

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

293 PQCB Meeting

Date: 25-09-2025

Time: 11:00 AM

Venue

24-COOPER ROAD, DIRECTOR GENERAL HEALTH SERVICES LAHORE

TABLE OF CONTENTS

- **Item No. 1**
- **REGULAR CASES**
 - **Case No. 1**
 - PQCB/MSS-175814/2023 (Case Id: 0000128106)
 - **Case No. 2**
 - PQCB/R-489/2023 (Case Id: 0000117088)
 - **Case No. 3**
 - R-650/2021 (Case Id: 0000065976)
 - **Case No. 4**
 - PQCB/MSS-222297/2025 (Case Id: 0000185936)
 - **Case No. 5**
 - PQCB/MSS-216544/2025 (Case Id: 0000177584)
 - **Case No. 6**
 - PQCB/MSS-193513/2024 (Case Id: 0000146667)
 - **Case No. 7**

- PQCB/MSS-199630/2024 (Case Id: 0000155648)
- **Case No. 8**
- MSS-190501/2024` (Case Id: 0000143219)
- **Case No. 9**
- R-729/2021 (Case Id: 0000069040)
- **Case No. 10**
- PQCB/R-759/2022 (Case Id: 0000085084)
- **Case No. 11**
- PQCB/R-363/2023 (Case Id: 0000107791)
- **Case No. 12**
- PQCB/ MSS-212827,212828/2025 (Case Id: 0000174438)
- **Case No. 13**
- PQCB/MSS-197054/2024 (Case Id: 0000152288)
- **Case No. 14**
- PQCB- MSS-206562,206564,206563,206561/2024 (Case Id: 0000166963)
- **Case No. 15**
- PQCB/ MSS-193594, 193595/2024 (Case Id: 0000147026)
- **Case No. 16**
- R-639/2021 (Case Id: 0000068179)
- **Case No. 17**
- R-536/2022 (Case Id: 0000078043)
- **Case No. 18**
- PQCB/MSS-175441/2023 (Case Id: 0000127717)

ITEM No. 1

REGULAR CASES

Case No. 1

PQCB/MSS-175814/2023

Tehsil Chichawatni, District Sahiwal

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case:</u>
	<ol style="list-style-type: none">1. M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area North Karachi-Pakistan through its Managing Director, Asad Ilyas2. Asad Ilyas Managing Director3. Ekram-Uddin Production Incharge4. Ahmad Nadeem Qasmi Quality Control Incharge/ Warrantor <p>of M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area North Karachi-Pakistan</p>
Drug Inspector	

BRIEF FACTS OF THE CASE

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

- He, on 16-09-2023 inspected business premises M/s Doctor pharmacy Chak No. 11/14-L Burewala Road Near Primary Boys School Iqbal Nagar Tehsil Chichawatni Sahiwal, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, **Bahawalpur** vide memorandum no. 175814 dated 18-09-2023.
- Following drug sample after test/analysis was declared **Adulterated, Substandard & Misbranded** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Cream. Ephadex-N [Dexamethasone 1mg, Neomycin 3500iu] Mfg date: 10-2022 Exp. Date: 10-2024	EN199	M/S Epharm Laboratories A-40, Road No.1, S.I.T.E., Super Highway, Industrial Area, North Karachi	01-10097005081/DTL 28-10-2023

Specs Applied: MS

Composition Each gram contains:

Dexamethasone (as disodium salt) U.S.P. 1mg

Neomycin (as sulphate) U.S.P. 3500 IU

Description White to off-white color homogenous cream in sealed collapsible aluminum tube sealed with plastic cap and with printed label. Packed in outer carton hard carton.

(Stated: 15 Gram)

Note: Product label claim is USP Specs. and of the product is "Dexamethasone (as disodium salt) U.S.P.1mg and Neomycin (as sulphate) U.S.P. 3500 IU". Whereas USP monograph with the name of "*Neomycin Sulfate and Dexamethasone Sodium Phosphate Cream*" states in its definition "Neomycin Sulfate and Dexamethasone Sodium Phosphate Cream contains the equivalent of NLT 90.0% and NMT 135.0% of the labeled amount of neomycin, and the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of dexamethasone phosphate (C22H30FO8P)". So, the product label claim is contradictory to that of USP Monograph's definition. **Therefore, the Product is Misbranded.**

Identification Neomycin (as Sulphate) and Dexamethasone Na Phosphate are identified.

Assay of Neomycin (as Sulphate)

Stated 3500IU/g

Determined 3539.4IU/g (101.127%)

Limit 90.0-135.0%

Assay of Dexamethasone Phosphate

Stated 1mg/g

Determined 0.6827mg/g (68.27%)

Limit 90.0-110.0%

(Does not Comply with Specification)

Identification and Quantification of Adulteration

Dexamethasone (Base) 0.443mg/g

RESULT: The Sample is declared "**Sub-Standard**" and "**Adulterated**" on the Basis of "**Assay Test**". Moreover, the sample is also declared as "**Misbranded**" as per Section 3(s)(iv) of the Drugs Act 1976.

iii. M/s Doctor pharmacy Chak No. 11/14-L Burewala Road Near Primary Boys School Iqbal Nagar Chichawatni Sahiwal, provided invoice/warranty No. 19061 dated 12-07-2023 issued by M/s Jamshaid

Medicose Ishaq Market Pull bazar Sahiwal

- iv. Warrantor Portion was sent to M/s Jamshaid Medicose Ishaq Market Pull bazar Sahiwal.
- v. M/s Jamshaid Medicose Ishaq Market Pull bazar Sahiwal provided invoice/warranty no. 072-232 dated 24-02-2023 issued by M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area North Karachi-Pakistan.
- vi. A copy of Test/ Analysis report was sent to M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area North Karachi-Pakistan. Firm requested for retesting of sample. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.
- vii. Pursuant to the request of manufacturer, the retesting request was allowed in 32nd Committee meeting dated 25-01-2024 and sample sent to NIH, Islamabad, from where the sample was declared **Substandard & Misbranded** as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results															
Ephadex-N Cream 15gm	EN199	M/s Epharm Laboratories A-40, Road No.1, S.I.T.E., Super Highway, Industrial Area, North Karachi	013-P/2024 dated: 28-06-2024	<p><u>LABELLING:</u></p> <p><u>Determined:</u></p> <p>Product label claim USP Specification and the product is “Dexamethasone (as disodium salt) U.S.P.1mg and Neomycin (as sulphate) USP 3500 IU”. Whereas USP monograph with the name of “Neomycin Sulfate and Dexamethasone Sodium Phosphate Cream” states in its definition “Neomycin Sulfate and Dexamethasone Sodium Phosphate Cream contains the equivalent of Not Less Than 90.0% and Not more than 135% of the labeled amount of neomycin, and the equivalent of Not less than 90% and Not more than 110% of the labeled amount of dexamethasone phosphate (C₂₂H₃₀FO₈P)”. So, the product label claim is contradictory to that of USP Monograph’s definition. Therefore, the product is Misbranded.</p> <p><u>Limit:</u></p> <p>The label or container of which or anything accompanying which bears statement design or device which makes any false claim for the drug or which is false or misleading in any particular.</p> <p>Does not comply with Labeling Rules (Section 3 (s) (iv) of The Drugs Act 1976).</p> <table border="1"> <thead> <tr> <th>ASSAY</th> <th>Stated</th> <th>Found</th> <th>Limit</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Dexamethasone Phosphate</td> <td>1mg/gm</td> <td>0.7719mg/gm</td> <td>90-110%</td> <td>77.19%</td> </tr> <tr> <td>Neomycin</td> <td>3500IU/gm</td> <td>3376IU/gm</td> <td>90-</td> <td>96.45%</td> </tr> </tbody> </table>	ASSAY	Stated	Found	Limit	Percentage	Dexamethasone Phosphate	1mg/gm	0.7719mg/gm	90-110%	77.19%	Neomycin	3500IU/gm	3376IU/gm	90-	96.45%
ASSAY	Stated	Found	Limit	Percentage															
Dexamethasone Phosphate	1mg/gm	0.7719mg/gm	90-110%	77.19%															
Neomycin	3500IU/gm	3376IU/gm	90-	96.45%															

							135%	
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Does not comply with USP-2022.

Conclusion: The sample is of **Sub-standard** quality on the basis of test performed and Misbranded.

viii. A copy of NIH test/analysis report was sent to M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area North Karachi-Pakistan and they were asked to provide the requisite information in this regard.

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/stocking/selling of the Substandard & Misbranded drug**
- b. **Issuance of false warranty**

1. Show-cause notice(s) issued to the accused persons(s) dated 25-06-2025

Reply to show cause notice dated 01-07-2025

- Dear Sir.
- Reference to your letter No PQCB/MSS-175814/2023 Dated: 25-06-2025, received by us on 30-06-2025, in this regard our submission is as under, That we did not receive Original NIH report from D.I yet after asking through a letter to Di dated 11/12/2024(Copy attached) That we have not received yet manufacturer/Warrantor portion from D.I which is a mandatory provision of Drug act, 1976. That Government Analyst declared product Mis-branded on the basis that "Product label claim is USP Specs and of the product is Dexamethasone(as disodium salt) USP 1mg and Neomycin(as sulphate) USP 3500IU whereas USP monograph with the name of Neomycin Sulfate and Dexamethasone Sodium Phosphate Cream states in its definition Neomycin Sulfate and Dexamethasone sodium phosphate Cream contains the equivalent of NLT 90% and NMT 135% of the labeled amount of Neomycin, and the equivalent of NLT 90% and NMT 110% of the labeled amount of Dexamethasone phosphate so, the product label claim is contradictory to that of USP Monograph's definition" Dear Sir now we have rectified the matter in the art work of Unit carton of the product as per requirement That Government Analyst declared product substandard and adulterated on the basis of assay result of Dexamethasone Phosphate ie 68.27% (Limit:90-110%) Other Physical and Neomycin assay result are within limit.
- That "Reference Sample" of the same batch of subject drug Ephadex-N Cream B. No. EN199 retained at Q.C Labs, of the Epharm, Karachi under prescribed condition was tested and found within the specifications as well as of standard quality.
- That NIH declared product substandard on the basis of assay result of Dexamethasone Phosphate i. e 77.19%(Limit:90-110%). Other Physical and Neomycin assay result are within limit of USP
- That DTL Bahawalpur test result and NIH test result does not matched with each other and our retention sample results found within limits so we request you to kindly give us a chance of personnel hearing so that we defense

2. Personal Hearing notice(s) issued to the accused persons(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	16-09-2023
Sent to DTL (Form 6):	18-09-2023
Date of receipt in DTL	19-09-2023
DTL Report Date (Form 7):	28-10-2023
Time Extension granted	N/A
1st DI Communication with firm dated	13-11-2023
Date of Retesting Request of Firm:	16-11-2023
Fate of Retesting request	Retesting Request allowed in in 32 nd Committee meeting dated 25-01-2024 Substandard from NIH vide test repot no. 013-P/2024 dated 28-06-2024
Investigation Report Dated	28-08-2024
Firm History 3 years	Firm:11 Product: 2

Note DTL declared adulterated, Substandard & Misbranded by using MS specifications& but NIH declared substandard & Misbranded using USP Specification

PROCEEDING AND DESCION BY THE BOARD



Neomycin (as sulphate) U.S.P. 3500IU

DESCRIPTION

White to off-white color homogenous cream in sealed collapsible aluminum tube sealed with plastic cap and with printed label. Packed in outer carton hard carton.

(Stated: 15 Gram)

Note: Product label claim is USP Specs. and of the product is “Dexamethasone (as disodium salt) U.S.P.1mg and Neomycin (as sulphate) U.S.P. 3500 IU”. Whereas USP monograph with the name of “*Neomycin Sulfate and Dexamethasone Sodium Phosphate Cream*” states in its definition “Neomycin Sulfate and Dexamethasone Sodium Phosphate Cream contains the equivalent of NLT 90.0% and NMT 135.0% of the labeled amount of neomycin, and the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of dexamethasone phosphate (C₂₂H₃₀FO₈P)”. So, the product label claim is contradictory to that of USP Monograph’s definition. **Therefore, the Product is Misbranded.**

IDENTIFICATION

Neomycin and Dexamethasone Phosphate are identified.

<u>ASSAY</u>	<u>Stated</u>	<u>Determined</u>	<u>Percentage</u>	<u>Limit</u>
Neomycin	3500 IU/gm	3420.90 IU/gm	97.74%	90.0-135.0%
Dexamethasone Phosp.	1mg/gm	0.5902mg/gm	59.02%	90.0-110.0%

(Does not Comply with Specification)

RESULT: The Sample is declared “**Sub-Standard**” on the basis of “**Assay Test**”. Moreover, The Sample is declared as “**Misbranded**” as per Section 3(s)(iv) of the Drugs Act 1976.

- iii. M/s Shahzad Medical store Khizar Town, Tehsil Renala Khurd, District Okara provided bill/warranty invoice No. 7512 dated 23-04-2023 issued by M/s Al-Riaz Drug Pharmacy at 62/C Small Industrial Estate Sahiwal who in turn provided invoice/warranty no. 071-392 dated 30-11-2022 issued by M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area North Karachi-Pakistan.
- iv. Warrantor Portion was sent to M/s Al-Riaz Drug Pharmacy at 62/C Small Industrial Estate Sahiwal.
- v. A copy of Test/ Analysis report was sent to M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area North Karachi-Pakistan. Firm requested for retesting of sample. In response, the Committee in its 26th meeting dated 11-10-2023 and decided to allow the request of the firm. The sample sent to NIH, Islamabad and declared **substandard and misbranded**. The detail is as follow:

Name of Drug	Batch No.	Name of Manufacturer	NIH report no & Date	NIH test details
Ephadex-N cream 15gm	EN201	Epharm laboratories A-40 road no. 1 SITE	0222-P/2023 dated 28-06-2024	<u>LABELING:</u> Determined: Product label claim USP specification and the product is “Dexamethasone (as disodium salt) USP 1mg and Neomycin (as sulphate) USP 3500 IU”. Whereas USP monograph with the name of “Neomycin Sulfate and Dexamethasone Sodium Phosphate

<p>Mfg date: 10-2022,</p> <p>Exp date: 10-2024</p>		<p>Super Highway Industrial Area North Karachi</p>		<p>Cream” states in its definition “Neomycin Sulfate and Dexamethasone Sodium Phosphate Cream contains the equivalent of NLT 90.0% and NMT 135.0% of the labeled amount of neomycin, and the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of dexamethasone phosphate (C₂₂H₃₀FO₈P)”. So, the product label claim is contradictory to that of USP Monograph’s definition. Therefore, the product is misbranded.</p> <p>Limit:</p> <p>The label or container of which or anything accompanying which bears any statement design or device which makes any false claim for the drug or which is false or misleading in any particular.</p> <p>Does not comply with Labeling Rules (section 3 (s) (iv) of Drugs Act 1976.</p> <table border="1" data-bbox="719 689 1410 1120"> <thead> <tr> <th>ASSAY</th> <th>Stated</th> <th>Found</th> <th>Limit</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Dexamethasone Phosphate</td> <td>1mg/gm</td> <td>0.6427mg/gm</td> <td>90-110%</td> <td>64.27%</td> </tr> <tr> <td>Neomycin</td> <td>3500 IU/gm</td> <td>4038.3 IU/gm</td> <td>90.0-135.0%</td> <td>115.38%</td> </tr> </tbody> </table> <p>Does not Comply with USP-2022</p> <p>Conclusion: The Sample is of Sub-Standard” quality on the basis of test performed and Misbranded</p>	ASSAY	Stated	Found	Limit	Percentage	Dexamethasone Phosphate	1mg/gm	0.6427mg/gm	90-110%	64.27%	Neomycin	3500 IU/gm	4038.3 IU/gm	90.0-135.0%	115.38%
ASSAY	Stated	Found	Limit	Percentage															
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Neomycin	3500 IU/gm	4038.3 IU/gm	90.0-135.0%	115.38%															

vi. A copy of NIH Test/ Analysis report was sent to M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area North Karachi-Pakistan and directed to provide requisite information in this regard.

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

- a. **Manufacture for sale/sale of Substandard & Misbranded Drug**
- b. **Issuance of false warranty.**

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

Reply to show cause notice dated 16-10-2024

Reference to your letter No. PQCB/R-489/2023 Dated: 09-10-2024, received by us on 14-10-2024(Copy of letter from post office and receiving attached), in this regard our submission is as under,

- That we did not receive Original NIH report from D.I yet after asking through a letter to D.I dated

01/08/2024(Copy attached) and a letter dated 16/08/2024(Copy attached). That we have not received yet manufacturer/Warrantor portion from D.I which is a mandatory provision of Drug act, 1976,

- That Government Analyst DTL Bahawalpur declared product Mis-branded on the basis that "Product label claim is USP Specs and of the product is Dexamethasone (as disodium salt) USP. 1mg and Neomycin (as sulphate) USP 3500IU whereas USP monograph with the name of Neomycin Sulfate and Dexamethasone Sodium Phosphate Cream states in its definition Neomycin Sulfate and Dexamethasone sodium phosphate Cream contains the equivalent of NLT 90% and NMT 135% of the labeled amount of Neomycin, and the equivalent of NLT 90% and NMT 110% of the labeled amount of Dexamethasone phosphate so, the product label claim is contradictory to that of USP Monograph's definition. Dear Sir now we have rectified the matter in the art work of Unit carton of the product as per requirement.
- That Government Analyst DTL Bahawalpur declared product substandard on the basis of assay result of Dexamethasone Phosphate i.e 59.02% (Limit:90-110%). Other Physical and Neomycin assay result are within limit of USP.
- That "Reference Sample" of the same batch of subject drug Ephadex-N Cream B. No. EN201 retained at Q.C Labs, of the Epharm, Karachi under prescribed condition was tested and found within the specifications.
- That NIH declared product substandard on the basis of assay result of Dexamethasone Phosphate i.e 64.27% (Limit:90-110%). Other Physical and Neomycin assay result are within limit of USP
- That DTL Bahawalpur test result and NIH test result does not matched with each other and our retention sample results found within limits so we request you to kindly give us a chance of personnel hearing so that we defense the case in the best manner.

2. Personal Hearing notice(s) issued to the accused persons(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	26-04-2023
Sent to DTL (Form 6):	28-04-2023
Date of receipt in DTL	29-04-2023
DTL Report Date (Form 7):	17-06-2023
Time Extension granted	N/A
1st DI Communication with firm dated	10-07-2023
Date of Retesting Request of Firm:	24-07-2023
Fate of Retesting request	Retesting Request allowed in in 26175814th Committee

	<p>meeting dated 11-10-2023</p> <p>Substandard from NIH vide test report no. 0222-P/2023 dated 28-06-2024</p>
Investigation Report Dated	28-08-2024
Firm History 3 years	<p>Firm:11</p> <p>Product: 2</p>
<p>Note DTL declared, Substandard & Misbranded by using MS specifications& but NIH declared substandard & Misbranded using USP Specification</p>	

PROCEEDING AND DECISION BY THE BOARD

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Case No. 3

PQCB/ R-650/2021`

Tehsil and District Rahimyar Khan

ATTENDANCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <p>1. M/s Don Valley Pharmaceuticals (Pvt.) Limited, 31Km, Main Ferozepur Road, Lahore-Pakistan through its Managing Director Dr. Shehla Javed Akram</p> <p>,</p> <p>2. Dr. Shehla Javed Akram Managing Director</p> <p>3. Tariq Mehmood Quality Control Manager</p> <p>4. Shabana Kashif Production Manager</p> <p>5. Muhammad Yamin Warrantor</p> <p>of M/s Don Valley Pharmaceuticals (Pvt.) Limited, 31Km, Ferozepur Road, Lahore-Pakistan</p>
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BRIEF FACTS OF THE CASE:

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

- i. He, on 24-06-2021 inspected the business premises of M/s Usman Medicos & Saim Surgical Bano Bazar, Rahim Yar Khan, took subject sample of the drug on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memorandum no. 99271 dated 25-06-2021.
- ii. Following drug sample, after test/ analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Bahawalpur** as detailed below:

Name of drug	Batch no.	Name of manufacturer	TRA No & Date	DTL Test Report Results
Tablet Clamentin DS [Amoxicillin as amoxicillin trihydrate: 500mg, Clavulanic acid as potassium salt: 125mg] Mfg Date: 04-2021	AO-21-007	M/s Don Valley Pharmaceuticals (Pvt.) Limited, 31Km, Ferozepur Road, Lahore-Pakistan	No. 01-77004882 dated 27-10-2021	<p><u>Results of test/analysis with specifications applied:</u></p> <p>BP 2020</p> <p><u>COMPOSITION:</u> Each tablet contains 500mg Amoxicillin as amoxicillin trihydrate BP and 125mg Clavulanic acid as potassium salt</p> <p><u>DESCRIPTION:</u> white to off white oblong biconvex tablet engraved CLM on one side and plain on other side.</p> <p><u>IDENTIFICATION:</u> Amoxicillin is identified</p>

Exp. Date: 04-2023 Regn. No: 017757				Clavulanic acid is identified															
				<u>ASSAY: Amoxicillin</u> <table border="1"> <thead> <tr> <th>Stated</th> <th>Determined</th> <th>Limit</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>500mg/tab</td> <td>471.77mg/tab</td> <td>90-105%</td> <td>94.354%</td> </tr> </tbody> </table> <u>ASSAY: Clavulanic acid</u> <table border="1"> <thead> <tr> <th>Stated</th> <th>Determined</th> <th>Limit</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>125mg/tab</td> <td>23.483mg/tab</td> <td>90-105%</td> <td>18.786%</td> </tr> </tbody> </table> Does not comply with specifications RESULT: The sample is Substandard on the basis of Assay test	Stated	Determined	Limit	Percentage	500mg/tab	471.77mg/tab	90-105%	94.354%	Stated	Determined	Limit	Percentage	125mg/tab	23.483mg/tab	90-105%
Stated	Determined	Limit	Percentage																
500mg/tab	471.77mg/tab	90-105%	94.354%																
Stated	Determined	Limit	Percentage																
125mg/tab	23.483mg/tab	90-105%	18.786%																

- iii. M/s Usman Medicos & Saim Surgical Bano Bazar, Rahim Yar Khan provided Invoice/warranty No. 2431 dated 10-05-2021 issued by M/s Hammad Traders near Al Muslim School Chowk Pathanistan Rahim Yar Khan.
- iv. Warrantor Portion was sent to M/s Hammad Traders near Al Muslim School Chowk Pathanistan Rahim Yar Khan.
- v. M/s Hammad Traders near Al Muslim School Chowk Pathanistan Rahim Yar Khan provided invoice/warranty no. 2105-18583 dated 06-05-2021 issued by M/s Don Valley Pharmaceuticals (Pvt.) Limited, 31Km, Ferozpur Road, Lahore-Pakistan.
- vi. A copy of Test/ Analysis report was sent to M/s Don Valley Pharmaceuticals (Pvt.) Limited, 31Km, Ferozpur Road, Lahore-Pakistan and they were directed to provide requisite information in this regard. In response, Firm challenged the DTL report and requested retesting of the sample from NIH, Islamabad.
- vii. In response, the PQCB Board in its 245th meeting dated 16-06-2022 decided to allow the subject retesting request and the sample was sent to NIH, Islamabad for retest/analysis, from where subject drug sample also declared Substandard. The detail is as follow: -

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Tablet	AO-	M/s Don Valley	No. 0182-	<u>Assay:</u> Amoxicillin (as Amoxicillin Trihydrate)

Clamentin 625mg	21- 007	Pharmaceuticals (Pvt.) Limited, 31Km, Ferozepur Road, Lahore- Pakistan	P/2022 dated 29-08-2022	<p>Stated: 500mg/tablet</p> <p>Found 522.25mg/tablet</p> <p>Limit: 90-105%</p> <p>Percentage: 104.45%</p> <p>Assay: Clavulanic Acid (as the Potassium salt)</p> <p>Stated: 125mg/tablet</p> <p>Found: 38.925mg/tablet</p> <p>Limit: 90-105%</p> <p>Percentage: 31.14%</p> <p>Does not Comply with BP-2017</p> <p>CONCLUSION:</p> <p>The sample is Substandard quality on the basis of tests performed.</p>
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viii. A copy of Test/ Analysis NIH report was sent to M/s Don Valley Pharmaceuticals (Pvt.) Limited, 31Km, Ferozepur Road, Lahore-Pakistan vide letter dated 08-09-2022.

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

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

3. Show cause notice(s) issued to accused person(s) dated 22-12-2022.

Reply to Show Cause Notice:

1. his is in response to the Show Cause Notice No. PQCB/R-650/2021 dated 22-12-2022 wherein your good-office has instructed M/s Don Valley Pharmaceuticals (Pvt.) Limited (the "Company") to show cause as to why any legal action including but not limited to initiation of prosecution before the Honorable Drug Court along with cancellation/suspension of the Drug Manufacturing License and Drug Registration, may not be taken against the Company for allegedly contravening the provisions of the Drugs Act, 1976 and the DRAP Act, 2012.

2. At the very outset, it is submitted that the Company is one of the leading national pharmaceutical companies in the country.

It is a matter of fact that the Company has shown strict adherence with the Drug Laws and Good Manufacturing Practices. The aforementioned submission is substantiated by the fact that no complaint in relation to the quality of the pharmaceutical products manufactured by the Company has been received from any quarter whatsoever. In view thereof, the Company duly submits that the findings of the Government Analyst Drug Testing Laboratory Bahawalpur rendered vide TRA No. 01-77004882 dated 27-10-2021 (the "DTL Report") along with the findings of the Government Analyst National Institute of Health Islamabad vide TRA No. 0182-P/2022 dated 29-08-2022 (the "NIH Report") whereby its product, namely, Clamentin DS Batch No. AO-21-007 has allegedly been declared as "substandard" are defective, erroneous and without any merit.

3. Firstly, please note that the manner in which the Product has been obtained and tested is riddled with grave infirmities and discrepancies. As per the letter No. DLRYK/294 dated 16-12-2022 issued by the Drug Inspector Rahim Yar Khan, the Product was obtained on 24-06-2021 whereas as per the DTL Report the same is shown to have been obtained on 03-07-2021. Even otherwise, the mandatory requirement stipulated under Section 22(2) of the Drugs Act, 1976 has not been dispensed with hence the DTL Report is void ab initio and cannot be deemed as conclusive evidence in relation to the quality of the Product.

4. It is a matter of fact that the Company has a comprehensive testing framework and all of its pharmaceutical products are subjected to a rigorous testing regime prior to their release in the market. Similarly, the Product was subjected to a stringent testing protocol and was only given clearance for release in the market once it was affirmed that the same was of standard quality. Even otherwise, a thorough investigation has been conducted on the retained samples as-well as the in-process batches wherein no abnormality has been observed and it was confirmed that the Product is of standard quality.

5. In view of the foregoing, it is thus submitted that the alleged deviation observed in the DTL Report as-well as the NIH Report has solely occurred due to the inability of third parties to maintain/store the Product in specific storage conditions. In this regard, it is essential to submit that as per the label claim of the Product the same had to be stored below 30 C and in a cool and dry place. The foregoing submission is substantiated by the fact that the retention samples which were stored and maintained in a controlled environment by the quality control department of the Company have been tested and the results obtained in pursuance thereof have shown compliance with the requisite specifications. In view thereof, it is essential to dispense with the requirements stipulated under Section 32(3) of the Drugs Act, 1976 so as to prevent the unlawful and illegal prosecution of the Company and its officials.

6. Even otherwise, and without prejudice to the foregoing, it is submitted that the technical errors whilst testing the Product i.e., improper handling of the calibration apparatus as-well as environmental variables at the testing facility may have potentially affected the Assay of the Product. Additionally, it may also be noted that there is a significant lapse between the time frame within which the Product was obtained by the Drug Inspector till it was tested by the NIH. In this regard, no investigation has been conducted to ascertain whether the Product was stored properly during the aforementioned time-period. As such, it is essential to determine the external factors which had led to the decrease of Clavulanic Acid in the Product. This shall be in consonance with the principles of due process and administration of justice which bar the initiation of unlawful and arbitrary proceedings against the Company and its officials.

7. Notwithstanding the foregoing and despite the absolute and complete innocence of the Company and its officials in the subject matter, please find the following information/documents as per your requirement:

i. Name of CEO. (Dr.Shela Akram)

ii. Name of Production In-charge. (Shabana khasif)

iii. Insert Name of the Quality Control In-charge.(Mr.Tariq Mahmood)

iv. Drug Manufacturing License.

V. Drug Registration Certificate of Clamentin DS.

8. Accordingly, it is reiterated that the Product is of standard quality and the alleged non-compliance observed by the Government Analysts has not occurred due to any violation on behalf of the Company and its officials. Therefore, it shall be a great travesty of justice to penalize the Company and its officials for the offences alleged in the titled Show Cause Notice since the variation observed is a result of the omissions and negligence of third parties.

9. In view thereof, it is submitted that no case has been made out against the Company and its officials as they have not contravened the provisions of the Drug Laws and the rules framed thereunder. Accordingly, you are very kindly requested to withdraw the titled Show Cause Notice and all subsequent proceedings and consign the case to record.

Regards,

Personal Hearing notice(s) issued to accused person(s) dated 12-09-2025.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:04-2021**
- **Exp. Date: 04-2023**
- **Sampling date (Form 4): 24-06-2021**
- **Sent to DTL (Form 6): 03-07-2021(on 10th day)**
- **Date of receipt in DTL: 09-07-2021**
- **DTL Report Date (Form 7): 27-10-2021**
- **Time Extension to DTL: Yes, vide order no. PQCB/TEX-B-18/2021 dated: 13-09-2021**
- **DI 1st intimation to firm: 16-12-2021**
- **Retesting request if any: Yes**
- **Fate of Retesting Request: Substandard**
- **Investigation report Dated: 31-10-2023**
- **SCN Permission: 260th meeting dated: 04-05-2023**
- **History (from 2021) Firm: 39 cases**
- **Product: 01 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:



Case No. 4

ATTENDANCE:

Secretary DQCB Drug Inspector	Accused Persons involved in subject case. 1. M/S Wellcare Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha through its Managing Director, Malik Saeed Akhtar. 2. Malik Saeed Akhtar Managing Director/CEO /Warrantor 3. Shahid Inayat Quality Control Incharge 4. Dr. Ussama Rehman Production Incharge of M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha
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BRIEF FACTS OF THE CASE

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

- i. He, on 08-03-2025, inspected the premises of M/s Yasrab Trader Services Plaza, Block No.4 Liaqat Market Sargodha took below mentioned drug samples on Form.04 for the purpose of test/analysis and sent to Drug Testing Laboratory **Rawalpindi** vide Memo. No.222297.dated 09-03-2025.
- ii. Following Drug samples after test/analysis were declared as **Spurious** by Government Analyst Drug Testing Laboratory **Rawalpindi** as detailed below

DTL TEST REPORT

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Suspension Carefen 450ml (Each 5ml Contains: Ibuprofen 100mg), Mfg. Date: Exp Date: 12-2024 11-2026 Reg No.066500	CN-37	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.	01-75011253/DTL Dated. 26-05-2025
DTL Test Report Result			
<u>Analysis with specifications applied:</u> BP 2025/Others/In House;			
<u>PHYSICAL DESCRIPTION:</u>			

Orange colored suspension, filled in a white plastic bottle with affixed label, sealed with white colored plastic screw cap,

IDENTIFICATION:

Ibuprofen is not Identified (BP-2025) (FTIR)

(Does not Comply)

ASSAY:

Stated: 100 mg / 5 mL (BP-2025)
 Determined: 0.00mg mg / 5 mL (HPLC)
 Percentage: 0.00 % **(DOES NOT COMPLY)**

 Limit: 95.0% - 105.0%

Note: Time Extension was granted vide order No. POCB/ TEX-RWP-290/2025 dated 07-05-2025

RESULT: The above sample is Spurious as defined under clause (i) of subsection (z-b) of section 3 of The Drugs Act,1976

- iii. M/s Yasrab Trader services Plaza, Block No.4 Liaqat Market Sargodha provided invoice/warranty No.02122/25 dated 11-02-2025 issued by M/s Well Care Pharmaceuticals Pvt Ltd, Sargodha.
- iv. Warrantor portions of drug sample were sent to M/s Well Care Pharmaceuticals Pvt Ltd, Sargodha.
- v. A copy of test/analysis reports were sent to M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha with directions to explain their position and provide requisite information in this regard
- vi. The Provincial Inspector of Drugs requested for grant of permission for FIR/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:

Sr.No.	Product	Manufacturer	offences
1	Suspension Carefen 450ml (Each 5ml Contains: Ibuprofen 100mg), Batch No.CN-37	Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha	Manufacturing/sale/sale of Spurious Drugs Issuance of false Warranty Disobedient of Lawful authority
2	Syrup Sodium Acid Citrate 450ml Batch No.	Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha	Drug Inspector recommended cancellation of Drugs Manufacturing License (DML)/Drug Registration Certificates (DRCs) of Syrup Sodium Acid Citrate 450ml.

4..... Show cause notice/ Personal hearing notice(s) issued to accused person(s) dated 29-07-2025

PROCEEDING & DECISION BY THE COMMITTEE:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **51st meeting held on 05-08-2025** under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. Mr. Amir Mahmood Secretary DQCB, Sargodha attended the meeting online via zoom link and Mr. Zeshan Haider Kazmi Provincial Inspector of Drugs Tehsil & District Sargodha attended the meeting original case record. Among the nominated accused persons Malik Saeed Akhter Managing Director CEO/warrantor CEO of Well Care Pharmaceuticals A/7 P.S.I.E Sargodha. and stated that syrups of M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha have caps on which the name of firm was not printed. And these types of caps are freely available in market any one replace the cap of syrup bottle and this sample may be changed which DTL receive also stated that they have pass reports from Karachi DTL but he was unable to show before committee at that time because now factory was closed.

6. The Committee of Board after due deliberation and discussion unanimously decided to direct the applicant to prepare the whole case in support of your argument. and consider this case in next upcoming meeting

7. Personal hearing notice(s) issued to accused person(s) dated 07-08-2025

PERVIOUS PROCEEDING & DECISION BY THE BOARD

8..... Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **292nd meeting held on 20-08.2025** under the chairmanship of Vice-Chairperson, Provincial Quality Control Board, Punjab. Mr. Amer Mahmood Secretary, Sargodha attended the meeting online via zoom link, , Mr, Zeeshan Haider Kazmi Provincial Inspector of Drugs, Tehsil & District Sargodha appeared before the Board with original case record, No one among nominated accused persons appeared before the Board to plead the case. on the behalf of M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha. The firm submitted the adjournment request vide letter no. WC /4176/25 dated 16-08-2025 *stated that their council/Advocate (Mr. Khawaja Tahir on foreign tour as the firm filed the writ petition& there are leave session in high court.* The Board after due deliberation and discussion unanimously decided to **adjourn** the case.

9..... Personal hearing notice(s) issued to accused person(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	08-03-2025
Sent to DTL (Form 6):	09-03-2025
Date of receipt in DTL	13-03-2025

DTL Report Date (Form 7):	26-05-2025
Time Extension granted	290 th Meeting dated 07-05-2025
1st DI Communication with firm dated	29-05-2025
Fate of Retesting request	N/A
Investigation Report Dated	30-06-2025
Firm History 3 years	Firm: 20 Product:06 (Carefen)

Note: The firm filed the writ petition vide W.P No. 43717/2025 which is dismissed as withdrawn by Lahore high court order dated 04-08-2025

PROCEEDING & DECISION BY THE BOARD

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<p>07-2026</p> <p>Reg No 062644.</p>				<p>Acetaminophen is Identified (Test-A&B)(USP-2024) (HPLC)</p> <p>(DOES NOT COMPLY)</p> <p><u>ASSAY:</u></p> <p><u>Amlodipine</u></p> <p>Stated: 5 mg / Tablet (USP-2024) Determined....5.051mg/Tablet(HPLC) Percentage: 101.03 % (Complies the test)</p> <p>Rounded Off: 101 % (As per USP)</p> <p>Limit: 90 % - 110 %</p> <p><u>Acetaminophen</u></p> <p>Determined 0.168 mg / Tablet (USP-2024) (HPLC)</p> <p>(DOES NOT COMPLY)</p> <p><u>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 "Acetaminophen" as an ingredient/substance other than the prescribed substance i.e., Amlodipine.</u></p>
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- iii. M/S Madina Medical Store, Sargodha provided invoice/warranty 44776 dated 06-01-2025 issued by M/S Abdullah Pharma Distributors as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S Abdullah Pharma Distributors Sargodha who provided the invoice/warranty 36283 dated 27-09-2024.issued by Murfy Pharmaceuticals (Pvt) Ltd
- v. A copy of test/analysis report was sent to M/ Murfy Pharmaceuticals (Pvt) Ltd and they were asked to provide the requisite information in this regard.
- 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 Rule framed there under by the way of: -

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

3. Show-cause notice(s) issued to the accused persons(s) dated 04-09-2025

4. Personal hearing notice(s) issued to the accused persons(s) dated 12-09-2025

<p>Summary</p>	
<p>Sampling Date (Form 4):</p>	<p>11-01-2025</p>

Sent to DTL (Form 6):	12-01-2025
Date of receipt in DTL	18-01-2025
DTL Report Date (Form 7):	12-03-2025
1st DI Communication with firm dated	21-03-2025
Date of Retesting Request of Firm:	N/A
Fate of Retesting request	N/A
Investigation Report Dated	15-05-2025
Firm History 3 years	Firm: 15 Product: 3 (01substandard & 02 adulterated)

PROCEEDING & DECISION BY THE BOARD:

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Case No. 6

PQCB/MSS-193513/2024

Tehsil Ahmed Pur East, District Bahawalpur

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case:</u>
	<ol style="list-style-type: none">1. Wilsons Pharmaceuticals Plot No. 387-388 & 366, Sector I/9, Industrial Area, Islamabad-Pakistan through its CEO Tipu Sultan Akram2. Tipu Sultan Akram CEO3. Tipu Sultan Akram Production Incharge4. Gulzar Khan Quality Control Incharge5. Yasir Ghouri Warrantor <p>of M/s Wilsons Pharmaceuticals Plot No. 387-388 & 366, Sector I/9, Industrial Area, Islamabad-Pakistan.</p>
Drug Inspector	

BRIEF FACTS OF THE CASE

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

- i. He, on 26.02.2024, inspected the business premises of M/s Madina Medical Store situated at Chowk Bhatta Road, Mubarikpur Tehsil Ahmed Pur East District 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. 0000193513 dated 27.02.2024.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, Bahawalpur, as detailed below:

Drug Sample	Batch	Manufacturer	TRA No. and Date
Capsule Encid 40 [Omeprazole (enteric coated granules) eq. to Omeprazole activity 40mg] Mfg. date:08-2023 Exp. Date:08-2025 Reg.No.023059	2491	M/s Wilsons Pharmaceuticals Plot No. 387-388 & 366, Sector I/9, Industrial Area, Islamabad-Pakistan	01- 10097007752/DTL 31-05-2024
Specs Applied: USP 2024			

COMPOSITION: Each Capsule Contains: **Omeprazole (enteric coated granules) eq to Omeprazole activity 40mg**

DESCRIPTION: White color pellets/granules filled in hard gelatin capsule shell, red cap and off white body.

DISSOLUTION TEST: Acid Stage:

Limits: NMT 10% in 02 hours

Results: Comply

Buffer Stage:

Limit: NLT 75% in 45mins

Result: Comply

IDENTIFICATION OF OMEPRAZOLE: Omeprazole is identified.

ASSAY OF OMEPRAZOLE:

Stated 40 mg/Capsule

Determined 46.67mg/Capsule (116.68%) **Does NOT Comply**

Limit 90.0%-110.0%

Note: The extension is granted via PQCB order no. **PQCB/TEX-BWP-37/2024** Dated 30-04-2024.

RESULT: The Sample is declared as “**SUB-STANDARD**” on the basis of Assay Test of Omeprazole.

- iii. M/s Madina Medical Store situated at Chowk Bhatta Road, Mubarikpur Tehsil Ahmed Pur East District Bahawalpur provided the Invoice/Bill/Warranty No. SOB-0097432 Dated 21-10-2023 issued by M/s Pakistan Pharma 177-B, Muhammadia Colony Bahawalpur as a proof of purchase of the said drug.
 - iv. Warrantor portion of drug sample was sent to M/s Pakistan Pharma 177-B, Muhammadia Colony Bahawalpur who in-turn provided the Invoice/Bill/Warranty No. 157618 dated 15-09-2023 issued by M/s Wilsons Pharmaceuticals Plot No. 387-388 & 366, Sector I/9, Industrial Area, Islamabad-Pakistan.
 - v. A copy of test/analysis report was provided to M/s Wilsons Pharmaceuticals Plot No. 387-388 & 366, Sector I/9, Industrial Area, Islamabad-Pakistan and they were asked to provide the requisite information in this regard. In response the firm submitted retesting request where the Board in its 44th committee meeting dated 19-09-2024 decided to accept firm's request for withdrawal of retesting and directed the Drug Inspector to expedite investigation of the subject case and submit final report.
1. 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 Substandard Drug**
- b. **Issuance of False Warranty**

2. Show-cause notice(s) issued to the accused persons(s) dated 01-08-2025

Reply to show cause Notice Dated 13-08-2025

Respected Sir, AOA

With reference to Show Cause Notice No. PQCB/MSS-193513/2024, dated 01-08-2025, regarding DTL Bahawalpur report No. TRA 01-10097007752/DTL, dated 31-05-2024, received by us on 04-08-2025, we wish to place on record our detailed technical response for your kind consideration, supported by internationally recognized pharmacopeial, WHO, and ICH references.

1. Compliance at Time Release

At the time of Batch Release Encid Capsules Batch #2491 fully complied with the approved specifications under the United States Pharmacopeia (USP) monograph for Omeprazole. All required compendial test including assay, were performed those the official range of 00.0% to 110.0% of label claim (Blatch release report is enclosed as

2. Retained Sample Reanalysis

Following receipt of the show cause notice, retained samples were reanalyzed using the validated USP method compliance with ICH C2(R2) guidelines for analyseal method validation. The assay values again confirmed compliance with pharmacopeial limits. Testing report of retained sample is enclosed

3. Discrepancy in DTL Bahawalpur Report

The DTL report records: Specified range: 80.0% to 110.0% of 40mg Reported value: 46.67mg (116.68%) This result marginally exceeds the upper limit but also presents a practical inconsistency when compared to capsule capacity

4. Physical Impossibility Based on Size 0 Capsule Capacity

Our in-house data shows that for Batch #2491, the average pellet weight per capsule is 402 mg and the average empty shell weight is 97 mg. With a pellet potency of 8.5%, the weight required to achieve 40 mg of omeprazole is 470.6 mg, which fits comfortably within a size 0 capsule. We have checked and verified the maximum capacity for filling of pellets (content weight) in size 0 capsule shell is 500mg. The DTL-reported value implies a pellet weight of 549.07 mg per capsule, which exceeds our measured capacity

5. Mandatory Tests Not Performed by DTL

Under USP <905> Uniformity of Dosage Units, uniformity is demonstrated by Content Uniformity or Weight Variation, as applicable, and is evaluated alongside assay to ensure batch homogeneity. Because the DTL report does not present weight variation or content uniformity results, its single assay value should not be treated as verified or conclusive.

6. No intentional irregularity

We categorically state that there has been no intentional irregularity in this matter. All manufacturing and quality control steps were undertaken in good faith and in strict compliance with regulatory and SOP requirement

7. Stability Data and Ongoing Compliance

Ongoing stability studies in line with ICH Q1A(R2) confirm that the product remains compliant with pharmacopeial limits to date. These results are available for inspection.

8. Supporting International References

- a) USP <905> Content Uniformity and Weight Variation: "Unless otherwise specified in the individual monograph, content uniformity or weight variation shall be demonstrated for all dosage units tested. Results for assay shall be interpreted only after confirming that content uniformity or weight variation requirements are met."
- b) BP (General monograph for Capsules) - Requires content uniformity and weight variation checks before concluding on assay results.
- c) WHO TRS 957, Annex 1 Good practices for pharmaceutical quality control laboratories, emphasizing validated methods, evaluation of test results, and systems to ensure the reliability of reported results.
- d) ICH Q2(R2)-Analytical validation requirements for accuracy, precision, and reproducibility
- e) ICH Q1A(R2)-Stability testing protocols for shelf-life assurance.

9. Conclusion and Request

In light of the above facts, supported by scientific data and global regulatory guidelines, it is evident that the present matter merits a lenient and sympathetic view. The reported deviation results from a value that is physically impractical and is not supported by all mandatory tests.

It is therefore most respectfully requested to the honorable Board that, by taking a lenient view in the larger interest of justice, the case may kindly be dropped and no further action taken.

We reaffirm our commitment to full regulatory compliance, patient safety, and adherence to the highest. manufacturing standards.

3. Personal Hearing notice(s) issued to the accused persons(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	26-02-2024
Sent to DTL (Form 6):	27-02-2024
Date of receipt in DTL	28-02-2024
DTL Report Date (Form 7):	31-05-2024

Time Extension granted	37 th Committee Meeting dated 30-04-2024
1st DI Communication with firm dated	06-06-2024
Date of Retesting Request of Firm:	14-06-2024
Fate of Retesting request	With drawn by firm in 44 th Committee meeting dated 19-09-2024
Investigation Report Dated	28-11-2024
Firm History 3 years	Firm: 5 Product: 1

PROCEEDING AND DECISION BY THE BOARD

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Orange coloured spots are observed on the tablets. DOES NOT CPOMPLY.

UNIFORMITY OF MASS:

Results: all 20units comply with the test. (complies the test)

Limit: $\pm 7.5\%$

DISINTEGRATION TEST:

Result: all 6 units comply with the test. (complies the test)

Limit: NMT 15min

ASSAY:

Stated: 5mg/tablet

Determined: 4.728mg/Tablet (HPLC)

Percentage: 94.56% complies the test

Limit: 90-110%

Result: The above sample is substandard with respect to physical Characteristics observed.

- iii. M/s Thal Pharmacy near Railway Crossing Tehsil Kallurkot provided Invoice/warranty No A 41888 dated 16-05-2024 issued by M/s Dani Pharma Near Sadiq Karyana Mandi Town, Bhakkar who in turn provided invoice/warranty no. 23244 dated 02-03-2024 issued by M/s Shaheen Pharmaceuticals, 3km Murghzar Road Saidu Sharif Swat.
- iv. Warrantor portion of drug sample was sent to M/s Dani Pharma Near Sadiq Karyana Mandi Town, Bhakkar.
- v. A copy of test/analysis report was sent to M/S Shaheen Pharmaceuticals, 3km Murghzar Road Saidu Sharif Swat and they were directed to explain their position and to provide the requisite information in this regard.

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

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

3. Show-cause notice(s) issued to the accused persons(s) dated 28-01-2025

Reply of show cause notice dated 18-02-2025

We acknowledge receipt of the show cause notice dated 28.01.2025 from the Provincial Quality Control Board Punjab, regarding the sample of our Folic Acid 5mg Tablets (Batch No. A-52). That was collected from

"M/s Thal Pharmacy near Railway Crossing Tehsil Kallur Kot and declared it substandard by the Drug Testing Laboratory. We understand the concern raised regarding the presence of yellow color (look like orange color) spots on the tablets.

We would like to provide a technical explanation for the observed phenomenon. The yellow color spots are an inherent characteristic of our formulation, which is due to the nature of the folic acid material. As you may be aware, folic acid is a yellow-colored substance, whereas all the other excipients in our formulation are white.

During the manufacturing process, we employ the wet granulation method, which involves compressing the folic acid-containing granules. When the compression force is applied, the folic acid particles form visible spots on the tablet surface. These spots are an integral part of our formulation and do not affect the quality, efficacy, or safety of the tablets.

In light of this, we will revise our specification to include the physical appearance of the tablets, which will take into account the presence of these yellow color spots. This will ensure that our product meets the required standards and is compliant with regulatory requirements.

(All the supporting documents are attached)

4. Personal Hearing notice(s) issued to the accused persons(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	28-05-2024
Sent to DTL (Form 6):	29-05-2024
Date of receipt in DTL	05-06-2024
DTL Report Date (Form 7):	10-07-2024
1st DI Communication with firm dated	21-03-2025
Date of Retesting Request of Firm:	N/A
Fate of Retesting request	N/A
Investigation Report Dated	28-11-2024

Firm History 3 years

Firm: 2

Product: 1

PROCEEDING AND DECISION BY THE BOARD

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Description: Orange color suspension packed in labeled plastic bottle sealed with white plastic screw cap.

“The Product does not contain Finished Drug Product Specifications on bottle”. Mis-Branded (Does not Comply)

Identification Ibuprofen Identified.

Assay by HPLC

Ibuprofen

Stated: 100 mg/ 5mL

Determined: 37.22 mg/ 5mL

Percentage: **37.22 %**

Limit: 95-105% **(Does not Comply)**

Time Extension granted via PQCB order No. PQCB/TEX-MLTN-36/2024, dated: 17-04-2024.

Result: The above-mentioned sample is **Misbranded** as defined under section 3(s)(vi) of the Drugs Act, 1976 and **Sub-Standard** on the basis of Assay Test.

- iii. M/s Arain Medical Hall, Kotli Nijabat, Tehsil Sujabad, Multan, provided invoice/ warranty No. 524268 dated: 15-01-2024 issued by M/S Rayyan Pharma, 1st Floor, Khughani Tower, Medicine Market, Multan, as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S Rayyan Pharma, 1st Floor, Khughani Tower, Medicine Market, Multan.
- v. M/S Rayyan Pharma, 1st Floor, Khughani Tower, Medicine Market, Multan in turn provided invoice/warranty no.001217/24, dated 11-09-2023 issued by M/S Well Care Pharmaceuticals, A/7. P.S.I.E, Sargodha-Pakistan as a proof of purchase.
- vi. A copy of test/analysis report was sent M/S Well Care Pharmaceuticals, A/7. P.S.I.E, Sargodha-Pakistan, and they were asked to explain their position and provide the requisite information in this regard.
- vii. 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 Substandard and Misbranded drug**
- b. **Issuance of false warranty**

2. Show cause notice(s) issued to accused person(s) dated 01-09-2025.

Personal Hearing notice(s) issued to accused person(s) dated 12-09-2025.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 07-2023**
- **Exp. Date: 07-2025**
- **Sampling date (Form 4): 26-01-2024**
- **Sent to DTL (Form 6): 27-01-2024**
- **Date of receipt in DTL: 27-01-2024**

- **DTL Report Date (Form 7): 04-05-2024 (on 98th day)**
- **Time Extension to DTL: Time Extension granted via PQCB order No. PQCB/TEX-MLTN-36/2024, dated: 17-04-2024**
- **DI 1st intimation to firm: 22-05-2024**
- **Retesting request if any: No**
- **Fate of Retesting Request: NA**
- **Investigation report Dated: 27-11-2024**
- **SCN Permission: 287th meeting dated: 08-01-2025**
- **SCN Issued: 01-09-2025**
- **Reply of the firm No**
- **History (from 2022) Firm: 20 cases**
- **Product: 06 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 9

PQCB/ R-729/2021`

Tehsil Shuja Abad, District Multan

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">1. M/S Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan, through its Managing Director, Khuram Munaf2. Khuram Munaf Managing Director3. Amir Badshah Production Incharge4. Amir Shahzad Quality Control Incharge/ Warrantor <p>of M/S Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan</p>
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BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Shuja Abad Town, District Multan, reported that: -

- i. The then Drug Inspector, on 02-09-2021, inspected the business premises of M/S Malik Pharmacy, Raja Ram, Lodhran Road, Zareef Shaheed, Tehsil Shuja Abad, Multan and took 3 different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.
- ii. The subject drug sample, sent vide memo no. 105647 dated:03-09-2021, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, Multan, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Enteric coated tablet Davitrans DS (diclofenac sodium 100 mg),	T865 Mfg. date: 07-2021 Exp. Date: 06-2023 Reg# 063201	M/s Davis pharmaceutical laboratories 121, industrial triangle area, Islamabad-Pakistan.	01-89006783/DTL, date: 02-11-2021

Specification applied: USP 2021

DESCRIPTION: Light red to red color, round, biconvex tablets plain on both sides packed in ALU-ALU blister of 10 units

in a labeled outer carton. Each outer carton contains three blisters of ten units each (3 × 10=30 Tablets).

Assay	Stated	Determined	Percentage	Limits	Comments
Diclofenac Sodium	100 mg/Tablet	103.5 mg/Tablet	103.5%	90-110%	COMPLIES

IDENTIFICATION: Diclofenac Sodium Identified

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

- **Tolerance Limit: Acid Stage: NMT 10% in 2 hours (120 mints) in 0.1 N HCl**

LEVEL	UNITS	% RELEASE						AVERAGE	REMARKS
A1	6	NMT 10% in Acid Stage						A1	COMPLIES
		U#1	U#2	U#3	U#4	U#5	U#6		
Determined	%	1.2	1.18	0.44	0.48	0.35	0.53		

- **Tolerance Limit: Buffer stage: NLT 75%(Q)of the labeled amount of Diclofenac Sodium is dissolved in 45 mints in pH 6.8 Phosphate Buffer**

LEVEL	UNITS	% RELEASE						AVERAGE	REMARKS
B1	6	No Unit is less than 80% (Q+5) in Buffer Stage						B1	Does not comply
		U#1	U#2	U#3	U#4	U#5	U#6		
Determined	%	63.3	61.3	61.6	56.9	55.2	43.9		

* As the criteria of B3 i.e. NMT 2 units are < Q-15%, And no unit is < Q-25% is achieved. So, the results conform at B1 Stage.

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

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

- iii. M/S Malik Pharmacy, Raja Ram, Lodhran Road, Zareef Shaheed, Tehsil Shuja Abad, Multan, provided invoice/ warranty No.18316 dated 15-08-2021 issued by M/S Sharay Pharma, H. No. 1456-1, Qadir Nawaz Road, Near Kachahri Chowk, Multan, as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S Sharay Pharma, H. No. 1456-1, Qadir Nawaz Road, Near Kachahri Chowk, Multan.
- v. M/S Sharay Pharma, H. No. 1456-1, Qadir Nawaz Road, Near Kachahri Chowk, Multan in turn provided invoice/warranty no. 23438 dated: 24-07-2021 issued by M/S Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan as a proof of its purchase.
- vi. A copy of test/analysis report was sent to M/S Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan and they were asked to explain their position and provide the requisite information in this regard.
- vii. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.
- viii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Enteric coated tablet Davitrans DS (diclofenac sodium 100 mg),	T865	M/S Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan.	035-P/2022 dated: 26-04-2022	<p>Analysis with specifications applied: USP-39</p> <p><u>Dissolution Test:</u></p> <p>Determined: all the six tablets deviated from the limit.</p> <p>Limit: Not less than 75.0% (Q) of the labeled amount of Diclofenac Sodium is Dissolved. (Does Not Comply with USP-39)</p> <p>Result: The sample is of Substandard quality on the basis of tests performed.</p>

ix. Copy of NIH report was sent to M/S Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan.

2. Drug Inspector requested for grant of permission for prosecution against the persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976(as amended)/DRAP Act 2012 and Rules framed there under by the way of:
3. **Manufacturing for sale /sale of Substandard drug**
4. **Issuance of false warranty**
5. Show cause notice(s) issued to accused person(s) dated 17-01-2024.

Reply to show cause notice:

Please refer to the subject cited above. We, M/s Davis Pharmaceuticals (Pvt.) Ltd. (the "Company" or "Davis Pharma") are in receipt of the show cause notice bearing reference No. PQCB/R-729/2021 dated 17-01-2024 and seek to reply to the same on, inter alia, the following grounds:

I) Davis Pharma is one of the leading national pharmaceutical companies in the country and is engaged in the manufacturing of premium quality pharmaceutical products at its state-of-the-art manufacturing site. The high quality, safety and efficacy of the pharmaceutical products manufactured by the Company is evinced by the fact that the same are being increasingly prescribed by healthcare practitioners across the country and no complaint with respect to the usage of the same has been reported so far. It is essentially in this backdrop that we categorically deny and vehemently refute the findings furnished by the Analyst of the National Institute of Health, Islamabad vide TRA No. 035-P/2022 dated 26-04-2022 (the "NIH Report") wherein our product, namely, enteric coated tablet Davitran DS T865 (the "Product") has allegedly been declared as substandard on account of the Dissolution Test.

II) At the out-set, please note that all our pharmaceutical products are subjected to a stringent testing regime prior to their release in the market and/or supply to the concerned institute. Such exercise is essentially carried out in compliance of our legal as-well as regulatory duties and to ensure that safe, efficacious and high-quality pharmaceutical products are being consumed by the general public. In context of the present case, it may be noted that a similar exercise was carried out and the subject batch i.e., T865 was only released in the market once it was affirmed that the same was of standard quality and in compliance with the quality parameters prescribed under the applicable specifications. As such, the alleged variation observed by the Analyst has arisen as a result of external factors completely beyond the control of the Company and/or its concerned officials. Even otherwise, we have thoroughly examined our retention records and in-process batches wherein it has transpired that the Product is of standard quality. All tests/procedures including raw data calculations and UV absorbance have been conducted on the retention samples by CR 21 certified UV- Spectrophotometer and the results have been determined at 95.45% which is well within the limits prescribed under the applicable specifications. In light of the reports of the testing conducted upon our retention samples, your good-self is requested to conduct a proper investigation in the present case to determine the extraneous factors that have led to the issuance of the NIH Report.

III) In pursuance thereof, it is submitted that exposure of the Product, more particularly its enteric coating, to high and humid temperature is likely to have led to the observance of the variation in the results of the Dissolution Test. In this regard, the requirements stipulated under Section 32(3) of the Drugs Act, 1976 (the "Drugs Act") have not been dispensed with as no inquiry has been conducted to ascertain whether the Product properly was maintained/stored in accordance with the specified storage conditions. Similarly, no measures have been undertaken to determine the conditions within which the Product was subsequently stored by the concerned government analyst(s) and the drug inspectors dealing with the subject case. In view thereof, your good-self is very kindly requested to conduct a detailed inquiry in the present case to ascertain whether the aforementioned parties were able to store the Product properly since the imposition of any penalty on the Company and/or its officials due to the negligence and carelessness of the third parties shall be violative of the principles of justice and equity.

IV) Even otherwise, the sample of the product has been tested by the Analyst after a considerable time period i.e., five (05) months after the same was tested by the government analyst of the Drug Testing Laboratory, Multan. No proof vis-à-vis the manner in which the same was stored has been brought on record. In addition to the foregoing, improper testing is likely to have caused the sample to not dissolve properly in the dissolution assembly leading to the varied results of the Dissolution Test. As such, the Company cannot be deemed liable for the alleged variation observed in the NIH Report. Even otherwise, please note that the list of external reasons mentioned hereinabove is not exhaustive and the Company reserves the right to agitate additional grounds at the time of hearing and/or arguments.

V) A perusal of the NIH Report reveals that the testing has been carried out by the Analyst improperly and in stark violation of the procedure/protocols prescribed under the USP. It is submitted that the standard solution required for carrying out the Dissolution Test must be prepared practically however the value applied by the Analyst has been derived theoretically

which clearly constitutes a violation of the prescribed testing protocols. Further, the Analyst has carried out incomplete testing as the Acid Stage has not been performed in the Dissolution Test and only the Buffer Stage has been performed. Such evident infirmities and illegalities clearly cast a doubt on the veracity of the findings contained in the NIH Report.

VI) It may further be observed that the manner in which the subject case has been dealt with suffers from several infirmities. It is evident that the requirements envisioned under Section 16 and Section 17 of the Drugs Act have not been dispensed with. In the presence of such evident discrepancies, no evidentiary value can be attached to the NIH Report.

VII) As such, in exercise of the powers conferred upon your good-self under the Drugs Act as-well as the Punjab Drug Rules, 2007, your good-self is very kindly requested to look into the violation(s), infirmities and 2. Notwithstanding the foregoing and despite our absolute innocence in the subject case, please note the following information and find attached the relevant documents as per your requirement:

- 1) Khurram Munaf Managing Director.
- ii) Amir Badshah Production In-charge.
- ii) Aamir Shahzad Quality Control In-charge.
- iv) Drug Manufacturing License.
- v) Drug Registration Certificate.
- vi) Certificate of Analysis.
- vii) Results of the tests conducted upon the retained samples.

3. Accordingly, it is reiterated that we have not contravened the provisions of the Drug Laws and the rules framed thereunder as has been erroneously alleged in the show cause notice under reply. It has always been our mandate to ensure strict adherence with all legal as-well as regulatory stipulations envisioned under the Drug Laws and the rules framed thereunder. Therefore, the initiation of adverse proceedings against us on the basis of the incorrect findings furnished by the Analyst shall be against the principles of fair trial and due process as envisaged under Article 4 and Article 10-A of the Constitution of Islamic Republic of Pakistan, 1973.

4. In view thereof, since no case is made out against us, your good-self is very kindly requested to withdraw the show cause notice along with all subsequent proceedings and consign the case to record.

Regards,

6. Personal Hearing notice(s) issued to accused person(s) dated 16-09-2024.

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

PQCB's 285th meeting held on 26-09-2024:

2. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in

its **285th Meeting held on 26-09-2024** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab (Chairperson PQCB). Mst. Irum Kaukab, Secretary DQCB, Multan attended the meeting online via zoom link. Among the nominated accused persons Aamir Shahzad (QC Head) along with Fatima Zahid (Lawyer) and Fatima Abbas (Advocate) of M/S Davis Pharmaceutical Laboratories, 121, Industrial Triangle Area, Islamabad-Pakistan were present. The case was left-over due to time constraint.

3. Personal Hearing notice(s) issued to accused person(s) dated 22-10-2024.

PQCB's 286th meeting held on 30-10-2024:

4. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **286th meeting held on 30-10-2024** under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson, PQCB). Mst. Irum Kaukab, Secretary DQCB, Multan, attended the meeting online via Zoom Link. Mr. Junaid Sanawan, Drug Inspector. Shuja Abad, Multan was present along with original case record. No one among the nominated accused persons of M/s Davis pharmaceutical laboratories 121, industrial triangle area, Islamabad- Pakistan was present. However counsel person Fatima Abbas (Advocate) appeared before the Board and requested for adjournment as the Technical staff of the firm could not manage to attend the meeting.
5. The Board after due deliberation and discussion unanimously decided to **adjourn the case** due to absence of the firm. The Board further decided to provide another opportunity of personal hearing to the accused in best interest of justice.

Personal Hearing notice(s) issued to accused person(s) dated 12-09-2025.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:07-2021**
- **Exp. Date: 06-2023**
- **Sampling date (Form 4): 02-09-2021**
- **Sent to DTL (Form 6): 03-09-2021**
- **Date of receipt in DTL: 04-09-2021**
- **DTL Report Date (Form 7): 02-11-2021**
- **Time Extension to DTL: report not time barred**
- **DI 1st intimation to firm: 09-11-2021**
- **Retesting request if any: Yes**
- **Fate of Retesting Request: NIH Substandard**
- **Investigation report Dated: 26-06-2023**
- **SCN Permission: 265th meeting dated: 03-08-2023**
- **SCN Issued: 17-01-2024**
- **Reply of the firm Yes**
- **History (from 2021) Firm: 07 cases**
- **Product: 03 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:



Case No. 10

Tehsil Phalia, District Mandi Bahauddin

ATTENDANCE:

Secretary DQCB Drug Inspector	Accused Persons involved in subject case. <ol style="list-style-type: none">1. WellCare Pharmaceuticals, A/7 P.S.I.E., Sargodha, Pakistan through its Managing Director, Malik Saeed Akhtar2. Malik Saeed Akhtar Managing Director / Warrantor3. Khalil Ahmad Production Manager4. Ambreen Sher Quality Control In-charge5. .Sheikh Muhammad Anwar Warrantor of M/s Medilinks Pharmaceutical Distributors Opp. Wapda Complaint Off. Old Power House Mandi Bahauddin
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BRIEF FACTS OF THE CASE

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

- i. He, on 27-06-2022 inspected the business premises of M/s Khalid Medical Store, situated at adda Manu Chak, Tehsil Phalia District Mandi Bahauddin, took two different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 131662 dated 29-06-2022.
- ii. The subject drug sample, after test/analysis was declared as **Substandard & Misbranded** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result		
Suspension. Paracare 60ml [Each 5mL contains Paracetamol B.P 120mg] Mfg. Date: March-2022	PE- 006	M/s WellCare Pharmaceuticals, A/7 P.S.I.E., Sargodha, Pakistan.	01- 68016786/DTL dated: 01-09- 2022	Result of test/ analysis with specifications applied: BP 2022 DESCRIPTION: Light pink color suspension contained in amber color glass bottle sealed and capped with white plastic cap, packed in outer hard carton. IDENTIFICATION: Paracetamol is identified. ASSAY: <table border="1" style="margin-left: auto; margin-right: auto;"><tr><td>Stated</td><td>120mg /5ml</td></tr></table>	Stated	120mg /5ml
Stated	120mg /5ml					

Exp. Date: March-2024 Reg. No: 024998				<table border="1"> <tr> <td>Determined</td> <td>14.918 mg/5ml</td> </tr> <tr> <td>Percentage</td> <td>12.432% (Does not Comply)</td> </tr> <tr> <td>Limit</td> <td>95-105% (BP 2022)</td> </tr> </table>	Determined	14.918 mg/5ml	Percentage	12.432% (Does not Comply)	Limit	95-105% (BP 2022)
	Determined	14.918 mg/5ml								
	Percentage	12.432% (Does not Comply)								
Limit	95-105% (BP 2022)									
<p><u>LABELLING REQUIREMENTS</u></p> <p><u>STATED:</u> According to Drugs Act 1976 Section 3 (s) (vi), “Misbranded” means a drug:</p> <p>“which is manufactured according to the specifications of a particular Pharmacopoeia or any other document as may be prescribed and the label does not bear the name of that Pharmacopoeia or document.”</p> <p><u>DETERMINED:</u> In case of given sample, the specifications of dosage form according to which it is manufactured, are not printed on the label of immediate container (bottle) and outer hard carton. (Does not comply)</p> <p><u>RESULT:</u> Given sample is Sub-standard with regards to Assay and Misbranded with regards to Labelling (as per section 3 (s) (vi) of The Drugs Act 1976.</p>										

- iii. M/s Khalid Medical Store, situated at adda Manu Chak, Tehsil Phalia District Mandi Bahauddin provided warranty No. 2863 dated 12-06-2022 issued by M/s Medilinks Pharmaceutical Distributors Opp. Wapda Complaint Off. Old Power House Mandi Bahauddin as a proof of its purchase.
- iv. Warrantor Portion of subject drug sample was sent to M/s Medilinks Pharmaceutical Distributors Opp. Wapda Complaint Off. Old Power House Mandi Bahauddin who in-turn provided warranty No. 001118/22 dated 04-04-2022 issued by M/s WellCare Pharmaceuticals, A/7 P.S.I.E., Sargodha, Pakistan
- v. A Copy of Test/ Analysis report was sent to M/s WellCare Pharmaceuticals, A/7 P.S.I.E., Sargodha, Pakistan with directions to explain their position and to provide requisite information in this regard.

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

Sr. No	Premises	Offences
1	1. M/s WellCare Pharmaceuticals, A/7 P.S.I.E., Sargodha, Pakistan through its Managing Director, Malik Saeed Akhtar 2. Malik Saeed Akhtar Managing Director / Warrantor	a) Manufacture for sale/ sale of Substandard Drug b) Issuance of False Warranty

	3. Khalil Ahmad Production Manager	
	4. Ambreen Sher Quality Control In-charge	
2.	1. Sheikh Muhammad Anwar Warrantor of M/s Medilinks Pharmaceutical Distributors Opp. Wapda Complaint Off. Old Power House Mandi Bahauddin.	i. Stock for sale/ Sale of Substandard & Misbranded Drug ii. Sale of drugs without having Authorization/ warranty from manufacturer

3. Show cause notice/ issued to accused person(s) dated 10-06-2024

Reply of showcase notice dated 15-06-2024

Respected Sir,

Ref to your letter No. PQCB/R-759/2022 of dated 10.06.2024, It is stated that please find here attachment, which clearly shows that we received an letter No. 122/DDC/PHL of dated 14.11.2023 from the office of Deputy Drugs Controller Phalia, In response of which, we replied, letter No. WC/2013/23 of dated 16.11.2023 and we disowned the authority letter including invoice because We are not at all working in District Mandi Bahauddin and there are no our distributor.

Further Sir, please find here the approved names of our technical staff

3. Personal hearing notice(s) issued to accused person(s) dated 08-08-2025

PERVIOUS PROCEEDING & DECISION BY THE BOARD:

4..... 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 Vice-Chairperson, Provincial Quality Control Board, Punjab. Miss Uzma Mazhar. Secretary, Mandi Burhanuddin attended the meeting online via zoom link, Mr. Atta-ul-Mustafa., Provincial Inspector of Drugs, Tehsil Phalia, District Mandi Burhanuddin appeared before the Board with original case record.,. No one among nominated accused persons appeared before the Board to plead the case. on the behalf of M/s.. Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha. However, Sheikh Muhammad Anwar Warrantor of M/s Med links Pharmaceutical Distributors Opp. Wapda Complaint Off. Old Power House Mandi Burhanuddin. appeared before the Board. The firm submitted the adjournment request vide letter no. WC /4176/25 dated 16-08-2025 *stated that their council/Advocate (Mr. Khawaja Tahir on foreign tour as there area leave session in high court.* The Board after due deliberation and discussion unanimously decided to **adjourn** the case.

5.....Personal hearing notice(s) issued to accused person(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	27-06-2022
Sent to DTL (Form 6):	29-06-2022
Date of receipt in DTL	05-07-2022
DTL Report Date (Form 7):	01-09-2022
Time Extension granted	Time Extension granted in 250TH Meeting dated 22-09-2022
1st DI Communication with firm dated	16-05-2023
Fate of Retesting request	N/A
Investigation Report Dated	22-12-2023
Firm History 3 years	Firm: 20 Product:09 (Paracare 450ml& 60ml)

PROCEEDING & DECISION BY THE BOARD

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Case No. 11

ATTENDANCE:

Secretary DQCB Drug Inspector	Accused Persons involved in subject case. 1. M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha through its Managing Director, Malik Saeed Akhtar. 2. Malik Saeed Akhtar Managing Director/ Warrantor 3. Shahid Inayat Quality Control Manager 4. Khawaja Farzand Ali Production Manager of M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha
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BRIEF FACTS OF THE CASE

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

- i. He, on 17.01.2023, inspected the business premises of M/s Usman Medical Store Ali khail Tehsil Kallur Kot, took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No. 154477 dated 18.01.2023.
- ii. Following Drug samples after test/analysis were declared as **Substandard & Misbranded** by Government Analyst Drug Testing Laboratory **Rawalpindi** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Suspension Carefen 90ml [5ml contains: Ibuprofen 100mg] Mfg. Date: 12.2022 Exp. Date:12.2024	CN-015	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.	01-75005751/DTL Dated. 14.03.2023
DTL Test Report Result <u>Analysis with specifications applied: USP 2022</u> <u>Physical Description:</u> orange colour suspension filled in amber glass bottle having affixed label, of claimed volume 90ml, sealed with white colour plastic screw cap. packed in label outer carton. Manufacturing specifications is not mentioned on bottle label/outer carton. whereas, ibuprofen oral suspension monograph is available in USP-2022 AND BP 2022. DOES NOT CPOMPLY.			

IDENTIFICATION: Ibuprofen identified

Assay:

Stated: 100mg/5mL

Determined: 29.944mg/5mL

Percentage: 29.94% **Does not comply**

Limit: **90-110%**

Result: The above sample is substandard on the basis of Assay test performed & Misbranded as defined under clause (vi) of subsection 9 (s) of section 3 of Drugs Act 1976.

- iii. M/S Usman Medical Store Ali khail Tehsil Kallur kot provided Invoice/warranty No AS4348 dated 05-01-2023 issued by M/s Ali Traders ward no. 4 Mohalla Bhakkar who in turn provided invoice/warranty no. 237 dated 01-01-2023 issued by M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.
- iv. Warrantor portion of drug sample was sent to M/s Ali Traders ward no. 4 Mohalla Bhakkar
- v. A copy of test/analysis report was sent to M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha and they were directed to explain their position and to provide the requisite information in this regard.

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

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

3. Show cause notice/ issued to accused person(s) dated 20-12-2024

Reply of showcase notice dated 08-01-2025

It is humbly submitted that,

1. We are a well reputed tax pays quality-oriented firm providing the best health services to the public in all aspect at our level best.
2. Your said show cause notice reflects that sample of Suspension Carefen 90ml Batch No. CN-015 was seized by the honorable drug inspector on 17.01.2023 from M/S Usman Medical Store Ali Khail Tehsil Kallur Kot & the same has been declare sub-standard by the Government Analyst DTL Rawalpindi.
3. It is stated that in response to the honorable Drug Inspector's letters we clearly disowned authority letter and invoice presented by M/S Ali Traders ward No.4, Mohalla Bhakkar. (Copy Attached)
4. Moreover Sir, We also registered a self-explanatory complain/Report to the relevant police station. (Copy Attached)

5. Personal hearing notice(s) issued to accused person(s) dated 08-08-2025

PERVIOUS PROCEEDING & DECISION BY THE BOARD

6.....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 Vice-Chairperson, Provincial Quality Control Board, Punjab., Mr. Imran Ahmed Khan Provincial Inspector of Drug Tehsil Kallur Kot, District Bhakkar appeared before the Board with original case record. No one among nominated accused persons appeared before the Board to plead the case. on the behalf of M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha. The firm submitted the adjournment request vide letter no. WC /4176/25 dated 16-08-2025 *stated that their council/Advocate (Mr. Khawaja Tahir on foreign tour as there are leave session in high court.* The Board after due deliberation and discussion unanimously decided to **adjourn** the case.

7.....Personal hearing notice(s) issued to accused person(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	17-01-2023
Sent to DTL (Form 6):	18-01-2023
Date of receipt in DTL	21-01-2023
DTL Report Date (Form 7):	14-03-2023
Time Extension granted	N/A
1 st DI Communication with firm dated	22-03-2023
Fate of Retesting request	N/A
Investigation Report Dated	20-11-2023
Firm History 3 years	Firm: 20 Product: 06 (Carefen 450ml& 90ml)

PROCEEDING & DECISION BY THE BOARD

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Case No. 12

Tehsil & District Sargodha

ATTENDANCE:

Secretary DQCB Drug Inspector	Accused Persons involved in subject case. 1. M/s Wellcare Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha through its Managing Director, Malik Saeed Akhtar. 2. Malik Saeed Akhtar Managing Director/CEO 3. Shahid Inayat Quality Control Incharge 4. Ussama Rehman Production Incharge/Warrantor of M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha
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BRIEF FACTS OF THE CASE

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

- i. He, on 10-12-2024, inspected the premises of M/s Al Usman Medicine company, Al Muneer Market Block #4 Sargodha took below mentioned drug samples on Form.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No.212827 & 212828 dated 11-12-2024.
- ii. Following Drug samples after test/analysis were declared as **Substandard /Misbranded** (DTL Test Report 1) & **Spurious Misbranded** (DTL Test Report 2) by Government Analyst Drug Testing Laboratory **Rawalpindi** as detailed below

1.DTL TEST REPORT

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Suspension Carefen 90ml (Each 5ml Contains: Ibuprofen 100mg), Mfg. Date: Exp Date: 11-2024 10-2026	CN-037	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.	01-75010318/DTL Dated. 27-01-2025

DTL Test Report Result

Analysis with specifications applied: USP 2024/Others/In House

Physical Description:

PHYSICAL DESCRIPTION:

Orange colored suspension, filled in an amber glass bottle with affixed label, sealed with white colored plastic screw cap, further packed in a labelled unit carton.

Product specifications are not mentioned, neither on the label nor on the unit carton of the sample.

(DOES NOT COMPLY)

pH:

Observed: 4.59 at 24.8 ° C (USP-2024)

Limit: 3.6 – 4.6 (Complies the test)

IDENTIFICATION:

Ibuprofen is Identified (Test-A & B) (USP-2024) (HPLC)

(Complies the test)

ASSAY:

Stated: 100 mg / 5 mL (USP-2024)

Determined: 23.139 mg / 5 mL (HPLC)

Percentage: 23.14 % (DOES NOT COMPLY)

Rounded Off: 23.1 %

(As per USP)

Limit: 90.0% - 110.0%

RESULT: The above sample is “Misbranded” as defined under clause (vi) of sub-section (s) of section 3 of The Drugs Act, 1976 and “Substandard”

with respect to Assay test performed.

2.DTL TEST REPORT

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Syrup Carenol Ammonium Chloride cough syrup 60ml (Each 5 ml contains Ammonium Chloride ..125 mg , Sodium Citrate ...55 mg, Chlorpheniramine	CL-036	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.	01-75010319/DTL Dated. 13-02-2025

maleate ...2.5 mg)

Mfg. Date: Exp Date:

08-2024 08-2026

DTL Test Report Result

Analysis with specifications applied: MS/Others/In House

Physical Description:

Red coloured solution, filled in amber coloured glass bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in an outer carton.

Manufacturing specification is not mentioned, neither on the label nor on the outer carton of the sample.

(DOES NOT COMPLY)

pH: Observed: 5.0 at 23.0 ° C (MS)
Limit: 4.0 – 6.0 (Complies the test)

ASSAY:

Ammonium Chloride:

Stated: 125 mg/ 5mL
Determined: 126.771 mg/ 5mL (Titration)
Percentage: 101.42 % (MS)
Rounded off: 101 % (Complies the test)

(As per USP)

Limit: 95 % - 105 %

Sodium Citrate:

Stated: 55 mg/ 5mL
Determined: 53.863 mg/ 5mL (Titration)
Percentage: 97.93 % (MS)
Rounded off: 98 % (Complies the test)

(As per USP)

Limit: 95 % - 105 %

Chlorpheniramine Maleate

Stated: 2.5 mg/ 5ml

Determined: 0.000 mg/ 5ml (UV Spectrophotometry)

Percentage: 00 % (MS)

Limit: 95 % - 105 % **(DOES NOT COMPLY)**

RESULT: The above sample is "Spurious" as defined under clause (i) of sub-section (z-b) of section 3 of The Drugs Act, 1976 and "Misbranded" as defined under clause (vi) of sub-section (s) of section 3 of The Drugs Act, 1976.

- iii. M/s Al Usman Medicine company, Al Muneer Market Block #4 Sargodha provided invoice/warranty No.001217/24 dated 02-12-2024 issued by M/s Well Care Pharmaceuticals Pvt Ltd, Sargodha.
- iv. Warrantor portions of drug sample were sent to Dr. Ussama Rehman (Production Manager/Warrantor) of M/s Well Care Pharmaceuticals Pvt Ltd, Sargodha.
- v. Copies of test/analysis reports were sent to M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha with directions to explain their position and provide requisite information in this regard
- vi. Drug Inspector further recommended suspension/cancellation Drugs Manufacturing License (DML)/Drug Registration Certificates (DRCs) of M/S Well Care Pharmaceuticals Pvt Ltd A/7 P.S.I.E Sargodha.

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

- a. **Manufacturing of Substandard & Misbranded Drugs** (Suspension Carefen 90ml, Batch No. CN-037)
- b. **Manufacturing of Misbranded & Spurious Drugs** (Syrup Caremol 60ml, Batch No CL-036)
- c. **Issuance of false Warranty**

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

Reply of showcase notice dated 02-05-2025

It is humbly submitted that,

It is astonishing to note the DTL reports that are Substandard, Mis branded & even Spurious of our products, we are well reputed firm & manufacturing standard quality products and one tax payee to the Government since long time.

As it is mentioned regarding warrantor portion, that have not been received at our end.

It seems that the drug inspector managed the manipulation in the samples in connivance with the M/S AI-Usman Medicine company Sargodha, No doubt we have manufactured the same batch of the products and sold in the market & no complaint anywhere else has been received regarding the quality of these drugs. On the other hand, on receiving the DTL reports, we checked the retention samples at our level and found all of standard quality

As the warrantor portions not sending to us is solid prof of manipulation due to reasons behind known to best the drug inspector as the worthy secretary health has been informed about all these games.

It is requested that an inquiry be initiated regarding the fact finding of this act.

Please find enclosed here with all the required documents as needed.

3. Personal hearing notice(s) issued to accused person(s) dated 07-08-2025

PERVIOUS PROCEEDING & DECISION BY THE BOARD:

6..... 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 Vice-Chairperson, Provincial Quality Control Board, Punjab. Mr. Amer Mahmood Secretary, Sargodha attended the meeting online via zoom link, , Mr, Zeeshan Haider Kazmi Provincial Inspector of Drugs, Tehsil & District Sargodha appeared before the Board with original case record, No one among nominated accused persons appeared before the Board to plead the case. on the behalf of M/sWell Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha. The firm submitted the adjournment request vide letter no. WC /4176/25 dated 16-08-2025 *stated that their council/Advocate (Mr. Khawaja Tahir on foreign tour as there are leave session in high court.* The Board after due deliberation and discussion unanimously decided to **adjourn** the case.

7. Personal hearing notice(s) issued to accused person(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	10-12-2024
Sent to DTL (Form 6):	11-12-2024
Date of receipt in DTL	16-12-2024
DTL Report Date (Form 7):	27-01-2025
Time Extension granted	N/A

1st DI Communication with firm dated	03-02-2025
Date of Retesting Request of Firm:	N/A
Fate of Retesting request	N/A
Investigation Report Dated	08-03-2025
	Firm: 20 Product:06 (Carefen),03 (Carenol)

PROCEEDING & DECISION BY THE BOARD

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Case No. 13

Tehsil& District Sargodha

ATTENDANCE:

Secretary DQCB Drug Inspector	Accused Persons involved in subject case. 1. M/S Wellcare Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha through its CEO/Managing Director, Malik Saeed Akhtar. 2. Malik Saeed Akhtar CEO/Managing Director 3. Shahid Inayat Quality Control Incharge /warrantor 4. Khawaja Farzand Ali Production Incharge of M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha
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BRIEF FACTS OF THE CASE

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

- i. He, on 20.04.2024, inspected the business premises of M/s Umer Medicine Distribution Shop # 2-3 V.I.P Market Block no. 4 Sargodha, took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No. 197054 dated 22.04.2024.
- ii. Following Drug samples 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 TRA No. & Date
Suspension Paracare 450ml [Paracetamol 120mg/5ml (suspension not to be a suspension)] Mfg Date: Exp Date: 10.2023 10.2025	PE-026	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.	01-75009181/DTL Dated. 31.07.2024
DTL Test Report Result			
<u>Analysis with specifications applied:</u> BP 2024/MS			
<u>Physical Description:</u> Brown colored suspension fille din white colored plastic bottle having affixed label sealed with white colored plastic screw cap.			

Pink colour” is mentioned in Manufacturer’s Specification while in actual sample is of “Brown colour”.

IDENTIFICATION:

Paracetamol identified (complies the test)

(HPLC, BP 2024)

Assay:

Stated: 120mg/5mL

Determined: 80.97mg/5mL (HPLC)

Percentage: 67.48% **Does not comply**

Limit: 95-105% (BP 2024)

Note: Time extension was granted vide order no. PQCB/TEX-RWP-41/2024 dated 27-06-2024

Result: The above sample is substandard on the basis of Assay test performed and Physical characteristics observed.

- iii. M/S Umer Medicine Distribution Shop # 2-3 V.I.P Market Block no. 4 Sargodha provided Invoice/warranty No. 001217/24 dated 22-03-2024 issued by M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.
- iv. Warrantor portion of drug sample and a copy of test/analysis report was sent to M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha and they were directed to explain their position and to provide the requisite information in this regard.

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

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

3. Show cause notice/ issued to accused person(s) dated 04-11-2024

Reply of showcase notice dated 16-11-2024

It is humbly submitted that,

1. We are a well reputed tax pays quality-oriented firm providing the best health services to the public In all aspect at our level best.
2. Your said show cause notice reflects that sample of suspension Paracare 450ml Batch No. PE-026 was seized by the drug inspector on 20.04.2024 & the same has been declare sub-slandered by the Government Analyst DTL Rawalpindi on 31.07.2024.
3. The Government Analyst relised upon.

a. Color change of Syrup.

The label claim of our product is "Store in a cool & dry place Protect from light" The color can be changed due to climatic factor; we assure the product was in original color as per specification at the time of sale.

b. Assay i.e. determined 80.97mg/5ml.

The assay determination is done on HPLC while our product follows UV determination.

It is requested that while considering all above clarification please file our case, your favor will be highly appreciated in this regard.

5. Personal hearing notice(s) issued to accused person(s) dated 08-08-2025

PERVIOUS PROCEEDING & DECISION BY THE BOARD:

6.....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 Vice-Chairperson, Provincial Quality Control Board, Punjab. Mr. Amer Mahmood Secretary, Sargodha attended the meeting online via zoom link, , Mr, Zeshan Haider Kazmi Provincial Inspector of Drugs, Tehsil & District Sargodha appeared before the Board with original case record, No one among nominated accused persons appeared before the Board to plead the case. on the behalf of M/s.. Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha. The firm submitted the adjournment request vide letter no. WC /4176/25 dated 16-08-2025 *stated that their council/Advocate (Mr. Khawaja Tahir on foreign tour as there are leave session in high court.* The Board after due deliberation and discussion unanimously decided to **adjourn** the case.

7.....Personal hearing notice(s) issued to accused person(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	20-04-2024
Sent to DTL (Form 6):	22-04-2024
Date of receipt in DTL	26-04-2024
DTL Report Date (Form 7):	31-07-2024
Time Extension granted	Time Extension granted in 41th Committee Meeting dated 27-06-2024
1 st DI Communication with firm dated	07-08-2024

Fate of Retesting request	N/A
Investigation Report Dated	28-09-2024
Firm History 3 years	Firm: 20 Product:09 (Paracare)

PROCEEDING & DECISION BY THE BOARD

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Case No. 14

PQCB- MSS-206562,206564,206563,206561/2024

Lisencenced Manufacturer Sargodha

ATTENDANCE:

Secretary DQCB Drug Inspector	Accused Persons involved in subject case. 1. M/S Wellcare Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha through its Managing Director, Malik Saeed Akhtar. 2. Malik Saeed Akhtar Managing Director 3. Shahid Inayat Quality Control Incharge 4. Ussama Rehman Production Incharge of M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, For Licenced/ Enlisted Manufacture of Therapeutic Goods FSD/GRW/SGD/Gujrat Division reported that:

- i. He, on 24-09-2024, inspected the premises of M/s WellCare Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha took below mentioned drug samples on Form.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No.206562,206564,206563,206561, & 206565 dated 29-09.2024.
- ii. Following Drug samples after test/analysis were declared as **Substandard** (DTL Test Report 1) & **Spurious Misbranded** (DTL Test Report 2) **Spurious** (DTL Test Report 3) & **Spurious Misbranded** (DTL Test Report 4) by Government Analyst Drug Testing Laboratory **Rawalpindi** as detailed below

1.DTL TEST REPORT

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Suspension Paracare 450ml (Each 5ml contains: Paracetamol 120 mg) Mfg. Date: Exp Date: 09-2024 09-2026	PE-036	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.	01-75009953/DTL Dated. 29-11.2024

DTL Test Report Result

Analysis with specifications applied: BP 2024/Others/In House

Physical Description:

Pink colored suspension, filled in a white-colored plastic bottle with affixed printed label, sealed with white colored plastic screw cap.

(Complies the Test)

IDENTIFICATION:

Paracetamol identified (Test-B)

(HPLC) (BP-2024)

(Complies the test)

Assay

Stated:	120 mg/5 mL	
Determined:	34.764 mg/5 mL	(HPLC) (BP-2024)
Percentage:	28.97 %	(Does not Comply)
Rounded off:	29.0 %	
(As per USP)		
Limit:	95.0 % - 105.0 %	

Result: The above sample is "Substandard" on the basis of Assay test performed.

2.DTL TEST REPORT

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Syrup Carenol Ammonium Chloride cough syrup 60ml (Each 5 ml contains Ammonium Chloride ..125 mg , Sodium Citrate ...55 mg ,Chlorpheniramine maleate ...2.5 mg) Mfg. Date: Exp Date: 09-2024 09-2026	CL-037	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.	01-75009951/DTL Dated. 05-12.2024
DTL Test Report Result			

Analysis with specifications applied: MS/Others/In House

Physical Description:

Red coloured solution filled in amber coloured glass bottle having affixed label sealed with white coloured screw cap on further packed in an outer carton.

” Manufacturing Specification is not mentioned neither on the label nor on the outer carton of the sample

Does not comply)

Assay

Ammonium Chloride

Stated: 125 mg/5mL

Determined: 123.150 mg/5mL (Titration)

Percentage: 98.52% (MS)

Rounded off: 98.5 (Complies the Test)

(As per USP)

Limit: 95%-105%

Assay

Sodium Citrate

Stated: 55 mg/5mL

Determined: 53.863 mg/5mL (Titration)

Percentage: 97.93% (MS)

Rounded off: 97.9 (Complies the Test)

(As per USP)

Limit: 95%-105%

Assay

Chlorpheniramine Maleate

Stated: 2.5 mg/5mL

Determined: 0.000 mg/5mL (UV Spectrophotometry)

Percentage: 0.0% (MS)

Limit: 95%-105% (Does not Comply)

Result: The above sample is Spurious as defined under clause (i) of subsection (z-b) of section 3 of The Drugs Act,1976 and "Misbranded as defined under clause (vi) of subsection (s) of Section 3 of the Drugs Act 1976,.

3.DTL TEST REPORT

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Syrup Histacare 450 ml (Each 5mL contains Chlorpheniramine Maleate 2mg) Mfg. Date: Exp Date: 09-2024 09-2026	HE-036	M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha.	01-75009950/DTL Dated. 05-12.2024

DTL Test Report Result

Analysis with specifications applied: USP2024/Others/In House

Physical Description:

Green colored solution filled in a white-colored plastic bottle with affixed printed label and sealed with white colored plastic screw cap.

(Complies the test)

IDENTIFICATION:

Chlorpheniramine Maleate not identified (TEST-B) (UV-Visible Spectroscopy)

(USP-2024)

(DOES NOT COMPLY)

ASSAY:

Stated: 2 mg /5 mL

Determined: 0.000 mg/ 5 mL (UV-Visible Spectroscopy)

Percentage: 0.0 % (USP-2024)

Limit: 90.0 – 110.0% (DOES NOT COMPLY)

Stated:	100 mg / 5 mL	(USP-2024)
Determined:	0.00 mg / 5 mL	(HPLC)
Percentage:	0.0 %	(DOES NOT COMPLY)
Limit:	90.0% - 110.0%	

Acetaminophen

Determined: 47.112 mg / 5 mL (USP-2024) (HPLC)

(DOES NOT COMPLY)

Note: Time Extension was granted vide order No. POCB/ TEX-RWP-46/2024 dated

17-12-2024.

RESULT: The above sample is "Spurious" as defined under clause (i) & (iii) of sub-section (z-b) of section 3 of The Drugs Act, 1976 and "Misbranded" as defined under clause (vi) of sub-section (s) of section 3 of The Drugs Act, 1976.

- iii. Whereas firm did not provide method of one sample sent vide memo no. 206565 **Syrup Wellfer 60ml** Batch No. **WR-020** to Drug Testing Laboratory **Rawalpindi** and DTL file the case & send to POCB with recommendation of cancellation of license due to noncompliance of Method of Analysis
- iv. Copies of test/analysis reports were sent to M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha and they were directed to explain their position and to provide the requisite information in this regard.
- v. Drug Inspector further recommended suspension/cancellation Drugs Manufacturing License (DML)/Drug Registration Certificates (DRCs) of M/S Well Care Pharmaceuticals Pvt Ltd A/7 P.S.I.E Sargodha.

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

- a. **Manufacturing of Spurious Drugs**
- b. **Manufacturing of Substandard Drugs**
- c. **Manufacturing of Misbranded Drugs**
- d. **Disobedience of lawful authority**

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

Reply of showcase notice dated 23-04-2025

It is stated that the matter needs further inquiry, we have already informed the concerned drug inspector vide letter No. WC/320/24 of dated 23.12.2024 under intimation to the worthy Secretary health (copy enclosed)

The Drug Inspector entered the premises while threatening the Gate keeper/Chowkidar as the premises was closed and no one worker and machine was working at that time he entered along with unknown persons on finding the working area closed they entered in garbage area and some time spent there. That area is specified for garbage and rejected things to be destroyed from time to time.

If the drug inspector seized/sealed samples from garbage area even then the process is not done there physically & practically He did not delivered sealed portion to the person present there which is mandatory as per drug act. All the process has been adopted as pre-plain and some unknown motives against us due to unknown reasons behind the story.

It is further added that the products have not been analysis by applying method of analysis as per our monogram.

It is requested that all proceeding against us are baseless & self-created and the case needs further inquiry.

3. Personal hearing notice(s) issued to accused person(s) dated 07-08-2025

PERVIOUS PROCEEDING & DECISION BY THE BOARD:

...4..... 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 Vice-Chairperson, Provincial Quality Control Board, Punjab. Mr. Amer Mahmood Secretary, Sargodha attended the meeting online via zoom link, Miss Sara Provincial Inspector of Drugs, Licensed/ Enlisted Manufacture of Therapeutic Goods FSD/GRW/SGD/Gujrat Division appeared before the Board with original case record. No one among nominated accused persons appeared before the Board to plead the case. on the behalf of M/s. Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha. The firm submitted the adjournment request vide letter no. WC /4176/25 dated 16-08-2025 *stated that their council/Advocate (Mr. Khawaja Tahir on foreign tour as their area leave session in high court.* The Board after due deliberation and discussion unanimously decided to **adjourn** the case.

5.....Personal hearing notice(s) issued to accused person(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	24-09-2024
Sent to DTL (Form 6):	29-09-2024
Date of receipt in DTL	29-09-2024
DTL Report Date (Form 7):	29-11-2024 05-12-2024 24-12-2024
Time Extension granted	Time extension granted in 46 Committee Meeting dated 17-12-2024

1st DI Communication with firm dated	13-12-2024
Date of Retesting Request of Firm:	N/A
Fate of Retesting request	N/A
Investigation Report Dated	03-02-2025
History of firm 3 years	Firm: 20 Product: 06 (Carefen) 03 (Carenol, 01 (Histacare) 09 (Paracare)

Note: Firm did not provide method of one sample sent vide memo no. 206565 Syrup Wellfer 60ml Batch No. WR-020 to Drug Testing Laboratory Rawalpindi

DTL file the case & send to PQCB with recommendation of cancellation of license due to noncompliance of Method of Analysis

PROCEEDING & DECISION BY THE BOARD:

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Case No. 15

Item No. 1

Part A

Court Direction

One of the accused named Ahmad Ali s/o Rana Muhammad Ali in subject case filed a **Writ Petition No. 10191 of 2025** in the Honorable Lahore High Court Multan Bench, Multan titled as “**Ahmad Ali vs Secretary etc.**” The **court order dated: 11-09-2025** in subject petition is reproduced as below;

Through instant petition, petitioner has assailed the show cause notice dated 26.08.2025, issued by respondent No.1.

2. It is contended by learned counsel that impugned show cause has been issued by an incompetent authority. When asked as to whether petitioner has raised any objections against impugned show cause notice, learned counsel submits that petitioner has not raised any objections so far, however, requests that a copy of this petition, along with all the annexures, may be sent to respondent No.1. with a direction to treat it as objections and decide the same strictly in accordance with law.

3. When confronted, learned Law Officer has expressed no objection to the disposal of this petition as requested by learned counsel for petitioner.

4. In view of above, I am inclined to dispose of this petition while transmitting its copy, along with all the annexures, to respondent No.1, with a direction to treat it as objections 133 against impugned show cause notice and decide the same strictly in accordance with law after hearing petitioner and all concerned, through a speaking order within a period of seven days from the date of receipt of certified copy of this order. In order to facilitate the process, petitioner shall appear before said respondent on 15.09.2025 at 11:00 am. Learned Law Officer shall ensure compliance of this order.

History of Writ Petitions file by Ahmad Ali s/o Rana Muhammad Ali:

Ahmad Ali s/o Rana Muhammad Ali filed 2 more writ petition against PQCB order no. PQCB/RP-33-10/2024 in revision petition against M/s Square Pharmaceuticals situated at H# 195/O-CB, Near Qartaba Masjid, Muhallah Garden Town, Multan submitted by Drug Inspector Bosan Town, Multan.

- i. **Writ Petition No. 3741/2025** titled as “**Ahmad Ali vs Secretary etc.**” Dismissed by Honorable Lahore High Court Multan Bench, Multan in which PQCB order referring the case to RPO, Multan for reinvestigation was challenged.
- ii. **Writ Petition No. 7375/2025** titled as “**Ahmad Ali vs PQCB etc.**” **Disposed off on 24-06-2025** by Honorable Lahore High Court Multan Bench, Multan in which court directed the PQCB to decide review petition of the petitioner.

PQCB/ MSS-193594/2024`

Shah Rukan-e-Alam Town, Multan

ATTENDENCE

Secretary DQCB	<u>Accused Persons involved in subject case</u>
	<p>1. Mumtaz Hussain s/o Muhammad Munir Representative (CNIC # 36602-8211074-9) R/o Basti Eisan Shah P/o Tibba Sultan Pur, Sahib Ali, Tehsil Mailsi, District Vehari of M/S Incepta Pharmaceuticals Ltd., Korangi Industrial Area, Plot no. 88, Karachi</p> <p>2. Ahmad Ali S/o Rana Muhammad Ali Proprietor/Owner (CNIC # 36302-4941261-3)</p> <p>3. Muhammad Wahaj S/o Syed Ehsan Ullah Shah Proprietor/Owner (CNIC # 32304-5267575-7) R/o Ward No. 13, House no. 401, Mohallah Qamar Kota, Muzaffargarh of M/s Square Pharmaceuticals situated at H# 195/O-CB, Near Qartaba Masjid, Muhallah Garden Town, Multan.</p>
Drug Inspector	

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Shah Rukan-e-Alam Town, Multan, reported that:

- i. He, on 28-02-2024 inspected the business premises of M/s Dynam Pharma, House no. 387/10, Street # 6, Ahmed Park Near Gulistan Chowk, Multan, and recovered and seized a drug sample on Form No. 5 (Sr# 28685) as detailed below:

Sr. No.	Name of Drug	Batch No.	Name of Manufacturer	Quantity	Reason of seizure
1	Tab. Caryon 10mg	CRY-200-009	M/s Incepta Pharmaceuticals, Karachi	93 Packs (20 Tab/Pack)	<ol style="list-style-type: none">i. W/O warrantyii. Sale of drugs in the absence of Qualified Person

- ii. He also took sample of **Film Coated Tablet Caryon 10mg, Batch # CRY-200/009** on Form No. 4 (Sr #

56173) and sent to Drug Testing Laboratory, Multan for the purpose of test/analysis.

iii. The said drug sample, sent vide Form 6 memo no.193594, dated: 29-02-2024, after test/analysis was declared as **Spurious** by Government Analyst, Drug Testing Laboratory, **Multan**. as detailed below:

Drug Sample	Batch	Manufacturer	TRA No. and Date
Film Coated Tablet Caryon [Each film coated tablet contains Dydrogesterone...10mg] Mfg. date: 08-2023 Exp. Date: 07-2025 Reg. # 9997772	CRY-200/009	M/S Incepta Pharmaceuticals Ltd., Korangi Industrial Area, Plot no. 88, Karachi.	01-105005714/DTL Dated 03-06-2024.

Specs Applied: BP 2024

DESCRIPTION:

White, round biconvex tablets, plain on both sides in ALU-ALU blister of 10 units in a labeled outer hard carton. Each outer carton contains 2 blisters of 10 units each i.e (2*10= 20 Tablets).

Identification by FTIR Dydrogesterone is not Identified. **(DOES NOT COMPLY)**

Assay by UV Spectroscopy

Dydrogesterone

Stated: 10 mg/Tablet

Determined: 0.0 mg/Tablet

Percentage: 0.00%

Limit: 92.5-107.5% **(DOES NOT COMPLY)**

“Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-37/2024

Dated 30-04-2024”

Note: Drug Regulatory Authority of Pakistan, vide Letter No. F. 10-3/2022-Lic (AD-III) dated 03, June 2024 clarified that “No Firm namely M/s Incepta Pharmaceuticals Ltd., Korangi Industrial Area, Plot no. 88, Karachi has been licensed by Drug Licensing Division, DRAP” and also stated “ above-mentioned product is NOT REGISTERED under section 7 of the Drugs At 1976 and Rules framed thereunder” vide letter No. F.8-2/2020-Reg-I dated: 29, April 2024.

RESULT: The given sample is **Spurious** as described under Section 3(zb)(i) and (iv) of Drugs Act 1976.

- iv. M/s Dynam Pharma, House no. 387/10, Street # 6, Ahmed Park Near Gulistan Chowk, Multan disclosed the source of purchase of **Film Coated Tablet Caryon 10mg, Batch # CRY-200/009** from Mumtaz Hussain (representative of M/s Incepta Pharma) through a copy of Invoice/warranty # 3896 dated: 01-02-2024 and the same original invoice/warranty and authority letter as distributor issued to M/s Dynam Pharma by M/s Incepta Pharma was recovered and seized on Form 5 by the Deputy Drug Controller Bosan Town, Multan during the raid on M/s M Square Pharmaceuticals situated at H# 195/O-CB, Near Qartaba Masjid, Muhallah Garden Town, Multan on 02-03-2024.
- v. Mumtaz Hussain (representative of M/s Incepta Pharma) disclosed that he purchased tab. Caryon, Batch # CRY-200/009 from Rana Ahmad Ali (Proprietor/Owner of M/s M Square Pharmaceuticals) and supplied to M/s Dynam Pharma, Multan.
- vi. Ahmad Ali and Muhammad Wahaj of M/s M Square Pharmaceuticals both failed to produce any concrete evidence, however, they disclosed that Sajjad Ali of M/s Dynam Pharma is the stockiest and authorized Distributor of Tab. Caryon in District Multan and he offered Muhammad Wahaj to work as a sub-distributor of M/s Incepta Pharma, Karachi.
- vii. A copy of test/analysis report of **Film Coated Tablet Caryon 10mg, Batch # CRY-200/009** was sent to Sajjad Ali, Proprietor of M/s Dynam Pharma, House no. 387/10, Street # 6, Ahmed Park Near Gulistan Chowk, Multan and to Mumtaz Hussain s/o Muhammad Munir, representative of M/S Incepta Pharmaceuticals Ltd., Korangi Industrial Area, Plot no. 88, Karachi to explain their position and provide requisite information in this regard.
- viii. The Provincial Inspector of Drugs requested for grant of permission for registration of F.I.R against you, as you have contravened the provisions of Section 23/27 of Drugs Act 1976 (as amended)/DRAP Act 2012 and the Rules framed thereunder by the way of:

Accused	Offences
<p>1. Mumtaz Hussain s/o Muhammad Munir Representative (CNIC # 36602-8211074-9) R/o Basti Eisan Shah P/o Tibba Sultan Pur, Sahib Ali, Tehsil Mailsi, District Vehari of M/S Incepta Pharmaceuticals Ltd., Korangi Industrial Area, Plot no. 88, Karachi</p>	<p>a. Selling/Stocking of Spurious Tab. Caryon, Batch # CRY-200-009 b. Selling/Stocking drugs without Drug Sale License c. Selling/Stocking drugs without Warranty</p>
<p>1. Ahmad Ali S/o Rana Muhammad Ali Proprietor/Owner (CNIC # 36302-4941261-3) 2. Muhammad Wahaj S/o Syed Ehsan Ullah Shah Proprietor/Owner (CNIC # 32304-5267575-7) R/o Ward No. 13, House no. 401,</p>	<p>a. Selling/Stocking of Spurious Tab. Caryon, Batch # CRY-200-009 b. Selling/Stocking drugs without Drug Sale License c. Selling/Stocking drugs without Warranty</p>

Mohallah Qamar Kota, Muzaffargarh

of M/s M Square Pharmaceuticals situated at H# 195/O-CB, Near
Qartaba Masjid, Muhallah Garden Town, Multan

2. Show cause notice(s) issued to accused person(s) dated 26-08-2025.

Personal Hearing notice(s) issued to accused person(s) dated 12-09-2025.

Case is placed before the board for decision.

PQCB/ MSS-193594, 193595/2024`

Shah Rukan-e-Alam Town, Multan

ATTENDENCE

Secretary DQCB	<u>Accused Persons involved in subject case</u>
	1. Sajjad Ali s/o Sultan Ahmad Proprietor (CNIC # 36302-5924862-5)
Drug Inspector	2. Saira Bilal D/o Muhammad Bilal Qualified Person (CNIC # 36303-5078562-0)
	of M/S Dynam Pharma, House no. 387/10, Stret no. 6, Ahmad Park, Near Gulistan Chowk, Multan. (DSL #04-361-0171-02295D)

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Shah Rukan-e-Alam Town, Multan, reported that:

- i. He, on 28-02-2024 inspected the business premises of M/s Dynam Pharma, House no. 387/10, Street # 6, Ahmed Park Near Gulistan Chowk, Multan, and recovered and seized a drugs/items on Form No. 5 (Sr#

28685 and Sr # 28686) as detailed below:

Form-5 (Sr #28685)

Sr. No.	Name of Drug	Batch No.	Name of Manufacturer	Quantity	Reason of seizure
1	Tab. Caryon 10mg	CRY-200-009	M/s Incepta Pharmaceuticals, Karachi	93 Packs (20 Tab/Pack)	iii. W/O warranty iv. Sale of drugs in the absence of Qualified Person

Form-5 (Sr #28686)

Sr. No.	Name of Drug	Batch No.	Name of Manufacturer	Quantity	Reason of seizure
1	Inj. Fاستriaxone 500mg	F374	Fassgen	95 packs	i. Stocking/ Selling of drugs W/O warranty ii. Qualified Person absent
2	Tab. Invid 600mg	T278	Invictus	4 packs *12	
3	Inj. Fاستriaxone 1g	F375	Fassgen	254 packs	
4	Tab. Stropin 50 mg	1986	Fassgen	136 Pack *10	
5	Tab. Cyto 500mg	686	MTI Medical	212 Packs *10	
6	Tab. P-Beta 20mg	T0400	Wellborne	108 Packs* 20	
7	Inj. Cytozone 1g	CT-344	MTI Medical	158 Packs	
8	Inj. Gotec 40 mg	GT-020	MTI Medical	36 Packs	
9	Tab. Dydownen 10mg	736	Weather Folds	03 Packs * 20	
10	Tab. Josef 10mg	004	Winlet Pharma	10 Packs * 14	

11	Tab. Fa-Cin 250mg	T288	Farm Aid Group	15 Packs * 10
12	Inj. Cefzy 1g	23J078	Bio Labs	15 Packs
13	Tab. Oxidex 20mg	G024	Aptcure	15 Packs * 20
14	Tab. Piproxcin 500mg	T3010	Farm Aid Group	13 Packs * 10
15	Cap. Feprazole 40mg	C139	Farm Aid Group	10 Packs * 14
16	Cap. Zemco 250mg	696	MTI Medical	09 Packs* 10
17	Inj. Chroncef 250mg	CH423	English Pharma	14 Packs
18	Original Invoice/warranty no. 3783, dated: 20-06-2023, issued by Incepta Pharma Karachi (Caryon Tab. 10mg, B # CRY-200/008)			
19	Authority Letter (Original) Issued by M/s Incepta Pharmaceuticals, Karachi in the name of M/s Dynam Pharma, Multan, dated: 20-06-2023			
20	Hitachi Hard Disk, Bar Code # QA38963BA30670C05, Cap320GB of main CPU Dynam Pharma.			
Note: Product at Sr. # 6, some quantity shifted to Form 4 for test/analysis by DTL.				

- ii. He also took sample of **Film Coated Tablet Caryon 10mg, Batch # CRY-200/009** on Form No. 4 (Sr # 56173) and sent to Drug Testing Laboratory, Multan for the purpose of test/analysis.
- iii. The said drug sample, sent vide Form 6 memo no.193594, dated: 29-02-2024, after test/analysis was declared as **Spurious** by Government Analyst, Drug Testing Laboratory, **Multan**. as detailed below:

Drug Sample	Batch	Manufacturer	TRA No. and Date
Film Coated Tablet Caryon [Each film coated tablet contains Dydrogesterone...10mg] Mfg. date: 08-2023 Exp. Date: 07-2025	CRY-200/009	M/S Incepta Pharmaceuticals Ltd., Korangi Industrial Area, Plot no. 88, Karachi.	01-105005714/DTL Dated 03-06-2024.

Reg. # 9997772

Specs Applied: BP 2024

DESCRIPTION:

White, round biconvex tablets, plain on both sides in ALU-ALU blister of 10 units in a labeled outer hard carton. Each outer carton contains 2 blisters of 10 units each i.e (2*10= 20 Tablets).

Identification by FTIR Dydrogesterone is not Identified. **(DOES NOT COMPLY)**

Assay by UV Spectroscopy

Dydrogesterone

Stated: 10 mg/Tablet

Determined: 0.0 mg/Tablet

Percentage: 0.00%

Limit: 92.5-107.5% **(DOES NOT COMPLY)**

“Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-37/2024

Dated 30-04-2024”

Note: Drug Regulatory Authority of Pakistan, vide Letter No. F. 10-3/2022-Lic (AD-III) dated 03, June 2024 clarified that “No Firm namely M/s Incepta Pharmaceuticals Ltd., Korangi Industrial Area, Plot no. 88, Karachi has been licensed by Drug Licensing Division, DRAP” and also stated “ above-mentioned product is NOT REGISTERED under section 7 of the Drugs At 1976 and Rules framed thereunder” vide letter No. F.8-2/2020-Reg-I dated: 29, April 2024.

RESULT: The given sample is **Spurious** as described under Section 3(zb)(i) and (iv) of Drugs Act 1976.

- iv. During Inspection, he further took sample of Tab. Dydownen 10mg, Batch # 736, on Form-4 (Sr# 56174) and sent to Drug Testing Laboratory, Multan for the purpose of test/analysis vide Form-6 memorandum no. 193595 dated: 29-02-2024.
- v. After test/analysis, the sample was also declared as **Spurious** by Government Analyst, Drug Testing Laboratory, **Multan**. as detailed below:

Drug Sample	Batch	Manufacturer	TRA No. and Date
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<p>Dydowen 10mg tab [Dydrogesterone 10mg]</p> <p>Mfg. date: 12-2022</p> <p>Exp. Date: 12-2024</p> <p>Reg. # 101507</p>	<p>736</p>	<p>M/S Weather Folds Pharmaceuticals, 69/2, Phase II, Industrial Area Hattar Pakistan</p>	<p>01-105005713/DTL</p> <p>Dated 24-05-2024.</p>
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Specs Applied: USP 2024

DESCRIPTION:

White, round biconvex tablets with both sides plain packed in ALU-ALU blister of 10 units in a labeled outer hard carton. Each outer carton contains 2 blisters of 10 units each i.e (2*10= 20 Tablets).

Identification by FTIR Dydrogesterone is not Identified. **(DOES NOT COMPLY)**

Assay by HPLC

Dydrogesterone

Stated: 10 mg/Tablet

Determined: 0.0 mg/Tablet

Percentage: 0.00%

Limit: 90-110% **(DOES NOT COMPLY)**

“Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-37/2024

Dated 30-04-2024”

RESULT: The given sample is **Spurious** as described under Section 3(zb)(i) of Drugs Act 1976.

- vi. M/s Dynam Pharma, House no. 387/10, Street # 6, Ahmed Park Near Gulistan Chowk, Multan provided invoice/warranty SP-056 dated: 10-02-2023 of the product Tab. Dydowen 10mg issued by M/S Medivision Pharma, 207-Umar Block, Allama Iqbal Town, Lahore as a proof of purchase. M/S Medivision Pharma, 207-Umar Block, Allama Iqbal Town, Lahore provided invoice/warranty no. 22420 dated: 01-02-2023 issued by M/s John Foster Pharma, 27-C, Gosha-e-Ahbab, Phase II, Azam Garden, Lahore who in turn provided invoice/warrant no. 539/2022 dated: 12-12-2022 issued by M/s Weather Folds Pharmaceuticals, 69/2, Phase II, Industrial Area, Hattar, Pakistan as a proof of purchase.
- vii. M/s Dynam Pharma, House no. 387/10, Street # 6, Ahmed Park Near Gulistan Chowk, Multan disclosed the source of purchase of **Film Coated Tablet Caryon 10mg, Batch # CRY-200/009** from Mumtaz Hussain (representative of M/s Incepta Pharma) through a copy of Invoice/warranty # 3896 dated: 01-02-2024 and the same original invoice/warranty and authority letter as distributor issued to M/s Dynam Pharma by M/s Incepta Pharma was recovered and seized on Form 5 by the Deputy Drug Controller

Bosan Town, Multan during the raid on M/s M Square Pharmaceuticals situated at H# 195/O-CB, Near Qartaba Masjid, Muhallah Garden Town, Multan on 02-03-2024.

- viii. Mumtaz Hussain (representative of M/s Incepta Pharma) disclosed that he purchased tab. Caryon, Batch # CRY-200/009 from Rana Ahmad Ali (Proprietor/Owner of M/s M Square Pharmaceuticals) and supplied to M/s Dynam Pharma, Multan.
- ix. Ahmad Ali and Muhammad Wahaj of M/s M Square Pharmaceuticals both failed to produce any concrete evidence, however, they disclosed that Sajjad Ali of M/s Dynam Pharma is the stockiest and authorized Distributor of Tab. Caryon in District Multan and he offered Muhammad Wahaj to work as a sub-distributor of M/s Incepta Pharma, Karachi.
- x. A copy of test/analysis report of **Film Coated Tablet Caryon 10mg, Batch # CRY-200/009** was sent to Sajjad Ali, Proprietor of M/s Dynam Pharma, House no. 387/10, Street # 6, Ahmed Park Near Gulistan Chowk, Multan and to Mumtaz Hussain s/o Muhammad Munir, representative of M/S Incepta Pharmaceuticals Ltd., Korangi Industrial Area, Plot no. 88, Karachi to explain their position and provide requisite information in this regard.
- xi. The Provincial Inspector of Drugs requested for grant of permission for registration of F.I.R against you, as you have contravened the provisions of Section 23/27 of Drugs Act 1976 (as amended)/ DRAP Act 2012 and Rules framed there under by the way of:
- Selling/Stocking of **Spurious** Tab. Caryon, Batch # CRY-200-009
 - Selling/Stocking of **Un-registered** Tab. Caryon, Batch # CRY-200-009
 - Selling/Stocking of **Spurious** Tab. Dydownen 10mg, Batch # 736 **without authorization letter from the distributor**
 - Selling/Stocking of Drugs **in the absence of Qualified Person**

2. Show cause notice(s) issued to accused person(s) dated 26-08-2025.

Reply to Show Cause Notice:

With reference to your kind office Show Cause Notice No. PQCB/MSS-193594, 193595/2024 dated 26-08-2025 and received to the me on 05-09-2025 on the subject cited above.

I have the honour to submit that;

1- On 28-02-2024 Deputy Drug Controller Shah Rukn e Alam Town Multan alongwith Drug Controller Sher Shah Town Multan, DDC Bosan Town Multan, DI Mumtazabad Town Multan and Di Jalalpur Pirwala Town Multan inspected my business premises M/S Dynam Pharma situated at House No. 387/10 Street No.6, Ahmad Park Near Gulistan Chowk Multan and seized different types of Drugs on Form 5 & Form 4 respectively.

2- Four Drugs taken on Form 4 were sent to Drug Testing Laboratory Multan for test/analysis. Out of Four Drugs two Drugs namely Tab Caryon Batch No. CRY 200/009 Manufactured by M/S Incepta Pharmaceutical Karachi and Second Drug namely Tab. Dydownen Batch No. 736, Manufactured by M/S Weatherfold Pharmaceutical Hattar, Pakistan were declared Spurious by DTL Multan.

3- The detail regarding purchase of Tab. Dydowen 10mg Batch No. 736 Manufactured by M/S Weatherfold Pharmaceutical Hattar is as under:-

a) I purchased the said Drug Tab Dydowen 10mg Batch no. 736 from M/S Medivision Pharma, Allama Iqbal Town Lahore and provided the Invoice No. SP-056 dated 10-02-2023 to the DDC Shah Rukn e Alam Town Multan.

b) The Invoice No. SP-056 provided by me in favour of my purchase has also been owned by M/S Medivision Pharma, Allama Iqbal Town Lahore and who in turn has provided his source of purchase of said Drug from M/S Johns Faster Pharma who has provided his source of Purchase from M/S Weatherfolds Pharmaceuticals Industrial Area Hattar Pakistan. The complete chain regarding purchase of Tab. Dydowen 10mg Batch No. 736 is also mentioned in the Show Cause Notice issued to me at Para(VI).

4. The detail regarding Purchase of Tab. Caryon Batch No. CRY-200/009 Manufactured by M/S Incepta Pharmaceutical Karachi is as under:-

a) It is submitted that I disclosed the source of Purchase of Tab. Caryon Batch No. CRY. 200/009 on Form 5 at the Spot to the DDC Shah Rukn e Alam Town Multan by giving written statement on Form 5 that one Mumtaz Hussain S/O Muhammad Munir has supplied the said Drug to me by presenting himself as a representative of M/S Incepta Pharmaceutical Karachi. Mumtaz Hussain also send me the Authority Letter & Invoice No. 3896 issued by M/S Incepta Pharmaceutical Karachi to M/S Dynam Pharma on my whatsapp no. in the presence of DDC Shah Rukn e Alam Town Multan.

b) It is also worth mentioning fact that on my call after telling the whole story regarding the raid conducted by DDC Shah Rukn e Alam Town Multan alongwith his other colleagues /Drug Inspectors, Mumtaz Hussain reached at the spot within no time and also endorsed and owned by giving his written statement on Form 5 to the DDC Shah Rukn e Alam Town Multan in the presence of all Drug Inspectors Multan District that he has supplied the Drug Tab. Caryon Batch No. CRY-200/009 Manufactured by M/S Incepta Pharmaceutical Karachi to Mr. Sajjad Ali Owner of M/S Dynam Pharma Gulistan Chowk Multan (Copy of Form 5 with written statement of Mumtaz Hussain attached Anex-A).

c) Mumtaz Hussain also mentioned in his written statement on Form 5 at the spot to DDC Shah Rukn e Alam Town Multan that he has purchased the said Drug Tab. Caryon B.No. CRY-200/009 from one Rana Ahmad Ali owner of M/S M-Square Pharmaceutical Garden Town Multan and also mentioned his cell no at Form 5 as well as also mentioned that Rana Ahmad Ali has also send the Invoice No. 3896 & Authority letter of M/S Incepta Pharmaceutical Karachi in favour of M/S Dynam Pharma Multan to him.

5-It is also submitted that DDC Shah Runk e Alam Town Multan has mentioned in his investigation report sent to PQCB Punjab, Lahore that raid on M/S Dynam Pharma Multan was conducted on information received by DDC Ali Pur District Muzaffar Garh. In response to this Mumtaz Hussain also submitted an affidavit to DDC Ali Pur on 02-03-2024 (Copy attached Anex-B) in which Mumtaz Hussain again owned that he has supplied the said Drug to M/S Dynam Pharma Multan after getting purchased from one Rana Ahmad Ali Owner of M/S M-Squares Pharmaceuticals Garden Town Multan. Mumtaz Hussain also mentioned the complete residential and business address of Rana Ahmad Ali on Affidavit. He also informed to DDC Ali Pur that he has complete Bank transactions regarding his purchase from Rana Ahmad Ali and also provided the complete record to DDC Ali Pur District Muzaffar Garh.

6- Simultaneously; after presenting an affidavit to DDC Ali Pur on same date ie 02-03-2024 Mumtaz Hussain informed all the facts to DDC Bosan Town Multan and accompanied him for raid at the premises of Rana Ahmad Ali M/S Square Pharmaceutical situated at Garden Town Multan. (Pictorial evidence of Mumtaz Hussain & DDC Bosan Town at premises of Rana Ahmad Ali is attached Anex C).

The whole picture was cleared after recovery of Spurious Tab. Caryon Batch No. CRY-200/009 Manufactured by M/S Incepta Pharmaceutical Karachi from business premises of Rana Ahmad Ali by DDC Bosan Town Multan and seized on Form 5 (Copy of Form 5 attached Anex D) in the presence of Mumtaz Hussain. DDC Bosan Town Multan also got registered FIR No. 460/24 at PS Qutab Pur Multan against Rana Ahmad Ali and other accused persons (Copy of FIR attached Anex E).

It is also important to note that original Invoice NO. 3896 of M/S Incepta Pharmaceutical Karachi issued in the name of M/S Dynam Pharma Multan as well as original Authority Letter issued to M/S Dynam Pharma Multan were also recovered during the raid from M/S M-Squares Pharmaceutical Garden Town Multan and the both documents ie Invoice & Authority letter were also seized on Form 5 by DDC Bosan Town Multan along with thirty letter heads of M/S Incepta pharmaceuticals karachi. The same is also highlighted in the investigation report submitted by DDC Shah Runk e Alam Town Multan as well as in the Show Cause Notice issued by PQCB Punjab Lahore to me.

7- Mumtaz Hussain also submitted his reply alongwith complete evidences in the form of Bank Transactions, Voice Messages, as well as FBR record of Rana Ahmad Ali to DDC Shah Rukn e Alam Multan in response to his letter No. 299/DDC Shah Rukn e Alam Town Multan dated 02-07-2024 (Reply of Mumtaz Hussain attached Anex F) and the same reply has been forwarded by DDC Shah Rukn e Alam Town Multan to PQCB Punjab, Lahore alongwith his investigation report.

8. After receiving of investigation report in FIR No. 460/24 at PS Qutab Pur, DDC Bosan Town Multan referred the case to DQCB Multan for permission for prosecution against Rana Ahmad Ali and other accused persons. Mumtaz Hussain also appeared in person before the DQCB Multan dated on 24-07-2024 and also endorsed his previous statements and again owned that he has supplied the Said Drug (Tab. Caryon Batch No. CRY-200/009) to M/S Dynam Pharma Multan.

9. DDC Bosan Town Multan also filed revision Petition against the order of DQCB Multan dated 24-07-2024 before PQCB

Punjab Lahore and simultaneously; PQCB Punjab Lahore has directed DDC Bosan Town Multan to submit the application for change of investigation in FIR No. 460/24 PS Qutab Pur Multan before the Regional Police Officer Multan in the light of evidences and record provided by one Mumtaz Hussain against Rana Ahmad Ali vide PQCB Punjab order dated 30-10-2024.

PRAY:-

With due respect It is humbly prayed that after the above mentioned facts & reality, investigation conducted at length by DDC Shah Rukn e Alam Town Multan as well as evidence collected by DDC Bosan Town Multan in order to manifest my verdict, it is politely and submissively requested that I am innocent and have no fault on my behalf. It is therefore requested that I may please be exonerated from the said case in interest of justice. More over it is also humbly requested that all the witnesses Drug Inspectors present at the time of raid alongwith raiding Drug Inspector may also be Summoned for PQCB meeting at the time of hearing of subject titled case for verifying and substantiate the facts and figures of the case.

I will be very thankful and grateful for your kindness please

Personal Hearing notice(s) issued to accused person(s) dated 12-09-2025.

Case is placed before the board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 02

PQCB/ MSS-193595/2024

Shah Rukan-e-Alam Town, Multan

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <p>1. M/S Weather Folds Pharmaceuticals, 69/2 Phase II, Industrial Area Hattar Pakistan, through its CEO/MD, Arshad Mehmood</p> <p>2. Arshad Mehmood CEO/MD</p> <p>3. Munawar Javed Khattak Production Incharge</p> <p>4. Aftab Alam Khan Quality Control Incharge/Warrantor</p> <p>of M/S Weather Folds Pharmaceuticals, 69/2 Phase II, Industrial Area Hattar Pakistan.</p> <p>5. Hamza Malik Proprietor</p> <p>6. Attique Ur Rehman Proprietor/Warrantor</p> <p>7. Muhammad Rajmir Khan Niazi Qualified Person</p> <p>Of M/s Medivision Pharma, 207-Umar Block, Allama Iqbal Town, Lahore.</p>
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BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Shah Rukan-e-Alam Town, Multan, reported that:

- i. He, on 28-02-2024 inspected the business premises of M/s Dynam Pharma, House no. 387/10, Street # 6, Ahmed Park Near Gulistan Chowk, Multan, and took a drug sample on Form No. 4 and sent to Drug Testing Laboratory, Multan for the purpose of test/analysis.
- ii. Following drug sample, sent vide Form 6 memo no.193595, dated: 29-02-2024, after test/analysis was declared as **Spurious** by Government Analyst, Drug Testing Laboratory, **Multan.** as detailed below:

Drug Sample	Batch	Manufacturer	TRA No. and Date
Dydowen 10mg tab [Dydrogesterone 10mg] Mfg. date: 12-2022 Exp. Date: 12-2024	736	M/S Weather Folds Pharmaceuticals, 69/2, Phase II, Industrial Area Hattar Pakistan	01-105005713/DTL dated 24-05-2024.

Reg.# 101507

Specs Applied: USP 2024

DESCRIPTION:

White, round biconvex tablets with both sides plain packed in ALU-ALU blister of 10 units in a labeled outer hard carton. Each outer carton contains 2 blisters of 10 units each i.e (2*10= 20 Tablets).

Identification by FTIR Dydrogesterone is not Identified. **(DOES NOT COMPLY)**

Assay by HPLC

Dydrogesterone

Stated: 10 mg/Tablet

Determined: 0.0 mg/Tablet

Percentage: 0.00%

Limit: 90-110% **(DOES NOT COMPLY)**

“Time Extension granted via. PQCB order No. PQCB/TEX-MLTN-37/2024

Dated 30-04-2024”

RESULT: The given sample is **Spurious** as described under Section 3(zb)(i) of Drugs Act 1976.

- iii. M/s Dynam Pharma, House no. 387/10, Street # 6, Ahmed Park Near Gulistan Chowk, Multan provided invoice/warranty SP-056 dated: 10-02-2023 issued by M/S Medivision Pharma, 207-Umar Block, Allama Iqbal Town, Lahore as a proof of purchase.
- iv. Warrantor portion was sent to M/S Medivision Pharma, 207-Umar Block, Allama Iqbal Town, Lahore.
- v. M/S Medivision Pharma, 207-Umar Block, Allama Iqbal Town, Lahore provided invoice/warranty no. 22420 dated: 01-02-2023 issued by M/s John Foster Pharma, 27-C, Gosha-e-Ahbab, Phase II, Azam Garden, Lahore who in turn provided invoice/warrant no. 539/2022 dated: 12-12-2022 issued by M/s Weather Folds Pharmaceuticals, 69/2, Phase II, Industrial Area, Hattar, Pakistan as a proof of purchase.
- vi. A copy of test/analysis report was sent to M/s Weather Folds Pharmaceuticals, 69/2, Phase II, Industrial Area, Hattar, Pakistan to explain their position and provide requisite information in this regard.
- vii. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.
- viii. The retesting request was placed in PQCB's 43rd Committee meeting held on 29-08-2024. The Board after due deliberation unanimously decided to **Turn Down** the subject request for retesting of the sample.



To

The Secretary
Punjab Quality Control Board
Punjab

Scanned with
AD



Dated 15-9-25

Sub: Ref Letter PQC/B/MSS 193595/2024

Respected Sir,

This is to inform in your kind honour that few days before I receive the Show Cause Notice. As Regards to it I would request to inform that I just purchased Dydowin (dydrogesteron) Tab from M/s John Foster Pharma 27C Goshara-e-Ahbab Phase II Azam Garden Lhr and Sir I also receive Bill Warranty and Authority letter from John Foster Pharma and they also provided me the bill warranty and Authority letter of the manufacturer M/s Weather Fold Pharma which they give to John Foster Pharma.

Sir on behalf of above mentioned I sell the product to Dyma Pharma Multan and also issue the warranty on behalf of John Foster bill warranty and authority letter which they given to Medivision Pharma.

As Regards to it I also attached herewith the warranties of John Foster Pharma and Weather Fold Pharmaceuticals alongwith authority letters.

Sir here I request in your kind honour please consider my application as a distributor who sell a warranted medicine and who is not familiar with the manufacturer production pattern -

Thank You

AD ATIQ-UR-REHMAN



E-mail: medivision001@gmail.com
Cell: +92 331 4344 108, +92 300 6109 876
Address: 207-Omer Block Allama Iqbal Twn Lahore-Pakistan.

Personal Hearing notice(s) issued to accused person(s) dated 12-09-2025.

Case is placed before the board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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in a labeled outer carton. Each outer carton contains three blisters of ten units each (3 × 10=30 Tablets).

IDENTIFICATION: Diclofenac Sodium Identified

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

- **Tolerance Limit: Acid Stage: NMT 10% in 2 hours (120 mints) in 0.1 N HCl**

LEVEL	UNITS	% RELEASE						AVERAGE	REMARKS
A1	6	NMT 10% in Acid Stage						A1	COMPLIES
		U#1	U#2	U#3	U#4	U#5	U#6		
Determined	%	0.044	0.054	0.163	0.12	0.16	0.3		

- **Tolerance Limit: Buffer stage: NLT 75%(Q)of the labeled amount of Diclofenac Sodium is dissolved in 45 mints in pH 6.8 Phosphate Buffer**

LEVEL	UNITS	% RELEASE						AVERAGE	REMARKS
B1	6	No Unit is less than 80% (Q+5) in Buffer Stage						B1	Does not comply
		U#1	U#2	U#3	U#4	U#5	U#6		
Determined	%	51.39	23.61	46.93	29.21	32.38	33.67		

* As the criteria of B3 i.e. NMT 2 units are < Q-15%, And no unit is < Q-25% is achieved. So, the results conform at B1 Stage.

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

Assay	Stated	Determined	Percentage	Limits	Comments
Diclofenac Sodium	100 mg/Tablet	100.27 mg/Tablet	100.27%	90-110%	COMPLIES

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

- iii. M/S Sharay Pharma, H. No. 1456-1, Qadir Nawaz Road, Near Kachahri Chowk, Multan, provided invoice/warranty No.23438 dated 24-07-2021 issued by M/s Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan, as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/s Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan.
- v. A copy of test/analysis report was sent to M/S Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan and they were asked to explain their position and provide the requisite information in this regard.
- vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.
- vii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Enteric coated tablet Davitran DS (diclofenac sodium 100 mg),	T865	M/S Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan.	078-P/2022 dated: 16-06-2022	<p>Analysis with specifications applied: USP-39</p> <p><u>Dissolution Test:</u></p> <p>Determined: Five tablets out of six deviated from the limit.</p> <p>Limit: Not less than 75.0% (Q) of the labeled amount of Diclofenac Sodium is Dissolved. (Does Not Comply with USP-39)</p> <p>Result: The sample is of Substandard quality on the basis of tests performed.</p>

viii. Copy of NIH report was sent to M/S Davis Pharmaceutical Laboratories 121, Industrial Triangle Area, Islamabad-Pakistan.

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

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

- 3. Show cause notice(s) issued to accused person(s) dated 05-05-2023.
- 4. Personal Hearing notice(s) issued to accused person(s) dated 16-09-2024.

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

PQCB's 285th meeting held on 26-09-2024:

5. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **285th Meeting held on 26-09-2024** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab (Chairperson PQCB). Mst. Irum Kaukab, Secretary DQCB, Multan attended the meeting online via zoom link and Mr. Sabir Ali, Drug Inspector, Sher Shah Town, Multan was present along with original case record.. Among the nominated accused persons Aamir Shahzad (QC Head) along with Fatima Zahid (Lawyer) and Fatima Abbas (Advocate) of M/S Davis Pharmaceutical Laboratories, 121, Industrial Triangle Area, Islamabad-Pakistan were present. The case was left-over due to time constraint.
6. Personal Hearing notice(s) issued to accused person(s) dated 22-10-2024.

PQCB's 286th meeting held on 30-10-2024:

7. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **286th meeting held on 30-10-2024** under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson, PQCB). Mst. Irum Kaukab, Secretary DQCB, Multan, attended the meeting online via Zoom Link. No one among the nominated accused persons of M/s Davis Pharmaceutical laboratories 121, industrial triangle area, Islamabad- Pakistan was present. However counsel person Fatima Abbas (Advocate) appeared before the Board and requested for adjournment as the Technical staff of the firm could not manage to attend the meeting.
8. The Board after due deliberation and discussion unanimously decided to **adjourn the case** due to absence of the firm. The Board further decided to provide another opportunity of personal hearing to the accused in best interest of justice

Personal Hearing notice(s) issued to accused person(s) dated 12-09-2025.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:07-2021**
- **Exp. Date: 06-2023**
- **Sampling date (Form 4): 11-08-2021**
- **Sent to DTL (Form 6): 11-08-2021**
- **Date of receipt in DTL: 12-08-2021**
- **DTL Report Date (Form 7): 09-10-2021**
- **Time Extension to DTL: report not time barred**
- **DI 1st intimation to firm: 14-10-2021**
- **Retesting request if any: Yes**
- **Fate of Retesting Request: NIH Substandard**
- **Investigation report Dated: 26-11-2022**
- **SCN Permission: 254th meeting dated: 13-12-2022**
- **SCN Issued: 05-05-2023**
- **Reply of the firm No**
- **History (from 2021) Firm: 07 cases**
- **Product: 03 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:



Case No. 17

PQCB/ R-536/2022`

Tehsil DG Khan (Rural), District DG Khan

ATTENDENCE

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	1. M/s Pak Risen Pharmaceuticals, Plot No. 3, Block B Phase I-II, Industrial Estate Hattar through its Managing Director Sabir Khan
	2. Sabir Khan Managing Director/ Warrantor
	3. Muhammad Rafiq Mazari Production Manager
	4. Jahangir Alam Quality Control Incharge
	Of M/s Pak Risen Pharmaceuticals, Plot No. 3, Block B Phase I-II, Industrial Estate Hattar

BRIEF FACTS OF THE CASE:

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

- i. He, on 16-03-2022, inspected the business premises of M/s Saleem Medical Hall situated at Choti Road Kot Chutta, District Dera Ghazi Khan, took sample of three different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum No. 0000121499 dated 16-03-2022.
- ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:
- iii. M/s Saleem Medical Hall situated at Choti Road Kot Chutta, District Dera Ghazi Khan submitted Invoice/warranty No.91368 dated 30-11-2021 issued by M/s Al-Hadeed Medicine Company, St# 1, Justice Hameed Colony, Nishtar Road Multan as a proof of its purchase of the said drug.
- iv. Warrantor Portion of the drug sample was sent to M/s Al-Hadeed Medicine Company, St# 1, Justice Hameed Colony, Nishtar Road Multan who in turn provided invoice/ warranty no. AHM-2354/2021-001 dated 28-08-2021 issued by M/s Pak Risen Pharmaceuticals, Plot No. 3, Block B Phase I-II, Industrial Estate Hattar as a proof of its purchase of the said drug.
- v. A copy of test report was sent to M/s Pak Risen Pharmaceuticals, Plot No. 3, Block B Phase I-II, Industrial Estate Hattar and they were asked to provide requisite information in this regard.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Cure Water (Sterile water for injection 05 ml)	C-2106	M/s Pak Risen Pharmaceuticals, Plot No. 3,	TRA No. 01-94002795/DTL	<u>Result of Test/ Analysis with specifications applied:</u> BP 2021

<p>Mfg. Date:</p> <p>Aug-2021</p> <p>Exp. date:</p> <p>Aug-2023</p> <p>Reg. No.</p> <p>040386</p>		<p>Block B Phase I-II, Industrial Estate Hattar</p>	<p>Dated: -16-05-2022</p>	<p>Description: Colorless liquid filled in a sealed, transparent glass ampoule of 5 ml with white printed label, white colored neck ring in a labeled outer hard carton. 100 ampoules holding in beehives are packed in a unit outer hard carton (100*5 ml ampoules).</p> <p>Visible Particulates:</p> <p>According to BP “Inspected units must be free of visible particulate contamination when examined without magnification against a black background and white background approximately for 05 seconds”.</p> <p>Determined: “When examined against black and white background without magnification, 09 out of 50 units contain visible particulates”.</p> <p>(DOES NOT COMPLY)</p> <p>Extractable Volume: Limit: NLT stated</p> <p>Determined: 5.1 ml (Complies)</p> <p>Conductivity: Limit: NMT 25 µ/ cm</p> <p>Determined: 12.1 µ/ cm (Complies)</p> <p>Sterility: It conforms to sterility test (Complies)</p> <p>Chemical Test:</p> <p>Sulphates (Complies)</p> <p>RESULT: The above sample is Substandard, on the basis of visible particulates.</p>
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2. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended), DRAP Act 2012 and Rules framed there under by the way of:

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

3. Show cause notice(s) issued to accused person(s) dated 18-09-2023.
4. Personal Hearing notice(s) issued to accused person(s) dated 23-10-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

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

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **271st** meeting held on **01-11-2023** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab. Mr. M. Asif Abbas, Secretary DQCB, District Dera Ghazi Khan attended the meeting online via zoom link and Mr. Muhammad Farhan, Drug Inspector Tehsil Dera Ghazi Khan (Rural), District Dera Ghazi Khan was present along with the original case record. No one among the nominated accused persons of **M/s Pak Risen Pharmaceuticals, Plot No. 3, Block B Phase I-II, Industrial Estate Hattar** appeared before the Board.
6. The Board after careful perusal of the case record observed that the drug sample Cure Water (Sterile water for injection 05 ml) batch No. C-2106 has been declared of substandard by Drugs Testing Laboratory Multan on the basis of visible particles i.e. “When examined against black and white background without magnification, 09 out of 50 units contains visible particulates”.
7. The Board after due deliberation and discussion unanimously decided to **adjourn the case** in best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons with directions to Federal Drug Inspector to ensure the service of personal hearing notice to the accused persons.

Note:

The firm submitted the documents regarding the GMP inspection conducted by area FID on 5th and 6th August, 2021. A **Show-Cause Notice/Suspension of Production Order** in all sections of M/s Pak Risen Pharmaceuticals was issued on 23-08-2021 by DRAP, which concluded as:

“Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities., **the firm is not complying GMP requirements as defined under Schedule B-ii of the Drugs (Licensing, Registering & Advertising) Rules, 1976.**”

“..... You are, therefore, directed to **Suspend the Production Activities in all Sections and Show Cause in writing within 15 days of issuance of this notice,** ”

- The firm in response submitted CAPA against the observations during the inspection by Area FID.
- On **30th October, 2023**, a panel was constituted for GMP inspection of M/s Pak Risen Pharmaceuticals, Plot no 3, Phase I,II, Industrial Estate, Hattar, wherein the panel recommended resumption of production in liquid section along with risk assessment of all the changes done by the firm, while production in Dry Vial injectable (Ceph) section shall remain suspended till installation of automatic filling and stoppering machine, equipment validation and aseptic process validation.
- In the light of recommendation of panel, the Director, QA< vide **letter no. F.4-2/2006-QA**, dated: **05-12-2023**, approved the resumption of production in Liquid Injectable Section (General) ampoule/Vial as authorized by CLB in its 273rd meeting.

8. Personal Hearing notice(s) issued to accused person(s) dated 06-05-2024.

PQCB's 280th meeting held on 16.05.2024:

9. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **280th meeting** held on **16.05.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab /Vice-Chairperson PQCB. Mr. M. Asif Khokhar, Secretary DQCB District DG Khan attended the meeting online via Zoom Link. Mr. Muhammad Farhan, Drug Inspector, DG Khan (Rural) was present along with original case record. Among nominated accused persons CEO (Pak Risen Pharma) on behalf of **M/s Pak Risen**

Pharmaceuticals, Plot No. 3, Block B Phase I-II, Industrial Estate Hattar Pakistan appeared before the Board. Firm's representatives requested the Board to have a lenient view stating that a GMP inspection of the firm has already been carried out by Area FID and the firm has submitted CAPA in this regard to DRPA. He presented the related documents before the Board.

10. Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample of **Cure Water (Sterile water for injection 05 ml)**, Batch No. **C-2106**, has been declared substandard by the Drugs Testing Laboratory, Multan. Cure Water (Sterile water for injection 05 ml), batch No. **C-2106**, has been declared of substandard by Drugs Testing Laboratory Multan on the basis of visible particles i.e. "When examined against black and white background without magnification, 09 out of 50 units contain visible particulates". The Board further assessed the documents of GMP Inspection carried out by Area FID presented by the firm's representative. The Board further observed that after GMP inspection the production in Dry Vial injectable section was to remain suspended till installation of automatic filling and stoppering machine.
11. The Board was of the view that in order to further ensure the GMP compliance and dig out the root cause of the fault, the Production and Quality Control & Assurance for subject drug need to be evaluated. The Board after due deliberation and discussion, unanimously decided to **pend the case** and constitute a committee comprising of the followings officers to conduct **Product Specific Inspection (PSI) of M/s Pak Risen Pharmaceuticals, Plot No. 3, Block B Phase I-II, Industrial Estate Hattar Pakistan** and submit report at earliest for consideration by the Board:
12. Furthermore, the Board directed the committee to submit its report in this regard at earliest and further recommended to **send a sample of Cure Water (Sterile water for injection 05 ml)** to the Pakistan Drug Testing and Research Centre (**PDT&RC**), Lahore for the analysis of visible particles, on expenditure of the firm. The PDT&RC will submit the test/ analysis report to the firm and to the office of the Secretary PQCB which will be then placed before the Board along with the PSI Report for decision of the case.
13. The firm regarding the Product Specific Inspection vide letter no. Ref.# PRP/DRAP/258-1 dated: 11-08-2025 submitted as follows;

1.	Dr. Qalandar Khan AS(DC), P&SHD (Member PQCB)	Convener
2.	Director DTL, Lahore	Member

We have received your Letter No. PQCB/R-536/2022 Dated: 01 August 2025 About (PSI) for product Cure Water 5 MI Batch C-2106 (Sterile Water).

Its humble request to you that, we have just purchased M/S Pak Risen Pharmaceuticals, Plot no 3, Block B, Phase I-II, Industrial Estate Hattar **Dated 25-02-2025** from Mr. Sabir Khan, Proprietor (sole). **We are going through the process of up gradation in all standards & section of the firm according to GMP/DRAP rules & guidelines. Right now we are not prepared & unable to conduct the above cited subject as we are in phase of handed over & taken up stage in all legal & administrative matters.**

Kindly decide the verdict of this case in favor of Pak Risen pharmaceuticals.

Looking forward to your kind response

Thank you

New management transfer letter attached.

For Pak Risen pharmaceuticals

Personal Hearing notice(s) issued to accused person(s) dated 12-09-2025.

Case is placed before the board for decision.

Summary of the case:

- **Manufacturing Date: Aug-2021**
- **Expiry Date: Aug-2023**
- **Sampling Date (Form 4): 16-03-2022**
- **Sent to DTL (Form 6): 16-03-2022**
- **Date of receipt in DTL: 18-03-2022**
- **DTL Report Date (Form 7): 16-05-2022**
- **Time Extension: Not time barred**
- **1ST DI Communication with firm on dated: 14-05-2022**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: NA**
- **Investigation Report Dated: 19-04-2023**
- **Permission of SCN: 261st meeting dated 18-05-2023**
- **SCN Issued: 18-09-2023**
- **Reply of the firm Yes**
- **History (3 years) Firm: 05 case**
- **Product: 02 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 18

PQCB/MSS-175441/2023

Tehsil & District Mianwali

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case:</u>
	<ol style="list-style-type: none">1. M/S MTI Medical (Pvt) Ltd, 586-587, Sundar Industrial Estate, Lahore through its Chief Executive Officer Muhammad Ajmal Iqbal.2. Muhammad Ajmal Iqbal Chief Executive Officer.3. Muhammad Adrees Khan Production Incharge.4. Muhammad Amir Razzaq Quality Control Manager5. Muhammad Raza Shafaat of M/S MTI Medical (Pvt) Ltd, 586-587, Sundar Industrial Estate, Lahore.
Drug Inspector	

BRIEF FACTS OF THE CASE

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

- He, on 13-09-2023, inspected the premises of Medicine Store of CEO-DHA, Mianwali and took three different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No.0000175441, dated. 13-09-2023.
- Following Drug sample after test/analysis was declared as **Adulterated & Substandard** by Government Analyst Drug Testing Laboratory **Rawalpindi**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Injection Vinvin [Vancomycin as Hydrochloride 500mg/vial] Mfg Date: June-2023	VI-012	M/S MTI Medical (Pvt) Ltd, 586- 587, Sundar Industrial Estate, Lahore	01- 75007529/DTL Dated. 02-11- 2023	<u>Analysis with specifications applied: USP 2023</u> <u>PHYSICAL DESCRIPTION:</u> Off white coloured powder, filled in transparent glass vial with affixed label, sealed with grey coloured rubber stopper, aluminium seal and green coloured flip off cap. Black coloured particles are observed in reconstituted sample in all vials. Clear, Sterile WFI from different batches were used as solvent and upon reconstitution black coloured particles are observed in each vial. (Does not comply).

Exp Date:				pH								
June-2025				<table border="1"> <tr> <td>Observed</td> <td>2.88</td> </tr> <tr> <td>Determined</td> <td>2.5-4.5 (Complies the test)</td> </tr> </table>	Observed	2.88	Determined	2.5-4.5 (Complies the test)				
Observed	2.88											
Determined	2.5-4.5 (Complies the test)											
Registration No.				ASSAY:								
084915				<table border="1"> <tr> <td>Stated</td> <td>500mg/vial</td> </tr> <tr> <td>Determined</td> <td>450.803mg/vial</td> </tr> <tr> <td>Percentage</td> <td>90.16% (Complies the test)</td> </tr> <tr> <td>Limit</td> <td>90-115%</td> </tr> </table>	Stated	500mg/vial	Determined	450.803mg/vial	Percentage	90.16% (Complies the test)	Limit	90-115%
Stated	500mg/vial											
Determined	450.803mg/vial											
Percentage	90.16% (Complies the test)											
Limit	90-115%											
				<p>STERILITY TEST: No visible microbial Growth observed so it complies with the sterility test (Complies the test)</p> <p>Result: The Above sample is Adulterated and Substandard with regards to physical characteristics observed.</p>								

- iii. Drug Inspector also directed the store keeper not to dispose off stock vide Form No. 3, dated. 06-11-2023
- iv. Store Keeper of M/S Medicine Store CEO-DHA, Mianwali provided Invoice/warranty No 3367, dated 24-07-2023 issued by M/S MTI Medical (Pvt) Ltd, 586-587, Sundar Industrial Estate, Lahore as a proof of its purchase.
- v. Warrantor Portion was sent to M/S MTI Medical (Pvt) Ltd, 586-587, Sundar Industrial Estate, Lahore.
- vi. A copy of test/analysis report was sent to M/S MTI Medical (Pvt) Ltd, 586-587, Sundar Industrial Estate, Lahore and they were asked to provide the requisite information in this regard.

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

- a. Manufacture for sale/Sale of Adulterated & Substandard Drug
- b. Issuance of false warranty

3 Show-cause notice(s) issued to the accused persons(s) dated 26-02-2024

Reply of show cause notice dated 11-03-2024

With reference to the Letter No. P_iCB/MSS.No. 175441/2023 dated 26- 02-2024 received on 07 11-2024, we MTI Medical want to add into your kind knowledge that our subject product and Batch # VI-012 is dispatched in different cities and declared pass from the respective DTL, Copy of the DTL report is attached for your reference.

1. Details of DTL report shared below;

Sr no	DTL Receiver	Institution	Result status
1	DTL Multan	DHA Muzaffargarh	Pass
2	DTL Multan	District Headquarters Hospital Muzaffargarh	Pass

Further multiple sampling of the subject was performed on the basis of Acceptable quality limit (AQL) USP reference 1790 and reconstituted to conduct optical inspection. Multiple sampling offered maximum presentation of reconstituted vials whereas 100% General inspection was conducted to check the physical appearance of the product. All the results during the operation were satisfactory and within the specified limit. A preliminary inquiry was conducted in our retained samples and no particles were found.

Moreover, after the report received from Drug Testing Laboratory Rawalpindi, suspected the complete batch and hereby voluntarily recalled our product from the market and an advertisement is also made in the newspaper copy of which is enclosed. This recall is in line with our commitment to patient safety.

We recalled the drug under consideration according to the SOP of Drug Recall procedure and informed the relevant authorities of the Hospital and DRAP.

CNIC copies of the Managing Director, Production Manager, Quality Control Manager, and Warrantor: details are mentioned below and CNIC Copies are attached

Sr no	Designation	Name	CNIC NO.
1	Chief Executive Officer	Muhammad Ajmal Iqbal	34603-0599177-9
2	Production Manager	Muhammad Adrees Khan Niazi	38301-4183697-7

3	Quality Control Manager	Muhammad Amir Razzaq	35202-2556643-3
4	Warrantor	Muhammad Raza Shafaat	35302-8843883-5

Furthermore, we request you to return the subject product and allow us to replace it with the fresh stock. The requisite documents DML attached and Drug Registration Certificate attached

6 Personal hearing notice(s) issued to the accused persons(s) dated 22-10-2024

PERVIOUS PROCEEDING & DECISION BY THE BOARD:

5 Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **286th meeting** held on **30.10.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab /Vice-Chairperson PQCB. Mst. Mahwish Nigah Secretary DQCB Mianwali attended the meeting via zoom link and Mr. M. Amir, Drug Inspector, Mianwali was present along with original case record. No one among nominated accused of M/s MTI Medical (Pvt) Ltd, 586-587, Sundar Industrial Estate, Lahore appeared before the Board and submitted written request for adjournment vide letter dated 29-10-2024.

6 The Board after discussion decided to **adjourn** the case and provide another opportunity of hearing to the firm in the best interest of justice

. 7 Personal hearing notice(s) issued to the accused persons(s) dated 12-09-2025

Summary	
Sampling Date (Form 4):	13-09-2023
Sent to DTL (Form 6):	13-09-2023
Date of receipt in DTL	22-09-2023
DTL Report Date (Form 7):	02-11-2023
Form 3	06-11-2023
1st DI Communication with firm dated	06-11-2023

Date of Retesting Request of Firm:	No
Fate of Retesting request	N/A
Investigation Report Dated	04-01-2024
Firm History 3 years	Firm: 11 Product: 1 (subject case)

PROCEEDING & DECISION BY THE BOARD:

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