel's a. Master training plan has not been developed b. Training & competency record of the staff were not available C. Medical fitness/ Check-up record were not available	4.2.2 a. Training record has been developed b. Working has been started as per your advice strictly. C. Copies of Medical fitness certificates are attached.
4.2.3 Issues related to microbiology a) ATCC-Type reference culture strains were not available b) Area monitoring record were not available c) Although bio indicators were available but sterilization process assessment study was not available. d) Performance qualifications of autoclave was not available. e) Microbiologist training and competency	4.2.3 a) Has been purchased and now available b) Record available c) Bio-indicator available and sterilization assessment also available d) PQ of autoclave is completed, documents attached. e) Training is done.

<p>4.2.4 Issues related to quality control</p> <p>a) Complete testing of absorbent cotton was not performed as required by BPC</p> <p>b) The firm does not have HPLC and polarimeter required in testing of framycetin sulphate.</p> <p>c) The firm does not have reference standard of framycetin sulphate</p> <p>d) The firm does not have electronic leak test apparatus</p>	<p>4.2.4</p> <p>a) Now all tests of cotton wool are going to performed according to BPC.</p> <p>b) Agreement for Testing the product is now approved from third party (document attached)</p> <p>c) As we have contracted with third party for testing antibiotic assay in raw and in finish so no need to have reference standard of framycetin sulphate.</p> <p>d) Leakage tester has been purchased and its calibration certificate has been attached for proof</p>
<p>4.2.5 Issues related to material</p> <p>a) Gauze roll were stacked along with the wall</p> <p>b) Shredding of paint was observed in storage area.</p> <p>c) Status labelling was missing</p> <p>d) The record of receiving and issuance were not maintained</p> <p>e) The firm has not installed dispensing hood, laminar flow hood was being used to dispense material and no weighing balance was available.</p>	<p>4.2.5</p> <p>a) Now the rolls are attached properly away from walls, pictorial evidence attached</p> <p>b) walls maintained; pictorial evidence attached</p> <p>c) status labeling is mentioned</p> <p>d) its maintained now (ledger copy attached)</p> <p>e) dedicated dispensing hood and weighing balance is installed</p>
<p>4.2.6 Issue related to complaint handling</p> <p>a) Firm has not developed the complaint handling system.</p>	<p>4.2.6 a) Firm have developed complaint handling system SOP attached</p>
<p>4.2.7 Issues related to validation</p> <p>a) The validation of ethylene oxide chamber was due since 01.03.2004.</p> <p>b) Validation of HVAC was not available.</p>	<p>4.2.7</p> <p>a) It has been renewed (DONE)</p> <p>b) Available</p>
<p>4.3. Minor finding and observation</p>	
<p>4.3.1</p> <p>Non-performance annual product review</p>	<p>4.3.1</p> <p>Working started immediately on it and developed APR from Aug-2024</p>

	- Dec-2024
<p>4.3.2 Issues related to deviations control</p> <p>a) The firm do not set standard batch size and will depend upon order size.</p>	<p>4.3.2</p> <p>Firm developed SOP standard batch sizes (copy attached).</p>
<p>4.3.3 Issues related to availability of compendia</p>	<p>4.3.3. Official compendia is available in soft form</p>
<p>4.3.4 Issues related to documents</p> <p>a) Machine specific utilization logs were not available.</p> <p>b) Sampling and dispensing hood operational logs were not available.</p>	<p>4.3.4</p> <p>a) Log book developed copy attached</p> <p>b) Sampling and dispensing hood operational log books has been developed.</p>

17. Personal hearing notice(s) issued to accused person(s) dated 27-01-2026

18. Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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ITEM No. 6

MISBRANDED CASES (RECTIFIED LABEL)