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

259 PQCB Meeting

Date: 18-04-2023

Time: 11:00 AM

Venue

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

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ITEM No. 1
LEFT OVER CASES OF 258 MEETING (CASE 1 - 18)

Case No. 1

PQCB R-541/2021

Tehsil Rojhan, District Rajanpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan** through its Chief Executive officer, Mr. Shaukat Hayat Khan 2. Shaukat Hayat Khan Chief Executive Officer/ Warrantor 3. Fwad Ali Khan Production Manager 4. Ahtesham ul Haq Quality Control Incharge of M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan**.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Rojhan, District Rajanpur reported that: -

i. He, on 27-01-2021, inspected the business premises of M/S Kaleem Medical store/Hall, Thana Road, Tehsil Rojhan and took 4 different types of drug samples on Form No. 4 for the purpose of test and analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memo no. 83973 dated 27-01-2021.
ii. Following drug sample, after test/ analysis was declared as **Misbranded** by Government Analyst, Drug Testing laboratory **Multan** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Pwder for Ijection Cefocef 500mg (Ceftriaxone as Sodium 500mg) **Mfg. date**: Oct 2019 **Exp. Date**; June 2021 **Regs. #** 086272	278	M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan	01-89002585/DTL dated: 02-04-2021	**Result of test/ analysis with specifications applied:** USP 2019/PQCB Approved Method **DESCRIPTION**: White to off white color fine powder for reconstitution in transparent labeled glass vial closed with a rubber stopper and blue color flip off cap sealed with aluminum, in an ampoule of Lignocaine 1% (Lacain). The product does not contain Finished Drug Product Specifications on vial as well as on outer carton. **(Misbranded) (Does Not Comply)** **IDENTIFICATION USP:** Ceftriaxone as Sodium identified **ASSAY:** Ceftriaxone Stated 500mg/vial Determined 493.96mg/vial Percentage 98.79**%** Limit: 90-110% **(Complies)** **Sterility:** It conforms to Sterility test. **(Complies)** **RESULT:** The sample is **Misbranded** as defined under clause (vi) of subsection (s) of section 3 of the Drug Act 1976.

iii. M/S Kaleem Medical store/Hall, Thana Road, Tehsil Rojhan, District Rajanpur provided invoice/warranty No. 1025805 dated 03-01-2021 issued by M/S “City Pharma” Adda Fatehpur, Rajanpur.

iv. Warrantor Portion was sent to M/S City Pharma” Adda Fatehpur, Rajanpur with directions to explain their position and provision of requisite information.

v. M/S City Pharma” Adda Fatehpur, Rajanpur.in turn provided the invoice warranty No. SOB-0000723 dated 19-02-2020 issued by M/S Marketing Services, 759-Naqashband Colony, Chowk Rashidabad , Multan.

vi. M/S Marketing Services, 759-Naqashband Colony, Chowk Rashidabad, Multan provided Invoice/warranty No. 7035 dated: 06-02-2020 issued by M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan.

vii. Copy of test/analysis report was sent to M/S EG Pharmaceuticals, 13-A, Industrial Triangle, Khauta Road, Islamabad, Pakistan with directions to explain their position and provision of requisite information in this regard.

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

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

3. Show cause notice(s) issued to the accused vide 10-02-2023.

Reply to Show Cause Notice:

This is with reference to your letter No PQCB/R-541/2021, Dated 10-02-2023, received on 17-02- 2023, regarding the misbranded drug cefocef injection 500mg in which product specification was not mention either on label and unit carton of injection, it was a printing mistake which is rectified. Copy of corrected unit carton and label is attached for record.

We would like to informed that Cefocef injection 500mg Batch # 278, expired in 06/2021 and no stock is available in market.

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

Case is placed before the Board for Decision.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD

PQCB's 258th Meeting held on 05-04-2023

4. The case was left over case due to time constraints.

5. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 2

PQCB/R-441/2020

Tehsil & District Pakpattan

ATTENDANCE:

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

BRIEF FACTS OF THE CASE:

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

i. He, on 06-06-2020 inspected the medicine Store O/o CEO DHA Pakpattan, District Pakpattan and took sample of the six different types of drugs on Form No. 4 for the purpose of test and analysis.
ii. One out of six drug samples, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, Bahawalpur as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result

Gauze Curay Gauze Swab [Absorbent cotton gauze swab 10cm*10cm, 8ply]	75B20	M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore	01-25005732/DTL dated: 27 Jul 2020	**Result of test/ analysis with specifications applied** BP 2020/BPC 1973 **DESCRIPTION (MS)**: Absorbent cotton gauze consists of cloth of plain weave, bleached to good white odorless clean, reasonably free from weaving defects. **WEIGHT/UNIT AREA (BPC):** **Limit:** Average 15gm/m^2 (SD 0.33) **Determined:** 14.84gm/ m^2 **WARP (BPC):** **Limit:** Average 73/10cm (SD 1.33) **Determined:** 73.5/10cm **WEFT (BPC):** **Limit:** Average 57/10cm (SD 1.33) **Determined:** 56.0/10cm **SINKING TIME (BPC):** **Limit:** Not more than 10sec **Determined:** 1.47sec **ACIDITY/ ALKALINITY (BPC):** **Limit:** No pink color with Phenolphthalein and Yellow color with Methyl orange. **Determined:** Phenolphthalein: No pink color Methyl orange: yellow color **SURFACE ACTIVE SUBS (BPC)** **Limit:** Not more than a ring of froth **Determined:** Ring of froth appeared **STERILITY (BP):** **Limit:** Must be sterile **Determined: Non-sterile** **(Does not comply with the specifications)** **RESULT:** The sample is declared Sub-Standard on the basis of sterility Test.

iii. The Storekeeper Medicine Store, District Pakpattan provided invoice/ warranty No. 0812 dated 04-06-2020 issued by M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore.

iv. Warrantor Portion was sent to M/s Cotton Craft (Pvt) Ltd., Plot No. 407, 408 Sunder Industrial Estate, Raiwind Road, Lahore.

v. A copy of Test/ Analysis report was also sent to M/s Cotton Craft (Pvt) Ltd., Plot No. 407- 408 Sunder Industrial Estate, Raiwind Road, Lahore and they were directed to provide requisite information in this regard.

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

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

Summary:

Manufacturing Date: 02-2020

Expiry Date: 01-2023

Sampling Date: 06-06-2020

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

Date of receipt in DTL: 08-06-2020

DTL Report Date: 27-07-2020

1ST DI Communication with firm on dated: 21-08-2020

Date of Retesting Request of Firm: No (**but in reply of Show cause notice**)

Investigation Report Dated: 06-11-2020

3. Showcause notice(s) issued to the accused dated 20-04-2021

Firm submitted reply of Show cause vide letter Ref: 786/0735/2021 dated 26-05-2021

We would like to bring to your kind notice that the sample of the same Batch No. 75B20 of the same item has also been taken from the Jampur and tested by the DTL Punjab Multan and declared as "Pass of Standard Quality". In the light of above DTL report we are unable to understand that how the analyst DTL Punjab Bahawalpur declared the same batch 75B20 as "Sub-standard", whereas the other DTL Multan is declaring the same Batch as "Pass of Standard Quality". It is stated that the same batch was supplied at the same time to the consignees including CE0, DHA Pakpattan.

As regards the test results reported in the DTL Report No. TRA-01-25005732/DTL dated 27.05.2020, it is observed that all chemical and other test of the Drug/ Medical Device under reference mentioned here under has been complies the specifications. But the Analyst declared it sub-standard based on Sterility, whereas we tested the warrantor portion as well as retained sample at our Microbiological Lab and confirm the sample is sterile.

Hence our submissions are as under:-

We are very much conscious about the quality and quantity of the products, especially in sterility process, which is done through Ethylene Oxide (ETO) Sterilization process over the best equipment that has been calibrated and for which IQ and 0Q processes have been completed and we have no doubt about sterilization of this drug / Medical Device under reference.

It is stated that the stock under reference supplied to the Medicine Store CEO (DHA) Pakpattan was very small in quantity, shipped through local transport and maybe it damaged during the transportation or mishandling during loading/ unloading by the untrained laborers, due to which the sum of stock captured and loss its sterility or otherwise all other test complies the specification.

It is worthwhile to mention here that the Surgical Bandages (Gauzes/Gauze Swabs) is meant for external use only and it has many commercial usages other than medical purposes like Cleaning of Machinery, Polishing, Sanitary and Rexene are two major industries for used of Gauze Cloths / Gauzes called as Mulmul).

In the light of above said explanation it is stated that the Product (Medical Device) under reference is complies all test according to the BPC specifications and observations made by the Analyst for declaring sub-standard are unfortunate. Even though if the authority feel it necessary we are ready to replace the seized stock with the fresh stock of standard quality or otherwise **forward the sample of the same product under reference to the NIH for re-testing.**

Hence, It is submitted that we have not contravened the provisions of Section 23/72 of the Drug Act 1976 (as amended)/DRAP Act 2012 and Rules framed there under by the way of (a) Manufacturing for sale/ Selling of Substandard drug (b) Issuance of false warranty.

Keeping in view the above said explanation it is stated that the product (Medical Device) under reference is complies all test according to the BPC specifications and observations find by the Analyst for declaring sub-standard is unfortunate, which may kindly be ignored and consider our request as under:

i. Stock under reference may be accepted.
ii. Allow to return "out of specification" seized stock to us with the conditions of replacement by fresh stock of standard quality to settle this issue at your level.
iii. Forward the sample of the same product (Medical Device) under reference to the NIH for re-testing purposes.

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

Case is placed before the Board for Decision

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **247th meeting** held on **21-07-2022** under the chairmanship of Vice Chairperson, in the presence of Board members as mentioned above. Mr. Sarfraz Ali, Secretary DQCB Pakpattan, Mr. Aqeel Ahmed Provincial Inspector of Drugs, Tehsil Pakpattan was present along with the original case record. No one among the nominated accused persons of M/s Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind road Lahore was present. Firm submitted written request for adjournment that Managing Director of the firm was suffering from old flu and fever and unable to attend meeting dated 21.7.2022.

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

6**.** Personal Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD

7. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Sarfraz Ali, Secretary DQCB Pakpattan, Mr. Aqeel Ahmed, Provincial Inspector of Drugs, Tehsil Pakpattan was present along with the original case record. Among the nominated accused persons Salman (Director) of M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore was present.

8. The Board after due deliberation and discussion unanimously decided to **left over case** due to time constraints.

9**.** Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 3

PQCB R-162/2022

Tehsil and District Rajanpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Shawan Pharmaceuticals, Plot 37 Roads NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan** through its Director Operations, Amir Iqbal 2. Amir Iqbal Director Operations 3. Ziad Hussain Quality Control Manager/Warrantor 4. Usha Talat Toosi Production Manager of M/S **Shawan Pharmaceuticals, Plot 37 Road NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Jampur, District Rajanpur reported that: -

i. He, on 27-05-2022, inspected the business premises of M/S Punjab Medicine Store, Opposite THQ Hospital, Tehsil Jampur, and took 2 different types of drug samples on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Multan.

ii. Following drug sample, sent vide memo no. 128105 dated28-05-2022, after test/ analysis was declared as **Misbranded** by Government Analyst, Drug Testing laboratory **Multan** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Capsule Mixcef (Cefixime Trihydrate eq. to Cefixime: 400mg) **Mfg. date**: Oct-2021 **Exp. Date**; Sep-2023 **Regs. #** 056783	097	M/S Shawan Pharmaceuticals, Plot 37 Roads NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan	01-94003959/DTL dated: 18-07-2022	**Result of test/ analysis with specifications applied:** MS **DESCRIPTION**: Off-white to light yellow granular powder filled in hard gelatin capsules of blue color cap & body packed in ALU-ALU blister of 5 units in a labeled outer hard carton. Each outer carton contains1 blister of 5 units i.e., 1*5=5 Capsules. The product claims JP Finished Drug Product Specifications and in JP the monograph for 50 & 100 mg Cefixime capsule is given while the label claim of the product is “Cefixime capsule 400mg” which is false & misleading. **(Misbranded) (Does Not Comply)** **IDENTIFICATION USP:** Cefixime as Trihydrate identified **ASSAY:** Cefixime Stated 400 mg/capsule Determined 393.43 mg/capsule Percentage 98.35**%** Limit: 90-105% **(Complies)** **DISSOLUTION TEST:** **Acceptance Criteria**: NLT 80% of labeled amount of Cefixime is dissolved in 60 minutes. **(Complies)** **RESULT:** The sample is **Misbranded** as defined under clause (iv) of subsection (s) of section 3 of the Drug Act 1976.

iii. M/S Punjab Medicine Store, Opposite THQ Hospital, Tehsil Jampur provided invoice/warranty No. 9388 dated 26-05-2022 issued by M/S Hamas Pharma, Shop #12, Block# L, Near National Saving Bank#2, DG Khan, as a proof of purchase.

iv. Warrantor Portion was sent to M/S Hamas Pharma, Shop #12, Block# L, Near National Saving Bank#2, DG Khan.

v. M/S Hamas Pharma, Shop #12, Block# L, Near National Saving Bank#2, DG Khan, in turn provided invoice/warranty No. 10061, dated: 06-01-2022, issued by M/S Biogen Life Sciences, Plot No. 260, Industrial triangle, Kahuta Road, Rawalpindi, Pakistan as a proof of purchase of subject drug sample.

vi. M/S Biogen Life Sciences, Plot No. 260, Industrial triangle, Kahuta Road, Rawalpindi, Pakistan, provided invoice/warranty No. 191, dated: 27-12-2021, issued by M/S Shawan Pharmaceuticals, Plot 37 Road NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan, as a proof of its purchase.

vii. Copy of test/analysis report was sent to M/S Shawan Pharmaceuticals, Plot 37 Road NS-1, Industrial Zone Rawat, Rawalpindi, Pakistan, with directions to explain their position in this regard.

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

a. **Manufacture for Sale / Sale of Misbranded Drug.**

b. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused vide 10-02-2023.

Reply to Show Cause Notice:

Please refer your letter No. PQCB/R-162/2022 Dated: 10/02/2023 received at our office 21/02/2023 to the captioned subject regarding Mis-Branded Mixcef 400mg Capsule B#097 Mfg. Date 10-21 Exp 09-23.

It is to bring into your kind notice that as per decision of DRAP Minutes of Meeting Conducted on 16-18th November 2021, new revised specification for Cefixime 400mg Capsule have been approved.

DRAP issued a Letter No F.14-1/2022-PEC Dated 14th March 2022 for implementation of revised specification within 6 months. We have implemented the same for all batches manufactured after decision of the DRAP.

We are attaching herewith Minutes of 313th Meeting of Registration Board Conducted on November 2021, DRAP Letter No F.14-1/2022-PEC Dated 14th March 2022 and Artwork of Mixcef 400mg Capsule with revised Shawan's Specification along with this letter for your kind perusal.

As our Product was manufactured on 10-2022 before issuance of DRAP letter. Hence your kind cooperation and kindness based on DRAP Letter No F.14-1/2022-PEC Dated 14th March 2022 & within 6 months time frame relaxation, which shall be highly appreciated.

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

PROCEEDINGS & DECISION BY THE BOARD:

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 258th meeting held on 05-04-2023:

5. The case was left-over due to time constraint.

Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

Case is placed before the Board for Decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 4

R-423/2021

Tehsil Jampur, District Rajanpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore** through its Chief Executive Officer Ali Ahmad Khan 2. Ali Ahmad Khan — Chief Executive Officer 3. Nabila Shaheen — Production Manager 4. Faiza Rashid — Quality Control Manager/Warrantor of M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs Tehsil Jampur District Rajanpur reported that: -

i. His predecessor, on 26-01-2021, inspected the business premises of M/s Madina Medical Store, Store at Adda Charagh Shah Tehsil Jampur and took two different types of Drug samples on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Multan.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Powder for Reconstitution Ceffest 30ml [Cefixim as Trihydrate Eq. to Cefixime 100mg/5ml]	0973	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore	01-89002557/DTL Dated 24-05-2021	**Analysis with specifications applied: USP 2019** **Description**: Light yellow to lemon color suspension after reconstitution in a labeled white plastic bottle sealed with Aluminum and covered with Red screw cap packed in a labeled outer hard carton along with water for suspension. **Identification**: Cefixime as Trihydrate identified. **Analytical Technique: HPLC** **Assay (**Cefixime)

Stated	100mg/5ml
Determined	**81.10mg/5ml**
Percentage	**81.10%**
Limit	90-120

(Does not comply)

Result: The above sample is **Substandard** on the basis of Assay Test.

iii. M/s Madina Medical Store, Store at Adda Charagh Shah Tehsil Jampur provided Invoice/warranty No. 275 Dated 05-01-2021 issued by M/s Al-Shifa Enterprises, Jampur who in turn provided invoice/warranty No. 0307 Dated 10-12-2020 issued by M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore as a proof of its purchase.

iv. A copy of test/analysis report was sent to M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore and they were asked to provide the requisite information in this regard.

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

vi. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>NIH Test Report No. & Date</th><th>NIH Test Report Results</th></tr>
<tr><td>Ceffest Dry Suspension 30ml</td><td>0973</td><td>M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Lahore</td><td>0263-P/2021
dated: 15-12-2021</td><td>Analysis with specifications applied: USP 39
<u>Description:</u>
Slightly off white powder contained in white labeled plastic bottle along with a bottle containing purified water packed in an outer carton produces off white suspension after reconstitution with water provided along with the pack.
<u>Identification:</u> Cefixime trihydrate identified.
<u>Assay:</u>
<table>
<tr><td rowspan="2">Cefixime (as trihydrate)</td><td>Stated</td><td>Found</td><td>Limit</td><td>Percentage</td></tr>
<tr><td>100mg/5ml</td><td>72.29mg/5ml</td><td>90-120%</td><td>72.29%</td></tr>
</table>
Does not comply with USP-39.
<u>Result:</u> The sample is of <u>Substandard</u> quality on the basis of tests performed.</td></tr>
</table>

vii. Copy of NIH report was sent to M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore.

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

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

3. Show cause notice(s) issued to the accused vide 28-06-2022.
4. Personal Hearing notice(s) issued to accused person(s) on 19-12-2022.

<u>PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:</u>

<u>PQCB's 255th Meeting held on 29-12-2022</u>:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **255th meeting held on 29-12-2022** under the Chairmanship of Secretary Primary and Secondary Healthcare Department Punjab. Mr. Adil Jameel, Secretary DQCB District Rajanpur and Mr. Kaleem Bhutta, Drug Inspector, tehsil Jampur, were present along with original case record. No one among the nominated accused persons was present on behalf of **M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore** was present.

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

Personal Hearing notice(s) issued to accused person(s) on 17-02-2023.

Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 05-2020

Expiry Date:04-2022

Sampling Date (Form 4): 26-01-2021

Sent to DTL (Form 6): 28-01-2021

Date of receipt in DTL: 30-01-2021

DTL Report Date (Form 7): 2 4 - 0 5 - 2 0 2 1

1ST DI Communication with firm on dated: 07-08-2021

Date of Retesting Request of Firm: 20-08-2021

Fate of Retesting Request: Allowed, NIH Substandard

Investigation Report Dated: 12-04-2022

<u>PQCB's 258th Meeting held on 05-04-2023</u>:

The case was left over due to time constraints.

7. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

Case is placed before the Board for Decision

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 5

R-492/2021

Tehsil Jampur, District Rajanpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan** through its Managing Director Amir Siddique 2. Amir Siddique Managing Director 3. Muhammad Uzair Bhatti Production Manager 4. Muhammad Aslam Quality Control Manager 5. Aamir Siddique Warrantor of M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Jampur, District Rajanpur reported that: -

i. His predecessor, on 31-12-2020, inspected the premises of M/S Irfan Medical Store, Near THQ Hospital Jampur and took 3 different types of drug samples on Form No.04 and sent to Drug Testing Laboratory Multan for the purpose of test/analysis. The subject sample was sent vide memorandum no. 82506 dated 06-01-2021.

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

iii. M/S Irfan Medical Store, Near THQ Hospital Jampur provided invoice/ warranty 349 dated 01-12-2020 issued by M/S Gul Brothers, Block #5, New College Road, D.G. Khan as a proof of its purchase.

iv. Warrantor portion was sent to M/S Gul Brothers, Block #5, New College Road, D.G. Khan with direction provide requisite information in this regard.

v. M/S Gul Brothers, Block #5, New College Road, D.G. Khan provided invoice/ warranty no. Oct/01001 dated: 13-10-2020 issued by M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan as a proof of its purchase.

vi. A copy of test/analysis report was sent to M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan, with directions 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. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

ix. Copy of NIH report was sent to M/s British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan.

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Manufacturer</th><th>DTL Report
TRA No. & Date</th><th>DTL Test Report Result</th></tr>
<tr><td>Syrup Beroline 60ml (Salbutamol as Sulphate 2mg/5ml)

Mfg. Date: Sep-2020

Exp. Date: Sep-2022

Regs # 094671</td><td>20280</td><td>M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan</td><td>01-89002252/DTL
Dated: 08-03-2021</td><td>Analysis with specifications applied: BP 2019

<u>Description:</u>
Clear, Colorless solution in amber plastic bottle of 60ml sealed with white Aluminum cap packed in a labelled outer hard carton

<u>Identification:</u> Salbutamol as Sulphate identified.

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

Analysis Method: HPLC
<table><tr><td>Stated</td><td>2mg/5ml</td></tr><tr><td>Determined</td><td>3.86mg/5ml</td></tr><tr><td>Percentage</td><td>192.81%</td></tr><tr><td>Limit</td><td>90-105%</td></tr></table><u>(Does not comply)</u>

<u>pH:</u>
<table><tr><td>Range</td><td>3.3-4.0</td></tr><tr><td>Determined</td><td>4.88 at 25°C</td></tr></table><u>(Does not comply)</u>

<u>Result:</u> The above sample is “Substandard” on the basis of Assay and pH.</td></tr>
</table>

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>NIH Test Report No. & Date</th><th>NIH Test Report Results</th></tr>
<tr><td>Syrup Beroline 60ml (Salbutamol as Sulphate 2mg/5ml)
Mfg. Date: Sep-2020
Exp. Date: Sep-2022
Regs # 094671</td><td>20280</td><td>M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan</td><td>021-P/2022
dated: 10-06-2022</td><td>Analysis with specifications applied: BP 2017
<u>pH</u>:
<table><tr><td>Determined</td><td>4.9</td></tr><tr><td>Limit</td><td>Not available in BP2017</td></tr></table>
<u>Assay:</u>
<table><tr><td>Stated</td><td>2mg/5ml</td></tr><tr><td>Determined</td><td>3.9mg/5ml</td></tr><tr><td>Percentage</td><td>195.47%</td></tr><tr><td>Limit</td><td>90-105%</td></tr></table>
(Does Not Comply with BP2017)
<u>Result:</u> The sample is of <u>Substandard</u> quality on the basis of tests performed.</td></tr>
</table>

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

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

3. Show cause notice(s) issued to the accused vide 14-12-2022.

Reply to Show Cause:

With reference to letter no. PQCB/R-492/2022, dated 19-10-2022 received at our factory premises on 29-10-2022 with the subject "SHOW CAUSE NOTICE" regarding "Beroline Syrup 60ml Batch No. 20280" which was allegedly declared substandard from DRUGS TESTING LABORATORY MULTAN on the basis of Assay and pH test vide test report No.TRA-01-89002252/DTL, dated 08-03-2021.

It is submitted that at the time of final release, all the tests were performed and product was found of standard quality.

After receiving of DTL Multan report, we retested our retaining samples of said batch of "Beroline Syrup 60ml (Salbutamol as sulphate)" and all the parameters including assay and pH test were found within specifications. Reports of tests are attached for your kind consideration.

This is submitted with due respect that, according to Drug act 1976 the Drug inspector is bound to send sample to concerned DTL within 7 days. But in this case the sample was send to DTL on 9th day clearly violating the Drug Law.

Also, sir, NIH test report is time barred. According to drug law 1976 NIH is bound to generate the test report of sample within 60 days. But in our case the report was generated after 109th days. It must be noted that the Expiry date of said Product was September 2022(Expired) and NIH perform test in the month of june 2022 so the storage condition of the product will remain suspected and questionable.

Therefore, this is requested that NIH test report may consider as Null & voided. It is also found contradictory that NIH follow's BP2017 specifications while DTL Multan follows BP 2019 specification. BP2017 and BP 2018 do not mention the pH of the product. We follow in-house pH specification range 4.5-5.5 at the time of manufacturing. We have updated product specification following cGMP.

We didn't receive the warrantor portion of the said product another drug rule violated.

As per direction of Provincial Quality control Board we have also recalled the available stock of above product from market detail attached. The Recalled stock of the product was later destroyed as Expiry product (Mfg 9/2020 Exp 9/2022) in the presence of qualified technical staff. all of the recalled stock

4. Personal Hearing notice(s) issued to accused person(s) on 19-12-2022.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 255th Meeting held on 29-12-2022:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **255th meeting held on 29-12-2022** under the Chairmanship of Secretary Primary and Secondary Healthcare Department Punjab. Mr. Adil Jameel, Secretary DQCB District Rajanpur and Mr. Kaleem Bhutta, Drug Inspector, Tehsil Jampur, were present along with original case record. No one among the nominated accused persons was present on behalf of **M/S British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore, Pakistan.**

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

Personal Hearing notice(s) issued to accused person(s) on 17-02-2023.

Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 09-2020

Expiry Date:09-2022

Sampling Date (Form 4): 31-12-2020

Sent to DTL (Form 6): 06-01-2021

Date of receipt in DTL: 08-01-2021

DTL Report Date (Form 7): 0 8 - 0 3 - 2 0 2 1

1ST DI Communication with firm on dated: 20-03-2021

Date of Retesting Request of Firm: 29-03-2021

Fate of Retesting Request: Allowed, NIH Substandard

Investigation Report Dated: 06-08-2022

PQCB's 258th Meeting held on 05-04-2023:

The Board after due deliberation and discussion unanimously decided to left over case due to time constraints.

7. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 6

R-587/2021

Tehsil Jampur, District Rajanpur

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Venus Pharma, 23-km, Multan Road, Lahore, Pakistan** through its Managing Partner Pervaiz Iqbal Siddiqui 2. Pervaiz Iqbal Siddiqui Managing Partner/Warrantor 3. Malik Muhammad Asif Production Incharge 4. Muhamad Adnan Tahir Quality Control Incharge of M/S **Venus Pharma, 23-km, Multan Road, Lahore, Pakistan.**

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Jampur, District Rajanpur reported that: -

i. His predecessor, on 17-03-2021, inspected the business premises of M/s Janjua Pharmacy, opposite THQ Hospital Jampur and took two different types of Drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.

ii. Following drug sample, sent vide memo no. 87325 dated: 17-03-2021, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory, Multan, as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date
THREEBION [VITAMIN B1 (THIAMINE HCl) 100mg/3mL, VITAMIN B6 (PYRIDOXINE HCl) 100mg/3mL & VITAMIN B12 (CYANOCOBALAMIN) 1000mcg/3mL] INJECTION 3mL	H-26320	VENUS PHARMA, 23-KM. MULTAN ROAD, LAHORE.	TRA 01-89003063 /DTL Multan dated 08-05-2021

Specification applied: MS

Description: Clear red color solution filled in a sealed amber glass ampoule of 3mL with white printed label, white colored neck ring in a labeled outer hard carton. 25 ampoules holding in beehives are packed in a unit outer hard carton (25 * 3 Ampoules).

Extractable Volume

Limit: NLT stated

Determined: 3.28 mL **(Complies)**

pH:

Limit: 3.5-4.5

Determined: 3.70 mL at 25 ºC **(Complies)**

Sterility:

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

Identification:

Vitamin B1 (Thiamine HCl), Vitamin B6 (Pyridoxine HCl) & Vitamin B12 (Cyanocobalamin) Identified.

Assay	Stated	Determined	Percentage	Limit	Result
Vitamin B1 (Thiamine HCl) (HPLC)	100 mg/ 3mL	64.69 mg/ 3mL	**64.69%**	90-115%	**Does Not Comply**
Vitamin B6 (Pyridoxine HCl) (HPLC)	100 mg/ 3mL	112.02 mg/ 3mL	112.02%	90-115%	**Complies**
Vitamin B12 (Cyanocobalamin) (UV-Spectrophotometer)	1000 mcg/ 3mL	958.4 mcg/ 3mL	95.84%	90-115%	**(Complies)**

Result: The above sample is **Substandard**, on the basis of **Tests** Performed.

iii. M/s Janjua Pharmacy, opposite THQ Hospital Jampur provided invoice/ warranty No. 1227 dated 02-01-2021 issued by M/S Venus Pharma, 23-km, Multan Road, Lahore, Pakistan, as a proof of purchase of subject drug sample.

iv. Warrantor portion of drug sample was sent to M/S Venus Pharma, 23-km, Multan Road, Lahore, Pakistan.

v. A copy of test/analysis report was sent to M/S Venus Pharma, 23-km, Multan Road, Lahore, Pakistan and they were asked to explain their position and provide the requisite information in this regard.

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

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

3. Show cause notice(s) issued to the accused vide 20-01-2023.

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

Case is placed before the Board for Decision.

Summary:

Manufacturing Date: 07-2020

Expiry Date:07-2022

Sampling Date (Form 4): 17-03-2021

Sent to DTL (Form 6): 17-03-2021

Date of receipt in DTL: 18-03-2021

DTL Report Date (Form 7): 08-05-2021

1ST DI Communication with firm on dated: 10-08-2021

Date of Retesting Request of Firm: 16-08-2021

Fate of Retesting Request: Allowed, FNA at NIH

Investigation Report Dated: 14-09-2022

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD

PQCB's 258th Meeting held on 05-04-2023

The case was left over due to time constraints.

4. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 7

PQCB/R-335/2022

Tehsil Chichawatni, District Sahiwal

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar** through Chief Executive Officer (CEO) Abdullah Shah 2. Abdullah Shah Chief Executive Officer (CEO)/Warrantor 3. Imran Khan Production Incharge 4. Umar Kamran Quality Control Incharge of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar

BRIEF FACTS OF THE CASE:

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

i. His predecessor, on 14-09-2022 inspected the business premises of M/s Ali Medical store, 90- More Chichawatni, Sahiwal, took following drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug testing Laboratory, Bahawalpur vide memorandum no. 140262 dated 15-09-2022

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report</th><th>DTL Test Report Result</th></tr>
<tr><td>Capsule Perl 20mg [Each capsule contains Enteric coated pellets eq to Omeprazole 20mg]

Mfg. Date:
08-2022
Exp. Date:
09-2024
Regn. No: 022859</td><td>F-914</td><td>M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar</td><td>01-10097000217/DTL dated: 31-10-2022</td><td>
Result of test/ analysis with specifications applied: USP 2022
<u>COMPOSITION:</u> Each capsule contains
Enteric coated pellets eq to Omeprazole (BP)…… 20mg
<u>DESCRIPTION</u>: off white color pellets filled in a pink color hard gelatin capsule. packed in a blister pack (primary packing) of 07 capsules. The capsule blister is packed in outer hard carton. (Secondary Packing)
Note: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states that “All registration holders shall follow official pharmacopeial specifications for all such formulation for which official monographs of drug product is available in the most recent edition of such pharmacopoeia”. Product specification of given sample is “Mfg. Stanley specifications” and it is manufactured after the expiration of timeline to apply such specifications despite the availability of “Omeprazole delayed release capsules” monograph in USP 2022. So, the manufacturer’s claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drug Act 1976. Therefore, the product is Misbranded
<u>DISSOLUTION TEST (USP)</u>: Tolerance limit: Each unit is NLT 75% in 45 mins in buffer stage.
<table>
<tr><th colspan="6">ACCEPTANCE CRITERIA</th><th rowspan="2">Avg</th></tr>
<tr><td colspan="6">Each unit is not less than 75% (Q) in 45 mins</td></tr>
<tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td></td></tr>
<tr><td>98.42%</td><td>98.4%</td><td>99.24%</td><td>100.67%</td><td>105.20%</td><td>107.59%</td><td>101.08%</td></tr>
</table>
<u>IDENTIFICATION (USP):</u> Omeprazole is identified
<u>ASSAY (USP): Omeprazole</u>
Stated: 20mg/cap
Determined: 20.35mg/cap
Percentage: 101.76%
Limit: 90-110%
<u>RESULT:</u> The sample is declared <u>Misbranded</u> as per Section 3 (s) (iv) of Drug Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) Human import dated 7th February, 2022.
</td></tr>
</table>

iii. M/s Ali Medical store, 90- More Chichawatni, Sahiwal, provided Invoice/Warranty No. SDB-0945612 dated 10-09-2022 issued by M/s Al- Noor Medicine Company House no. 15, Gulshan E Raheem Colony Burewala as proof of its purchase.

iv. Warrantor Portion of drug sample was sent to M/s Al- Noor Medicine Company House no. 15, Gulshan E Raheem Colony Burewala who in turn provided invoice/warranty no. 789 dated 24-08-2022 issued by M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar.

v. A copy of Test/ Analysis report was sent to M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar, Pakistan with direction to explain their position and provide requisite information in this regard.

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

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

3. Showcause notice(s) issued to the accused

Firm submitted reply to show cause notice dated 16-02-2023

We rectified both unicarton and innermost aluminum foil of capsule Perl immediately *where product specification Stanley spec replaced with* ***USP Specifications****.*

As per DRAP Order F.3-5/2020-I & V-II (M-297) dated 7th February 2022. We M/s Stanley Pharma immediately rectified both uni-carton and innermost Al. foil of capsule Perl 20mg

4. Personal Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision

PREVIOUS PROCEEDING & DECISION BY THE BOARD

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Ahmed Awais, Secretary DQCB Sahiwal via zoom meeting and Mr. M. Irfan Munir, Provincial Inspector of Drugs, Tehsil Chichawatni was present along with the original case record. Among the nominated accused persons Umar Kamran (Quality Control Manager) of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar was present.

6. The Board after due deliberation and discussion unanimously decided to **left over case** due to time constraints.

7. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 8

PQCB/R-576/2021

Punjab Health Facilities Management Company, District Sahiwal

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan** through its Chief Executive Officer/ Warrantor Abdullah Shah 2. Abdullah Shah Chief Executive Officer/ Warrantor 3. Imran Khan Production Incharge 4. Umar Kamran Marwat Quality Control Incharge Of **M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Punjab Health Facility Management Company (PHFMC), Lahore reported that:-

i. He, on 06-09-2021, inspected premises of PHMC Medicine Store (Store inside District Office PHFMC Ganj Shakar Colony Chak No. 89/6-R District Store PHFMC Sahiwal) and took sample of drug on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Bahawalpur vide memorandum no. 0000106016 dated 09-09-2021.

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

iii. Store Keeper PHMC Medicine Store (Store inside District Office PHFMC Ganj Shakar Colony Chak No. 89/6-R District Store PHFMC Sahiwal) submitted Invoice/warranty No. 1500042 dated 13-08-2021 issued by M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan as a proof of its purchase of the said drug.

iv. Warrantor Portion of the drug sample and a copy of test/analysis report were sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan and they were asked to provide the requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

v. Pursuant to firm's retesting request the Provincial Quality Control Board in its 241st meeting held on 31-03-2022 **allowed** to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>Syrup Broxol DM (Dextromethorphan 6.25mg + Diphenhydramine HCl 5mg/5ml)
Mfg.date:
Jul-2021
Exp. date:
Jul-2023
Regn No.
022854</td><td>E-509</td><td>M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan</td><td>TRA No. 01-25008152/DTL
Dated:-27-11-2021</td><td><u>Analysis with specifications applied:</u>
Manufacturer Specification (MS)
<u>Composition:</u>
Each 5 ml contains:
Dextromethorphan HBr…6.25mg
Diphenhydramine HCl…5mg
<u>Description (MS):</u>
Pink color liquid in amber color sealed glass bottle.
(stated volume: 120 ml)
<u>Identification (MS):</u> Dextromethorphan HBr & Diphenhydramine HCl are identified.
<u>Assay (MS):</u>
Dextromethorphan HBr
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>6.25mg/5ml</td><td>5.74mg/5ml</td><td>91.76%</td><td>90.0-110.0%</td></tr>
</table>
Diphenhydramine HCl
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>5.0mg/5ml</td><td>9.97mg/5ml</td><td>199.37%</td><td>90.0-110.0%</td></tr>
</table>
(Does not Comply with Specifications)
RESULT:
The sample is declared <u>SUB-STANDARD</u> on the basis of <u>ASSAY TEST OF DIPHENHYDRAMINE HCL.</u></td></tr>
</table>

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>NIH Test Report No.</th><th>NIH Test Report Result</th></tr>
<tr><td>Syrup Broxol DM</td><td>E-509</td><td>M/s Stanley Pharmaceuticals (Pvt.) Ltd., 84-B, Industrial State Hayatabad, Peshawar-Pakistan</td><td>096-P/2022 dated 13-06-2022</td><td>Analysis with specifications applied:
Manufacture Specifications
<u>ASSAY:</u>
<table>
<tr><th><u>ASSAY</u></th><th><u>STATED</u></th><th><u>FOUND</u></th><th><u>LIMIT</u></th><th><u>PERCENTAGE</u></th></tr>
<tr><td>Diphenhydramine HCl</td><td>5mg/5ml</td><td>8.52mg/5ml</td><td>90-110%</td><td>170.4%</td></tr>
<tr><td>Dextromethorphan HBr</td><td>6.25mg/5ml</td><td>5.93mg/5ml</td><td>90-110%</td><td>94.88%</td></tr>
</table>
Does not Comply with the Manufacturer’s specifications.
<u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of tests performed.</td></tr>
</table>

vi. The Copy of NIH report was sent to M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan.

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

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

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

Reply of the firm to Show cause notice vide letter no. Nil dated 02-11-2022:

We M/S Stanley Pharma Peshawar hereby clarified our position regarding to Broxol DM Syrup Batch No: E-509 declared substandard by NIH and DTL Bahawalpur on the basis of Diphenhydramine HCl assay i.e. 170.40% and 199.37% respectively. It is huge difference in assay results of NIH & DTL Bahawalpur i.e. 28.97% which clearly shows the mistake have done by both Laboratories during analysis based on titration.

Moreover we have manufactured the Broxol DM syrup Batch No. E-509 in high speed 2/800rpm silver son 10000 Liters Mixing Tank capacity at once, not manufactured in portion wise. The competent authority PQCB team also confirmed this type pf mixing tank Capacity 10000 Liters conducted PSI regarding Riam suspension batches held on dated 29.08.2022.

According to above said reason the same product Broxol DM syrup Batch No. E-509 is declared of Standard quality DTL Rawalpindi/ DTL Multan/ DTL Faisalabad Punjab.

Kindly consider our above said points and will give us **WARNING** in this regard and close the file.

Summary:

- **Manufacturing Date: 07-2021**
- **Expiry Date: 07-2023**
- **Sampling Date (Form 4): 06-09-2021**
- **Sent to DTL (Form 6): 09-09-2021**
- **Date of receipt in DTL: 15-09-2021**
- **DTL Report Date (Form 7): 27-11-2021**
- **Time Extension: Granted in 235th meeting dated 30-11-2021**
- **1ST DI Communication with firm on dated: 06-01-2022**
- **Date of Retesting Request of Firm:10-01-2022**
- **Fate of Retesting: Allowed (241th meeting dated 31-03-2022)**
- **Investigation Report Dated: 29-07-2022**

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

Case is placed before the board for decision.

PREVIOUS PROCEEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **254th meeting** held on 13-12-2022 under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Ahmed Awais, Secretary DQCB, District Sahiwal and Dr. M. Sheeraz, Drug Inspector Punjab Health Facilities Management Company were present along with the original case record. No one among the nominated accused persons of **M/s Stanley Pharmaceuticals, 84-B, Industrial State, Hayatabad Peshawar Pakistan** appeared before the Board. However, a written request for adjournment was received from the firm vide letter no. Nil dated 09-12-2022 on behalf of the firm. The Board after due deliberation and discussion unanimously decided to **adjourn** the case in best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

6. Personal Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the board for decision.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD

7. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Ahmed Awais, Secretary DQCB Sahiwal via zoom meeting and Mr. Sheraz, Provincial Inspector of Drugs, PHFMC, Lahore was present along with the original case record. Among the nominated accused persons Umar Kamran (Quality Control Manager) of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar was present.

8. The Board after due deliberation and discussion unanimously decided to **left over case** due to time constraints.

9. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 9

DISTRICT SARGODHA

PQCB/R-213/2022

Tehsil Bhera District Sargodha

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan through its** Chief Executive Officer Amin Notta 2. Amin Notta Chief Executive Officer 3. Muhammad Rizwan Production Manager/ Warrantor 4. Umar Farooq Quality Control Incharge Of **M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He on 28-06-2022 inspected the business premises of M/s Adnan Medical Store, Miani, Tehsil Bhera, District Sargodha, took sample of two different types of drugs on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Rawalpindi vide Memorandum No. 0000131879 dated 29-06-2022.

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

Name of drug	Batch no.	Name of manufacturer	DTL Test Report No. & Date	DTL Test Report Results
Film coated tablet Rhizin (Cetirizine Dihydrochloride: 10 mg) **Mfg. date:** Mar-2022 **Exp. Date:** Feb-2024 **Reg.No.** 021752	5046	M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan	TRA No. 01-75004118/DTL dated: 01-09-2022	**Result of Test/Analysis with Specifications applied:** USP 2022 **DESCRIPTION:** White colored, round shaped, biconvex tablet, plain from both sides, packed in Alu-PVC blister of 1*10s, further packed in outer labelled carton containing two blisters (20 Tablets). **Two different Manufacturing Specifications are mentioned on the label; Cibex specs on the blister whereas USP specs and Cibex specs on the outer carton. (DOES NOT COMPLY)** **IDENTIFICATION:** Cetirizine Dihydrochloride identified. **ASSAY:** Stated: 10mg/tablet; Determined: 10.703mg/tablet; Percentage: 107.03%; Limit: 90-110% **RESULT: The above sample is Misbranded as defined under clause (iv) of subsection (s) of section 3 of The Drugs Act 1976**.

iii. M/s Adnan Medical Store, Miani, Tehsil Bhera, District Sargodha provided invoice/ Warranty No. 210,271 dated 18-06-2022 issued by M/s Moeen Enterprises, House No. 102/2 Old Civil Lines Shamsher Road Sargodha as proof of their purchase.

iv. Warrantor Portion was sent M/s Moeen Enterprises, House No. 102/2 Old Civil Lines Shamsher Road Sargodha who in turn submitted Invoice/ Warranty No. 54588 dated 30-04-2022 issued by M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan as proof of their purchase.

v. A copy of Test/ Analysis report was sent to M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan and they were asked to provide requisite information in this regard.

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

i. **Manufacturing for Sale /Sale of Misbranded Drug**
ii. **Issuance of false warranty**

3. Show cause notice(s) issued to accused person(s) dated 05-01-2023.

Reply of firm to show cause notice vide letter no. nil dated nil

With reference to the show cause notice no. PQCB/R-213/2022 dated 05-01-2023, on the above noted subject the undersigned would like to explain as under;

As your kind self has mentioned in vour letter that the drug testing report dated 01-09-2022 of sample of our product Tab., RHIZIN 10mg, Batch No.S046. was declared Misbranded by Drug Testing Laboratory on the basis of misprinting / different specifications on the immediate and outer label.
That according to the report of analvst on the sample two different manufacturing specification were mentioned. *Cibex Specifications" was printed on blister whereas USP Specifications and Cibex Specs"
1as printed on the outer carton.
That the printing Mistake has now been rectified and corrected in accordance with law and labeling Rules. Copy of the Rectified Label of Outer Carton and blister are annexed herewith for ready reference.
That all the legal formalities and remedial measures have been taken in this regard and further, do hereby undertalke to be more careful in future. An undertaking to this effect is also annexed.
Regarding your queries mentioned in your letter referred above, copy of our Manufacturing License and Registration Certificate of the subject drug is annexed. It is also submitted that we have recalled almost 80% stock from the market.
The documents related to the subject case, as inquired by your kind self, are attached herewith for your kind perusal. Names of CEO/warrantor, Production Incharge and QC, already sent to you, are hereby verified as true.
Under the circumstances explained above it is most respectfully prayed that as the remedial measures had already been taken therefore the case may kindly be dropped or the warning may kindly be issued.

4. Personal Hearing notice(s) issued to accused person(s) dated 29-03-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Amer Mahmood, Secretary DQCB, District Sargodha attended the meeting online via zoom link & Mr. Mirza Asghar Baig, Drug Inspector, Tehsil Bhera, District Sargodha was present along with the original case record. No one among the nominated accused persons of **M/s Cibex (Private) Limited, F-405, S.I.T.E., Karachi-Pakistan** was present. However, Counsel of the firm, Sheikh Irfan Saeed was present on behalf of the firm. The case was **left-over** due to time constraints.

6. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 03-2022**
- **Expiry Date: 02-2024**
- **Sampling Date (Form 4): 28-06-2022**
- **Sent to DTL (Form 6): 29-06-2022**
- **Date of receipt in DTL: 04-07-2022**
- **DTL Report Date (Form 7): 01-09-2022**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 15-09-2022**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 25-11-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 10

PQCB/SM-24-11/2022

Tehsil Ferozewala, District Sheikhupura

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Neutro Pharma, 9.5 km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Zia-ud-din 2. Zia-ud-din Chief Executive Officer 3. Muhammad Faheem Production Incharge 4. Zartash Gul Production Manager 5. Muhammad Ahsan Quality Control Manager/ Warrantor of **M/S Neutro Pharma, 9.5 km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

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

i. He, on 29-12-2021, along-with other team members inspected the manufacturing premises of M/s Neutro Pharma situated at 9.5 km Lahore Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API on Form 5:

Sr.NO.	Name of drugs	Batch No.	Expiry Date	Quantity
1.	Powder (Raw material) Tropisetron HCl	200601	01-05-2022	500 gms (Approx.)
2.	Powder (API) Tramadol HCl	TM2106002	10-06-2024	500 gms (Approx.)

ii. Accused present could not produce any documents regarding the sale/ consumption of APIs at the time of inspection. One cabinet was sealed under the provision of 18(1) of The Drugs Act 1976.

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

Sr. No.	Name of Drug	Batch No.	TRA No.	Status
1	Inj. Indrop D	HP947	01-177000042/DTL dated 01-02-2022	Standard
2	Tab Affif 500 mg	2171PO85	01-171000353/DTL dated 09-02-2022	Standard
3	Inj. Neupine 1 g	1809PO54	01-177000044/DTL dated 11-02-2022	Standard
4	Tab. Lefoxin	1809PO86	01-171000352/DTL dated 18-01-2022	Standard

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

a. **Stock of Raw material without documentations**

b. **Violation of GMP conditions**

3. Show-cause was issued to accused person(s) vide dated 21-12-2022.

REPLY OF THE FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

4. M/s Neutro Pharma situated at 9.5 km Lahore Sheikhupura Road, Ferozewala, District Sheikhupura submitted written reply vide reference number Nil dated 07-02-2023 stating that:

*1. that in response to the show-cause Notice No. CB/SM-24-11/2022 dated 21-12-2022 wherein M/s Neutro Pharma Pvt. Ltd. (the **"company"**) has been directed to explain its position vis-à-vis allegations of "Stock of raw material without documentations" and violation of GMP conditions".*

2.At the very outset, company is highly respected and trusted pharmaceutical company in Pakistan engaged in the manufacturing and selling of high quality Pharmaceutical products. The company has consolidated its image by displaying firm commitment to quality and strict adherence to high standards and drug laws as well as GMP Guidelines.

3. In response to the mis-placed baseless allegations levelled in the show-cause notice under reply, we submit as under:

i. By way of background, it is submitted that on 29-12-2021 a team comprising of Drug Controller Sheikhupura, Drug Controller CDC, Provincial Drug Inspector and Deputy Controller Ferozewala conducted a raid on Company's Premises consequently one cabinet of API's at warehouse of the company had been sealed by the area inspector and two API's were seized. The sole reason for seizure of API's by the Provincial Drug Inspector were non-availability of requisite documents and records in hard copy/ form. The technical team of the company provided the Provincial Drug Inspector data of computerized software system (ERP) which was not accepted by the drug inspectors without any rhyme or reason.

ii. subsequently the company approached the Drug Court, Lahore for de-sealing purposes and sealed cabinet of API's was de-sealed vide order dated 09-05-2022.

iii. It is pertinent to mention here that at the time of de-sealing all necessary documents were submitted to the Provincial Drug Inspector. Furthermore, the company has adopted a protocol of keeping all record in physical form along-with the electronic record already being maintained by the same.

iv. *Furthermore, details of the seized API's are as under:*

Sr.NO.	Name of drugs	Batch No.	Expiry Date	Quantity
1.	Powder (Raw material) Tropisetron HCl	200601	01-05-2022	500 gms (Approx.)
2.	Powder (API) Tramadol HCl	TM2106002	10-06-2024	500 gms (Approx.)

It is clarified that 'Tropesetron HCl' was imported from Shandong Qidu Pharma. Co. Ltd. China and Tramodol HCl was imported from Virupaksha Organics Limited India. The purpose for import of Topesterone HCl" and "Tramadol HCl" was to manufacture registered products.

The Provincial Inspector also took sample of four different types of drugs on Form 4 for the purpose of test/ analysis. These sample were declared of standard Quality from Drug Testing Laboratory, Lahore as detailed below:

Sr. No.	Name of Drug	Batch No.	TRA No.	Status
1	Inj. Indrop D	HP947	01-177000042/DTL dated 01-02-2022	Standard
2	Tab Affif 500 mg	2171PO85	01-171000353/DTL dated 09-02-2022	Standard
3	Inj. Neupine 1 g	1809PO54	01-177000044/DTL dated 11-02-2022	Standard
4	Tab. Lefoxin	1809PO86	01-171000352/DTL dated 18-01-2022	Standard

Consequently, proceedings further against the company is futile and the captioned proceedings are liable to be dropped. In view of the above-mentioned reports from competent laboratory, it is pertinent to note that the company and its officials have engaged in the manufacturing of standard quality pharmaceutical products by using imported raw materials being purchased from approved vendors. There is no cavil to the fact that the company has always ensured strict compliance with Good Manufacturing Practices by manufacturing Quality Products.

4. In view of foregoing, it is most respectfully requested that the show-cause notice under reply may be withdrawn in the interest of justice, equity and fair-play.

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

PROCEEDINGS AND DECISION BY THE BOARD:

5.Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Shahzad Chaudhary, Drug Inspector Tehsil Ferozewala District Sheikhupura was present. Ms. Asma Rasheed, Secretary DQCB, Sheikhupura joined the meeting through zoom link. No-one among the nominated accused was present however, Counsel of the firm Sheikh Irfan Saeed (Advocate) was present on behalf of M/s Neutro Pharma, 9.5 km Lahore Sheikhupura Road, Ferozewala, District Sheikhupura. The case was leftover due to time constraints.

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

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 11

PQCB/SM-25-11/2022

Tehsil Ferozewala, District Sheikhupura

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Irza Pharma Pvt. Ltd., 10.2km Sheikhupura Road, Ferozewala** through its Chief Executive Officer Muhammad Imran Javed S/o Abid Ali Jawa 2. Muhammad Imran Javed Chief Executive Officer/ Warrantor 3. Dr. Iftekhar Masud Plant Manager 4. Dr. Azmat Ali Production Incharge 5. Dr. Asim Khan Quality Control Incharge of **M/S Irza Pharma Pvt. Ltd., 10.2km Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

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

i. He, on 13-01-2022, along-with other team members inspected the manufacturing premises of M/S Irza Pharma Pvt. Ltd., 10.2km Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API/ material on Form 5:

Sr.NO.	Name of drugs	Quantity
1.	A polythene bag without label/ information containing white powder	2 kg (Approx.)
2.	A polythene bag without label/ information containing white powder	1.5 Kg (Approx.)
3.	Workers in different sections without wearing hand gloves and safety kits.	

ii. Person present could not produce any documents regarding the sale/ purchase of raw materials/ drugs/ articles at the time of inspection.

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

Sr. No.	Name of Drug	Batch No.	TRA No.	Status
1	E/D Chloramphenicol 0.5%	1ASI1	01-171000495/DTL dated 22-02-2022	Standard
2	Tablet Irzacip 500 mg	1CYK2	01-171000494/DTL dated 11-02-2022	Standard
3	Tablet Famosib	1CL1	01-171000497/DTL dated 22-02-2022	Standard
4	Drops Jaxcil 125 mg	1ETL1	01-171000496/DTL dated 22-02-2022	Standard

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

a. **Stock of Raw material without Sale Purchase Record**

b. **Stock without Labellings- Misbranded**

c. **Violation of GMP conditions**

3. Show-cause was issued to accused person(s) vide dated 21-12-2022.

REPLY OF THE FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

4. M/S Irza Pharma Pvt. Ltd., 10.2km Sheikhupura Road, Ferozewala submitted written reply vide reference number IP/01/2023 dated 07-02-2023 stating that:

Sr. No.	*Name of drugs*	*Justification*
1	*A polythene bag without label/ information containing white powder. Quantity 2.0 Kg (approx.)*	*A polythene bag containing white powder (2.0 kg) was starch and was placed in PRE DISPENSED AREA waiting for identification tag by the dispensing pharmacist as the procedure was in progress.* *Rest of the materials were properly tagged along-with the name of the product under dispensing on dated 13.01.2022 (Invoice of material attached)*
2	*A polythene bag without label/ information containing white powder.* *Quantity 1.5 Kg (approx.)*	*A polythene bag containing white powder (1.5 kg) was Magnesium Stearate and was placed in PRE DISPENSED AREA waiting for identification tag by the dispensing pharmacist as the procedure was in progress.* *Rest of the materials were properly tagged along-with the name of the product under dispensing on dated 13.01.2022 (Invoice of material attached)*
3	*Workers in different sections without wearing hand gloves and safety kits.*	*The blisters were packing in both sections in their respective unit cartons (Secondary Packing stage) where the gloves and safety kits are not mandatory because the product is not directly exposed at secondary packaging level.*

Different dosage forms of the finished products were also sampled by the authority and all found of STANDARD QUALITY declared by the DRUG TESTING LABORATORY LAHORE as detailed below,

Sr. No.	***Name of Drug***	***Batch No.***	***TRA No.***	***Status***
1	*E/D Chloramphenicol 0.5%*	*1ASI1*	*01-171000495/DTL dated 22-02-2022*	*Standard*
2	*Tablet Irzacip 500 mg*	*1CYK2*	*01-171000494/DTL dated 11-02-2022*	*Standard*
3	*Tablet Famosib*	*1CL1*	*01-171000497/DTL dated 22-02-2022*	*Standard*
4	*Drops Jaxcil 125 mg*	*1ETL1*	*01-171000496/DTL dated 22-02-2022*	*Standard*

We M/s Irza Pharma (Pvt.) Ltd. Always step ahead to meet the quality standard as the above REPORTS of the DTL revealed. We assure to the honourable board about our commitment to provide the good quality medicines to our valuable customer. We assure our best co-operation and services to maintain the quality of the product and shall not leave any stone unturned to get compliance of GMP.

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

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Shahzad Chaudhary, Drug Inspector Tehsil Ferozewala District Sheikhupura was present. Ms. Asma Rasheed, Secretary DQCB, Sheikhupura joined the meeting through zoom link. Among the nominated accused Iftekhar Masud (Plant Manager) and Azmat Ali (Production Incharge) were present on behalf of M/S Irza Pharma Pvt. Ltd., 10.2km Sheikhupura Road, Ferozewala, District Sheikhupura. The case was leftover due to time constraints.

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 12

PQCB/SM-14-06/2022

Tehsil Ferozewala, District Sheikhupura

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Intervac Pvt. Ltd. 18-km, Sheikhupura Road, Ferozewala** through its Chief Executive Officer/ Warrantor Ashfaq Ahmad S/o Mumtaz Ahmad 2. Ashfaq Ahmad S/o Mumtaz Ahmad Chief Executive Officer/ Warrantor 3. Qasim Aziz S/o Abdul Aziz Production Incharge 4. Ammar Yasir S/o Amjad Baig Quality Control Incharge of **M/S Intervac Pvt. Ltd. 18-km, Sheikhupura Road, Ferozewala.**

BRIEF FACTS OF THE CASE

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

i. He, on 09-06-2022, along-with other team members inspected the manufacturing premises of M/s Intervac Pvt. Ltd. Situated at 18-km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API/ material on Form 5:

Sr.NO.	Name of drugs	Batch No.	Expiry Date	Quantity
1.	Powder Oxyclozanide vet BP 85	OX3191221	11-2026	20 Kg (Approx.)
2.	Powder API Sulpha-chlorpyridazine	Svd.21080401	03-2023	5 kg (Approx.)
3.	Material Vitamin B-12	HS181216	09/2023	500 g (Approx)

ii. Accused present could not produce any documents regarding the sale/ consumption of APIs at the time of inspection. Raw Material store was sealed under the provision of 18(1) of The Drugs Act 1976 (as amended) and the rules framed thereunder.

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

Sr. No.	Name of Drug	Batch No.	TRA No.	Status
1	Powder Negafus	NGF-184	01-17700610/DTL dated 28-07-2022	Standard
2	Liqued Leva-15	LV-241	01-171001611/DTL dated 03-08-2022	Standard

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

a. **Stocking of Raw material/ articles without sale purchase record**

b. **Stocking of Raw material/ articles without labellings- Misbranded**

c. **Violation of GMP**

3. Show-cause was issued to accused person(s) vide dated 21-12-2022.

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

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Shahzad Chaudhary, Drug Inspector Tehsil Ferozewala District Sheikhupura was present. Ms. Asma Rasheed, Secretary DQCB, Sheikhupura joined the meeting through zoom link. No-one among the nominated accused was present on behalf of M/s Intervac Pvt. Ltd. Situated at 18-km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura. The case was leftover due to time constraints.

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

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 13

PQCB/SM-19-03/2018

Tehsil Ferozewala, District Sheikhupura

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Paradise Pharma, 23-Km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura** through its Managing Partner Muhammad Shahzad Khan 2. Muhammad Shahzad Khan Managing Partner 3. Muhammad Sheraz Khan Managing Partner 4. Mian Tariq Mehmood Managing Partner 5. Muhammad Sajid Manzoor Quality Control Manager 6. Muhammad Ali Production Incharge of **M/S Paradise Pharma, 23-Km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura.**

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 20-02-2018, inspected the manufacturing premises of M/S Paradise Pharma, 23-Km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura. During inspection, he recovered and seized following different types of drugs/ API/ material on Form 5:

Sr.No.	Name of drugs	Batch No.	Manufacturer	Quantity	Reason for Seizure
1.	Adult Glycerol Suppositories 12's 70% w/v	GS017	Paradise Pharma	10x06=60 Suppositories	Manufacturing under unhygienic conditions in the room established in the backyard of factory premises
2.	Ammonia solution strong 10 x 50 ml	AM-012	Paradise Pharma	10 x 04=40 packs	Manufacturing under unhygienic conditions in the room established in the backyard of factory premises
3.	Material Vitamin B-12	GV-016	Paradise Pharma	07 bottles	Manufacturing under unhygienic conditions in the room established in the backyard of factory premises
4.	Tincture Iodine 450 ml (as said by M. Sajid Manzoor) filled in plastic bottles capped with white screwable lid without label			08 bottles	Misbranded Drugs
5.	Adult Glycerol Suppositories 70% w/v	GS-017		50 Approx.	filled in plastic jar capped with green lid bearing label without unit carton
6.	Adult Glycerol Suppositories 70% w/v	GS-017		300 Suppositories	Plastic jar bearing label without cap
7.	A suppository making mold (punch & dye) approx. 12 x 12 inches being used to manufacture suppositories in a room established in a backyard of the factory premises under unhygienic condition without Good Manufacturing Practices (GMP)				
8.	Green screwable cap embossed with company logo			500 caps	
9.	Unit cartons of Adult Glycerol Suppositories	GS-017		200 unit cartons Approx.	
10.	Parapipe Elixer 30 ml	PE006	Paradise Pharma	25 packs	Non-compliance of GMP

ii. Person present could not produce any documents regarding the sale/ purchase of raw materials/ drugs/ articles at the time of inspection. Raw Material store and the rooms where the drugs manufacturing was carried out and elixir packing area were locked and sealed under the provision of 18(1) of The Drugs Act 1976 (as amended) and the rules framed thereunder.

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

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

a. **Manufacturing/ Stocking of Misbranded Drugs**

b. **Manufacturing/ manufacturing for sale under unhygienic conditions.**

c. **Poor compliance/ violations of Schedule B-II (GMP) of Drugs (Licensing, Registration and Advertising) Rules.**

3. Show-cause was issued to accused person(s) vide dated 21-12-2022.

REPLY OF THE FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

4. M/S Paradise Pharma, 23-Km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura submitted written reply vide reference number Nil dated 03-02-2023 stating that:

a. Manufacturing/ Stocking of Misbranded Drugs	The drug was considered misbranded because of the missing primary packing material, i.e., without a label. The concerned drug were in the intermediate stage of the production processes at that time and was held due to shortage of packing material, which were filling and sealing of bottles (In-Process stage). After this stage, the drug was tested for in-process quality Check (IPQC) and released to the next stage of labeling and packing where the label adhered and the drug packed to final packing in shippers.
b. Manufacturing/ manufacturing for sale under unhygienic conditions.	The inspection team considered the area of plant used for storage of miscellaneous tools and objects which would be subjected to maintenance or discarded after thorough investigation as unhygienic conditions. The dubious areas were solely used for storage purposes for unnecessary tools and parts and not for manufacturing of any kind of product.
c. Poor compliance/ violations of Schedule B-II (GMP) of Drugs (Licensing, Registration and Advertising) Rules.	The organization responded to the team's concerns about non-compliance with Schedule B-II of GMP by reviewing and upgrading all relevant documents, processes, and records. This was done after an inspection by a panel of the DRAP (Drug Regulatory Authority of Pakistan), which revealed the guidelines and areas that needed improvement. The thorough inspection led to the decision to improve compliance with Schedule B-II GMP. The central Licensing Board (CLB) allowed to restart the production activities at the premises after reviewing the inspection report from the DRAP team. This decision was communicated in the letter, F.8-3/2019-QA (M-271-CLB), dated on October 1st , 2019. The team also collected samples of two different types of drugs on Form 4 for testing and analysis. After providing the method of analysis and necessary documents to the drug testing laboratories in Lahore, the samples were deemed to be of standard quality according to the results from the Laboratories.

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Shahzad Chaudhary, Drug Inspector Tehsil Ferozewala District Sheikhupura was present. Ms. Asma Rasheed, Secretary DQCB, Sheikhupura joined the meeting through zoom link. Among the nominated accused Muhammad Shahzad Khan (Managing Partner) was present on behalf of of M/S Paradise Pharma, 23-Km Lahore-Sheikhupura Road, Ferozewala, District Sheikhupura. The case was leftover due to time constraints.

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

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 14

PQCB/R-283/2022

Allama Iqbal Memorial Teaching Hospital, Sialkot

Misbranded

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan** through its Chief Executive Officer Bilal Ajmal 2. Bilal Ajmal Chief Executive Officer 3. Muhammad Shahid Iqbal Khan Production Manager 4. Muhammad Basit Quality Control Incharge/Warrantor of **M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Allama Iqbal Memorial Teaching Hospital, Sialkot reported that: -

i. She, on 01-04-2022 inspected the premises of Medicine Store of Allama Iqbal Memorial Teaching Hospital, Sialkot, took following drug sample on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memo no. 121724 dated 01-04-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Film coated tablet Demxet [Each film coated tablet contains: Fexofenadine HCl eq. to Fexofenadine…120mg] **Mfg. Date:** 01-2022 **Exp. Date:** 12-2023 **Regn. No:** 092561	T32014	M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.	01-68014904/DTL dated: 03-06-2022	**Result of test/ analysis with specifications applied:** Manufacturer's Specifications **DESCRIPTION**: Sea green colored oblong shaped biconvex tablet, engraved "DEMONT" on one side and scored line on reverse, contained in ALU-PVC packing of 10's, packed in outer hard carton. **Uniformity of Weight (Mass):** Comply the acceptance criteria of Uniformity of weight as per MS. (Average weight of Tablet: 355.20 mg). **Tolerance Limit:** ± 5% of Average weight. (Manufacturer's Specifications) **Reference Limit:** 337.4 -373.0 mg **Determined Limit:** 346.7-359.8 mg (Complies) **Identification:** Fexofenadine HCl is identified. **ASSAY:** Stated: 120 mg Fexofenadine/ Tablet (As per label Claim) Determined: 119.696 mg Fexofenadine / Tablet Percentage: 99.746 % (Complies) Limit: 93-107% (Manufacturer's Specifications) **Disintegration Test:** (Complies) **Labelling Requirements:** **Stated:** According to Drugs Act, 1976 Section 3 (s)(iv), Misbranded means: "it's label or container or anything accompanying which, bears any statement or design or device which makes any false claim for the drug or which is false or misleading in any particular." **Observed:** Product specs of given sample is printed as," USP Specs" According to USP 2022, "Fexofenadine Hydrochloride tablets contain NLT 93.0% and NMT 107.0% of the labelled amount of Fexofenadine Hydrochloride" whereas manufacturer specify label claim as "Each film-coated tablet contains: Fexofenadine Hydrochloride eq. to Fexofenadine…120 mg" which is contradictory to the statement of United States Pharmacopeia and is misleading and in violation to Drugs Act 1976. **(Does not Comply).** **RESULT:** Given sample is **Misbranded** with regards to Labelling (as per Section 3 (s)(iv) of The Drugs Act 1976).

iii. Storekeeper of Medicine Store of Allama Iqbal Memorial Teaching Hospital, Sialkot, provided invoice/ warranty No. Fac-22-03-012473 dated 18-01-2022 issued by M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.

iv. Warrantor Portion of the drug sample was sent to M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.

i. A copy of Test/ Analysis report was sent to M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan with directions to explain the position and provide requisite information in this regard.

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

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

3. Show-cause was issued to accused person(s) vide dated 17-02-2023.

Note: Firm has submitted rectified label of the product

4. Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Hafiz Muhammad Faisal, Secretary DQCB, Sialkot joined the meeting through zoom link. Among the nominated accused Muhammad Basit (Quality Control Incharge/ warrantor) was present on behalf of M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan. The case was leftover due to time constraints.

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 15

PQCB/R-284/2022

Allama Iqbal Memorial Teaching Hospital, Sialkot

Misbranded

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan** through its Chief Executive Officer Bilal Ajmal 2. Bilal Ajmal Chief Executive Officer 3. Muhammad Shahid Iqbal Khan Production Manager 4. Muhammad Basit Quality Control Incharge/Warrantor of **M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Allama Iqbal Memorial Teaching Hospital, Sialkot reported that: -

i. She, on 14-05-2022 inspected the premises of Medicine Store of Allama Iqbal Memorial Teaching Hospital, Sialkot, took following drug sample on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memo no. 126297 dated 14-05-2022.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Sustained release capsule Flowset-SR [Each capsule contains Tamsulusin HCl sustained release pellets eq. to Tamsulusin… 0.4mg] **Mfg. Date:** 02-2022 **Exp. Date:** 02-2024 **Regn. No:** 085175	C10018	M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.	01-68015851/DTL dated: 06-07-2022	**Result of test/ analysis with specifications applied:** Manufacturer's Specifications **DESCRIPTION**: off-white pellets filled in orange colored hard-gelatin capsule contained in ALU-PVC blister of 10's, packed in outer hard carton. **Identification:** Tamsulosin HCl is identified. **ASSAY:** Stated: 0.4mg mg Tamsulosin / Capsule (As per Label Claim) Determined: 0.368 mg Tamsulosin / Capsule Percentage: 92 % (Complies) Limit: 90-110% Dissolution Test: Complies Labelling Requirements: According to Drugs Act, 1976 Section 3 (s)(iv), Misbranded means: Stated: "it's label or container or anything accompanying which, bears any statement or design or device which makes any false claim for the drug or which is false or misleading in any particular." Observed: Product specs of given sample is printed as," USP Specs" According to USP 2022, "Tamsulosin Hydrochloride capsules contain NLT 90.0% and NMT 110.0% of the labelled amount of Tamsulosin hydrochloride" whereas manufacturer specify label claim as "Each capsule contains: Tamsulosin HCl sustained release pellets eq. to Tamsulusin…0.4mg" which is contradictory to the statement of United States Pharmacopeia and is misleading and in violation to Drugs Act 1976. (Does not Comply). **RESULT:** Given sample is **Misbranded** with regards to Labelling (as per Section 3 (s)(iv) of The Drugs Act 1976).

iii. Storekeeper of Medicine Store of Allama Iqbal Memorial Teaching Hospital, Sialkot, provided invoice/ warranty No. Fad-22-04-012906 dated 18-04-2022 issued by M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.

iv. Warrantor Portion of the drug sample was sent to M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan.

v. A copy of Test/ Analysis report was sent to M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan with directions to explain the position and provide requisite information in this regard.

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

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

3. Show-cause was issued to accused person(s) vide dated 17-02-2023.

Note: Firm has submitted rectified label of the product

4. Personnel Hearing notice(s) issued to accused person(s) dated 29-03-2023

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Hafiz Muhammad Faisal, Secretary DQCB, Sialkot joined the meeting through zoom link. Among the nominated accused Muhammad Basit (Quality Control Incharge/ warrantor) was present on behalf of M/s Demont Research Laboratories (Pvt.) Ltd. 20-km, Lahore Sharikpur Road, Sheikhupura-Pakistan. The case was leftover due to time constraints.

Personnel Hearing notice(s) issued to accused person(s)

Case is placed before the Board for Decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 16

PQCB/R-217/2022

Tehsil & District Vehari

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan** through its Managing Director Syed Saleem Asghar 2. Syed Saleem Asghar Managing Director 3. Sajjad Hussain Production Manager/Warrantor 4. Muhammad Mudassir Quality Control Manager of M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan**.**

BRIEF FACTS OF THE CASE:

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

i. She, on 25-08-2022, inspected the Main medicine store of Chief Executive Office (DHA) Vehari, took subject drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan vides memorandum no. 138113 dated 26-08-2022.

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

iii. Store Keeper, medicine store of Chief Executive Office (DHA) Vehari, provided invoice/warranty No. IP-6813 dated 02-08-2022 issued by M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan.

iv. Warrantor Portion was sent to M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan, with directions to provide the requisite information.

v. Copy of test/analysis report was sent to M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan. with directions to explain their position in this regard.

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Dispersible Tablet Orazinc 20mg (Each tablet contain: Elemental zinc (as Zinc Sulphate Monohydrate 20mg) **Mfg. date**: 07-2022 **Exp. Date**; 06-2024 **Regn. No.** 066593	268	M/S Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan	01-94005667 /DTL dated: 29-09-2022	**Result of test/ analysis with specifications applied:** MS **DESCRIPTION**: White colored, oval shaped tablet, engraved "AMSON" on one side & line of bisection on other side, in ALU-ALU blister of 10 units packed in a labelled outer hard carton. Each outer carton contains 3 blisters i.e., (3x10=30) tablets per pack. Product claims USP Finished Drug Product Specifications. According to USP monograph of Zinc Sulfate Tablets, under labeling **"Label the tablets in terms of Zinc Sulfate monohydrate and in terms of elemental Zinc"** while the label claim of the product states "*elemental zinc (as Zinc Sulphate monohydrate*…20mg/Tablet" which is false and misleading. **Misbranded (Does Not Comply)** **IDENTIFICATION** Elemental Zinc identified **ASSAY:** Elemental Zinc Stated 20mg/ Tablet Determined 19.30mg/ Tablet Percentage 96.48**%** Limit: 95-105% **(Complies)** **DISINTEGRATION TEST:** NMT 60 seconds **(Complies)** **RESULT:** The sample is **Misbranded** as defined under section 3 s (iv) of the Drug Act 1976.

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

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

3. Showcause notice(s) issued to the accused dated 22-12-2022

Firm submitted rectified label

4**.** Personal Hearing notice(s) issued to accused person(s) dated 29-03-2023

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD;

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Imran Rashid, Secretary DQCB Vehari, Mst Robina Taj, Provincial Inspector of Drugs, Tehsil Vehari was present along with the original case record. Among the nominated accused persons Sajjad Hussain (Production Manager), M. Mudassir (Quality Control Manager) of M/s Amson Vaccines and Pharma (Pvt). Ltd., 154, Industrial Triangle, Islamabad, Pakistan was present.

6. The Board after due deliberation and discussion unanimously decided to **left over case** due to time constraints.

4**.** Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD;

Case No. 17

PQCB/R-384/2020

Tehsil & District Vehari

ATTENDANCE:

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

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil Vehari, reported that: -

i. He, on 21-09-2020 inspected the premises of Main Medicine Store of CEO (DHA) Office Vehari and took samples of seven different type of drugs on Form No. 4 for the purpose of test/analysis.

ii. One out of seven drug samples, 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	DTL Test Report Result
Bandages. Elastocraft 10cm*4.5m [Cotton Crepe Bandage 10cm*4.5m]	30B20	M/s COTTON CRAFT, Plot No. 407, 408 SUNDER INDUSTRIAL ESTATE RAIWIND ROAD LAHORE.	01-89000336/DTL dated 26 Oct 2020	**Result of test/ analysis with specifications applied:** BPC 1973 **DESCRIPTION:** Cotton crepe bandage consists of characteristic fabric of plain weave, in one continuous length containing no joints, clean and reasonably free from weaving defects, cotton leaf, and shell having fast edges. **(Comply)** **Warps:** Limits: Avg NLT 17 / cm Determined: 15.68/ cm **(Does Not Comply)** **Wefts:** Limits: Avg NLT 78 / 10 cm Determined: 82.7/ 10 cm **(Comply)** **Weight g / m^2:** Limit: NLT 140 g / m^2 Determined: 126.67 g/ m^2 **(Does not Comply)** **RESULT:** The above sample is **Sub-standard** on the basis of tests performed.

iii. Storekeeper, CEO DHA Vehari, provided Invoice/Warranty bearing No. 0105 dated 12-08-2020 issued by M/s Cotton Craft, Plot No. 40 408 Sunder Industrial Estate Raiwind Road Lahore, Pakistan as a proof of its purchase.

iv. Warrantor Portion of drug sample was sent to M/s Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind Road Lahore, Pakistan

v. A copy of Test/ Analysis report was sent to M/s Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind Road Lahore, Pakista with direction to explain their position and provide requisite information in this regard.

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

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

ii. **Issuance of false warranty**

Summary:

Manufacturing Date: 02-2020

Expiry Date: 01-2025

Sampling Date: 21-09-2020

Sent to DTL (Form 6): 21-09-2020

Date of receipt in DTL: 24-09-2020

DTL Report Date: 26-10-2020

1ST DI Communication with firm on dated: 07-11-2020

Date of Retesting Request of Firm: No

Investigation Report Dated: 11-02-2021

3. Showcause notice(s) issued to the accused dated 24-02-2021

Firm submitted reply of Show cause vide letter Ref: 786/0458/2021 dated 09-03-2021

We would like to bring to your kind notice that the sample of the same batch No. 30B20 of the same item has also been taken from the Medicine Store CEO DHA Bahawalpur and tested by the DTL Bahawalpur and declared as "Pass of Standard Quality".

In the light of above DTL report we are unable to understand that how the analyst of the DTL Multan declared the same batch 30B20 as "Sub-standard", whereas the other DTL declared it as "Pass of Standard Quality. It is stated that the same batch was supplied at the same time to the consignees including CE0, DHA Vehari.

It is mentioning that as per Revised Specification Notification No.F.6/2005-Reg-II (South) dated 13.09.2006 issued by the Ministry of Health, Government of Pakistan Islamabad, a variation in the threads and weight is allowed ±5%.

We do understand that if the Thread count complies the specification, then it is understood that weight per unit area is also complies. And there is no question of any shortfall in the weight, hence we confirm the sample under reference is complies the required standards. We understand it might be happened in weighing the sample casually and ensure it is up-to the required limit.

other than the two test all necessary parameters (Weft, Width, Length, Elasticity etc.) required under the BPC specification also complies as per DTL Multan vide his report No. TRA-01-89000336/DTL dated 26.10.2020 and confirms it is up-to the standards.

Hence our submissions are as under: -

We are very much conscious about the quality and quantity of the products and do not compromise on the quality of our product in any case.

It is positive to mention here that we tested the retained sample of the said Batch No. 30B20 of Cotton Crepe Bandage BPC 10cm x 4.5m at our Quality Control Lab and observe it is of "Standard Quality" and there is no such shortfalls in the sample as reported by the Analyst in his report.

Further, it is worthwhile to mention here that the Surgical Bandages (Cotton Crepe Bandage) is meant for external use only and it has many commercial usages other than medical purposes like Cleaning of Machinery, Polishing etc. Further stated that the Product (Medical Device) under reference is complies all test according to

the BPC specifications and observations find by the Analyst for declaring sub-standard are of minor nature, unfortunate, ignorable and we understand has no such effect in externally use on human body. Even though if the authority feels it necessary, we are ready to replace the seized stock with fresh stock of standard quality.

In the light of above said facts it is submitted that we have not contravened the provisions of Section 23/72 of the Drug Act 1976 (as amended)/DRAP Act 2012 and Rules framed there under by the way of (a) Manufacturing for sale/Selling of Substandard drug (6) Issuance of false warranty.

Keeping in view the above said explanation it is stated that the Drug / Medical Device under reference is complies all test according to the BPC specifications and observations find by the Analyst for declaring sub-standard is unfortunate, which may kindly be ignored and stock under reference may be accepted or otherwise allow to return "out of specification"' seized stock to us with the conditions of replacement by fresh stock of standard quality for which we shall be highly obliged.

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

Case is placed before the Board for Decision

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **247th meeting** held on **21-07-2022** under the chairmanship of Vice Chairperson, in the presence of Board members as mentioned above. Mr. Imran Rasheed, Secretary DQCB Vehari, was present along with the original case record. No one among the nominated accused persons of M/s Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind road Lahore was present. Firm submitted written request for adjournment that Managing Director of the firm was suffering from old flu and fever and unable to attend meeting dated 21.7.2022.

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

6. Personal Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD

7. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Imran Rashid, Secretary DQCB Vehari, Mst. Robina Taj, Provincial Inspector of Drugs, Tehsil Vehari was present along with the original case record. Among the nominated accused persons Salman (Director) of M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore was present.

8. The Board after due deliberation and discussion unanimously decided to **left over case** due to time constraints

9. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 18

PQCB/R-435/2019

Tehsil Renal Khurd District Okara

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan. Lahore** through its Managing Director Muhammad Imran Asghar. 2. Muhammad Imran Asghar Managing Director 3. Junaid Zafar Manager Quality Control 4. Muhammad Adnan Jamil Manager Production 5. Ghulam Murtaza Warrantor Of **M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan.**

BRIEF FACTS OF THE CASE

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

i. He, on15-01-2019, inspected the business premises of M/S New Life Medical Store, Situated at Old Kachary Road, Anwaar Shaheed Colony, Tehsil Renala Khurd, District Okara and took samples of two different types of drug samples on Form.04 for the purpose of test and analysis.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Film Coated Tablet. Axifen SR (Diclofenac Sodium 100mg in sustained release formulation)	381	M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan	TRA No.01-25002569/DTL dated:22-05-2019	**Analysis with specifications applied:** MS/BP 2018. **Identification:** Diclofenac Sodium identified. **Assay (BP): Per Tablet:**

Determined	**101.06mg/tab**
Percentage	**101.06%**
Limit	95-105%

Dissolution Test (MS): Does not comply with the specifications of MS as detailed below:

Tolerance Limit: Dissolution should be**:**

After 01 Hour	After 03 Hour	After 05 Hour	After 10 Hour
NMT 10%	10-30%	20-50%	NLT 80%

Level	Numbr tested		Acceptance Criteria						Average	Remarks
L1 & L2			No individual value lies outside each of stated ranges, no individual value is less than stated range and is not less than the stated amount as the final test time (1,2)						L1 & L2	
Time	Limit or range		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		Average of 12 units is less than the stated amount after 10 hours and is less than the stated amount at the final test time
After 01 hour	NMT 10%	L1	1.79%	2.09%	2.09%	1.49%	2.09%	1.19%	1.67%	
		L2	4.49%	0.29%	0.59%	0.59%	1.49%	4.49%		
After 03 Hour	10-30%	L1	23.27%	21.07%	18.31%	22.40%	28.82%	22.43%	22.40%	
		L2	22.51%	20.48%	23.81%	27.41%	20.23%	18.01%		
After 05 Hour	20-50%	L1	54.52%	49.76%	44.16%	58.37%	48.84%	58.92%	49.38%	
		L2	39.19%	43.85%	53.33%	42.61%	54.92%	44.08%		
After 10 Hour	NLT 80%	L1	77.73%	75.98%	74.21%	78.09%	78.73%	78.65%	76.89%	
		L2	76.05%	74.48%	78.82%	74.11%	78.31%	77.89%		

Result: The sample is declared **substandard** on the basis of Dissolution test.

Note: The time extension against said sample vide order no. PQCB/Dtl-B/203/2019 dated 29-03-2019 has been granted by PQCB.

iii. M/S New Life Medical Store, Situated at Old Kachary Road, Anwaar Shaheed Colony, Tehsil Renala Khurd, District Okara provided invoice/ warranty No. 42075, dated 07-10-2018 issued by M/S New Shahzaib Pharmacy, 122, Umer Din Town, St No. 3, Okara who

inturn provided invoice/warranty No. 24672, dated 26-09-2018 issued by M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan as a proof of its purchase.

iv. Warrantor portion was sent to M/S New Shahzaib Pharmacy, 122, Umer Din Town, St No. 3, Okara.

v. Copy of test report of drug sample was sent to M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

Summary:

Manufacturing Date: 09-2018

Expiry Date: 09-2020

Sampling Date: 15-01-219

Date of Form 6: 21-01-2019

Date of Receipt in DTL BWP: 24-01-2019

DTL Report Date: 22-05-2019

1ST DI Communication with firm on dated: 08-06-2019

Date of Retesting Request of Firm: No

Investigation Report Dated: 30-11-2019

3. Show-cause/personal hearing notice(s) issued to accused person(s) dated 18-12-2019.

Reply of show cause notice dated 27-12-2019

We have not yet received any manufacturer's sample portion of subject batch of drug Axifen so we are not in a position to cross verify the said product from market.

Furthermore, to cross examine the result of DTL mentioned in the report, we have conducted analysis of retained sample of subject batch of product which was stored as per storage instructions mentioned on our product packaging and to our fullest satisfaction of Dissolution are well within limits.

Therefore, as per test results of the retained sample of the same batch of our product in our quality control laboratory, we are confident in stating that our product is of standard quality. If manufacturer portion was provided to us, it could have been easier for us to further clarify the situation. Moreover,

i. All the test results shown in above mentioned report clearly shows the compliance of our product in all areas except for deviation in dissolution at 10th hour with quite a minor change and such minor difference may be due to some uncertainty factor.
ii. Since the subjected product is sustained release, so by using this product there will be no adverse impact on patients as per declared results of DTL report. We hereby request you to ignore the matter and quash the show cause notice.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **216th meeting held on 28-12-2019**. Zaheer-ud-Din Babar Secretary DQCB District Okara & Mr Adnan Yaqoob Drug Inspector Tehsil Renala khurd were present along with original record of the case. Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons involved in the subject case.

5. Accused Persons Junaid Zafar (Manager Quality Control) appeared before the Board on the behalf of M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala, Sahianwala Road, Faisalabad. Pakistan and submitted that the product is declared substandard merely on the basis of dissolution test which does not affect the efficacy of the product and the difference in values of dissolution test may occur due to manual sampling of the sample instead of using Auto-sampler which are minorly deviated from its stated limit in four steps. Moreover, conditions in which dissolution test is performed is not mentioned in DTL Bahawalpur report. pH of the buffer and sample taking point from dissolution apparatus can also affects the results of dissolution test. He requested for lenient view in the subject case.

6. The Board, after detailed scrutiny of the case record, due deliberation and discussion and considering statement of the accused persons was of unanimous opinion that the Production and Quality Control/Assurance processes and the procedures regarding said drug need to be evaluated. Therefore, the Board decided to constitute a **committee comprising of following members to conduct Product Specific Inspection (PSI)** of **M/S Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad. Pakistan** and submit report for consideration by the Board.

1	**Prof. Dr. Sajid Bashir** Professor of Pharmacy, Dean, Faculty of Pharmacy, University of Sargodha, Sargodha.	**Convener/Member**
2	**Mr Muhammad Umair Chaudhary** PQCB, Punjab, Lahore	**Facilitator**

7. Committee submitted its Product Specific Inspection report received in PQCB dated 24-08-2022

PRODUCT SPECIFIC INSPECTION REPORT OF M/S AXIS PHARMACEUTICALS 3-B, VALUE ADDITION CITY, 1.5 Km KHURRIANWALA-SAHIANWALA ROAD, FAISALABAD, PAKISTAN.

Members of inspection committee:

Prof. Dr. Sajid Bahir	**(Member PQCB)**	**(Convener)**
Muhammad Umair Choudhary	**Scrutiny Officer, PQCB**	**(Facilitator)**

Date of Inspection:

Inspection was conducted on 18-09-2020 with reference to PQCB order No. PQCB/R-435/2019 dated 28-12-2019.

No. PQCB/R-435/19
Details of Test/Analysis by the DTL:
The sample Axifen SR is a film coated tablet containing {Diclofenac sodium 1mg in sustained release formulation}. Batch No. 381. The sample was declared Substandard by the Drug testing laboratory, Bahawalpur on the basis of dissolution test performed under TRA No.01-1252569/ DTL dated 22-05-2019.
The tested sample does not comply the stated limit of acceptance criteria which is, that, NO individual value lies outside each of stated ranges, no individual value is less than stated amount (L1) and Average of 2 units lies within each of the stated range and is not less than the stated amount at the final test time (L2). However, at the final test time after 10 hours the stated NLT percentage should be 80% but the reported value is 76.89%. Thus, the sample is declared Sub-standard on the basis of Dissolution test performed.

Premises Detail:

The manufacturing unit was established in 2009. Total area 72,000 sq. ft with the covered area of about 46,800 sq. ft. The firm has approved sections **(GMP Certificate)**.

Current Technical Staff

Designation	**Name**
Managing Director	M. Imran Asghar
Manager Quality Control	Junaid Zaffar
Manager Production	M. Adnan Jamil
Plant Manager	Ghulam Murtaza

Detail of Product:

No. PQCB/R-435/2019	
Name of Product	**AXIFEN-SR TABLETS**
Batch No.	**381**
Date of Mfg.	05-09-2018
Exp. Date	04-09-2020
Sample Taken by	Inspector of Drugs, Tehsil Renala Khurd, OKARA.
Sampling Date	15-01-2019
Date of Memorandum to Government Analyst	21-01-2019
Report of Government Analyst	22-05-2019

Detail of Inspection / Observations:

1. The inspection team has done the Product Specific Inspection and discussed the report of the Drug testing laboratory with the technical team which declared the specific product as of Sub-standard on the basis of dissolution test performed which didn't comply the standard limits. The technical teams presented the drug registration certificate of the Tablet Axifen SR (100mg) having DRAP registration No. 059648 which showed the drug manufacturing & testing specifications as of Manufacturer specifications.
2. The technical team presented the Standard Operating Procedures for AXIFEN SR Tablet (100mg) vide Doc. No. AP/QC/PSF/TAB-009, issued date: 06-02-2019 & Issue status: 04 of the Quality Control Department which depicted the Objective, Scope, Responsibility, Specifications & Procedure followed for the manufacturing the above said batch of AXIFEN SR. The specifications showed the following parameters;

Sr. No	Parameters	Reference	Specifications
1	Description	MS	Light pink, rounded, film coated tablets filled in blister "Alu-Pvc" packed in carton with leaflet
2.	Average Weight/ Weight variation	MS	285 mg/tablet 285 + 5% Limit: 270.75—299.95 --
3.	Identification Diclofenac Sodium	MS	Must Comply
4.	Dissolution Test	MS/ B. P	After 1 Hour NMT 10% (as labeled in 0.1N HCL After 3rd (including 1 hr of in acid stage) 10-30% (as labeled) in water After 5th hr (including 1 hr of in acid stage) 20% to 50% as (labeled) in water After 10th hr (including 1 hr of in acid stage) NLT 80% (as labeled) in water
5	Assay	B. P	95-105% of the labeled amount of Diclofenac Sodium
6	Composition	Reg. Letter	Each sustained release Film coated tablet contain: Diclofenac Sodium:……100mg/Tablet (Product complies with B.P Specifications)
7	Drug Registration Number	Reg. letter	059648
8	MRP.	Reg letter	RS.200.00
9	Batch No. Mfg. Date Exp. Date	As BPCR	As BPCR
10.	Pack size	Reg. Letter	3 *10's
11.	Blister Seal Test	MS.	Must Comply
12.	No. of Packs	MS	246 U/C per shipper

3. **The dissolution test followed the details as;**

Apparatus: II

RPM: 50

Medium: 0.1 N Hydrochloric acid 900 ml

Temperature: 37 C +/- 0.5 C

Sampling Interval: After 1 hour

4. **Acceptance criteria prolonged-release dosage forms (B.P)**

The requirements are met if the quantities of active substance dissolved from the dosage units tested conform to below mentioned criteria in table. Continue testing through the 3 levels unless the results conform at either L1 or L2. Limits on the amounts of active substance dissolved are expressed in terms of the percentage of labelled content. The limits embrace each value of Qi, the amount dissolved at each specified fractional dosing interval. Where more than one range is specified, the acceptance criteria apply individually to each range.

Level	Number Tested	Acceptance Criteria
L1	6	No individual value lie outside each of the stated range and no individual is less than the stated amount at the final test time
L2	6	The average value of the 12 units (L1 +L2) lies with in each of the stated ranges, and is not less than the stated amount at the final test time; none is more than 10% of the labeled content outside each of the stated range; and none is more than 10% of the labeled content below the stated amount at the final test time.
L3	12	The average value of the 24 units (L1+L2+L3) lies with in each of the stated ranges, and is not less than the stated amount at the final test time; not more than 2 of the 24 units are more than 10% of the labeled content outside each of the stated ranges; and none is more than 2 of the 24 units are more than 10% of the labeled content below the stated amount at the final test time, and none of the units is more than 20% of the labeled content outside each of the stated ranges or more than 20% of the labled content below the stated amount of the final test time.

5. The certificate of analysis of the finished product for AXIFEN SR (100mg) has shown the Q.C # 695/18, Batch Num. 381 & Batch size of 400,000 Tabs. performed on 14-09-2018 under B.P specifications followed by all the parameters after the production of the tablets which included the physical tests, Weight Variation, Average weight/ tablet, Assay & Dissolution respectively.

6. The instrument Dissolution apparatus No. AP/QC/INS-011 was used. The standard limit (NMT;10%) at the Acid stage after 1st hour showed the average result of 1.67% with the Max range of 2.59 % and Min range of 0.64%, which complies with the standard limit. At the 3rd hour of water stage (including 1 hr. of acid stage) the standard limit (NMT; 30%) where, the average result range to 23.05% with the Max. 0f 25.90% and Min. of 20.42, which complies with the standard limit.
7. At the 7th hour of water stage (including 1 hr. of acid stage) the standard limit (NMT; 60%) where, the average result range to 65.78% with the Max. 0f 75.45% and Min. of 60.42, which again complies with the standard limit.
8. At the 10th hour of water stage (including 1 hr. of acid stage) the standard limit (NLT; 80%), where the average result range between 87.65% to 95.42% which complies with the standard limit.

Re-testing of Retained Sample:

1. The certificate of analysis of the Re-tested retained sample has been observed, which showed that the testing was performed on 14-06-2019. The dissolution test was performed with 6 tablets with following protocols:

i) Medium Used = 0.1 M HCL

ii) Apparatus = No.2, at 50rpm

iii) Time = 60 minutes

The standard (Limit: NMT 10%) and the average result have shown the 2.10 %, such that the maximum value attained was of 3.66 % and the minimum value attained was of 0.66 % and therefore, complied the standard limit.

After 1st hour, all the 6 tablets have complied with the standard limit that marked within the standard limit of 10%. After 3rd hour, those 6 tablets have shown again the standard limit range between (10%- 30%). At the 5th hour, all the 6 tablets marked within the standard range of (20%-50%). At the 10th hour the standard range which marks the range of NLT (80%), none of the tablet fell below the 80%.

Raw Material Store:

- Raw material store area is properly cleaned & proper demarcation for passed & rejected material was labelled.
- Temperature of the area was 25.4 degrees and log book were maintained.
- Standard Operating Procedures were properly laid down with the help of flow chart.
- Material receiving hood was functional for performing the Dusting & De-dusting.
- Raw-material store was equipped with the electronic digital weighing scale.
- Passed material was separately quarantined under proper labeling.

Production:

- The pre-formulation & formulation area is properly designated.
- HVAC system was operational under proper SOP's.
- SOPs of the tablet manufacturing were laid down.
- Tablet coating section was operational under SOP's.
- Flow charts ensuring the processes were laid down.

Quality Control & Quality Assurance

- No. of functional HPLCs = 7
- The Quality Control laboratory is well equipped with HPLC, U.V spectrophotometer, dissolution apparatus, potentiometer, stability chambers, particle sizing system & polarimeter.
- Digital thermometer & hygrometer was present. Temperature & humidity log was maintained.
- HVAC system was installed in lab and was operational with HEPA filters.
- The calibration record of the instruments was available and updated.
- Three stability chambers were available and stability studies were being carried out.
- Reference standards were available.
- Testing of water is operational.

Finished Goods Store

i). Thermometer was installed & functional and temperature record log is available.

ii). Hygrometer was installed and humidity record log was updated.

iii). The finished goods were placed under quarantine with proper segregation.

iv). Fire-extinguishers were updated and installed properly according to ISO requirement.

v). Cartons with proper labeling were placed on the racks/ pallets.

Each film coating contains, Diclofenac Sodium (B.P) …….. 100 mg

Batch Processing Record of specific product: AXIFEN-SR TABLETS (100mg)

D. Reg # 059648 **BPCR: TB-15**

Batch # 381 **Batch Size**: 4,00,000 Tabs

MFG. Date: 05-09-2018 **EXP. DATE**: 04-09-2020

Process	SR#	INGREDIENTS	EACH TABLET CONTAINS	4,00,000 TABLET CONTAINS (KG)
MIXING	1	Diclofenac sodium	101.00	40.400
	2	Lactose	131.00	52.400
	3	Methocel k-15	35.00	14.000
	4	IPA	0.075 ml	30.00 Lit
	5	Purified Water	0.045 ml	18.00nLit
LUBRICATION	1	Magnesium Stearate	3.00	1.200
	2	Talcum	10.00	4.000
TOTAL			280.00mg	112.000 Kg
COATING	1	EUDRAGIT	3.00	1.200
	2	PVP K-30	1.00	0.400
	3	PEG-6000	1.00	0.400
	4	TITANIUM DIOXIDE	3.25	1.300
	5	TALCUM	3.00	1.200
	6	RED COLOR (Lake)	0.310	0.124
	7	SUN SET YELLOW COLOR (Lake)	0.250	0.100
	8	ISOPROPYL ALCOHOL	0.15 ml	60.000 Lit.

Conclusion:

During the inspection, the batch process & control record was observed for the respective batch # 381. The batch size was consisted of 4,00,000 Tabs. The process of mixing & lubrication was being performed according to the SOP's undersigned by Production In-charge & Quality Assurance In-charge. The stock book record has shown the release of 40.400kg of Diclofenac sodium for the production of respective batch no.381 of Tab. AXIFEN-SR (100mg).

According to the DTL report where, all the criteria of the dissolution testing were complied except the last one where "**after 10th Hour the average of the 12 units is less than the stated amount after 10 Hour and is less than the stated amount at the final test time which has to be Not Less Than 80% and showed up to be 77%".** This difference could be achieved at another 1 hour as the release profile of the product is satisfied. However, the testing protocol would have to be shifted to L3 as the criterion of the L2 was not met in the DTL Bahawalpur's report and for that purpose this minor difference at the 10th hour could be achieved. This is because the release profile of the tablet shown was satisfactory. The overall, inspection of the BMR, testing protocols & the inspection of the Re-testing of that specific batch has found to be satisfactory.

PSI report provided to the firm M/s Axis Pharmaceuticals, Faisalabad on dated 30-08-2022.

CORRECTIVE & PREVENTIVE ACTIONS (CAPA)

Firm submitted Corrective & Preventive Actions (CAPA) vide letter Ref no. Axis/AP/RA/6092 dated 06-09-2022

With reference to Product Specific Inspection Report No. 42340, received to us on 30-08-2022 against PQCB order No. PQCB/R-435/2019 dated 28-12-2019, we hereby submit CAPA plan.

The following areas were visited and found satisfactory.

1. Premises
2. Raw material store and record related to Batch
3. Production
4. Quality control
5. Documents BMR, testing protocols

Moreover, equipment used by us for tests bears internationally traceable calibration and verified frequently with proficiency test standards Pharmassure UK & LGC London to ensure equipment performance. Axis Pharmaceutical is a responsible law-abiding company, which not only maintain GMP standard but also has an independent well-equipped Testing & Research Quality Control laboratory accredited from PNAC for ISO/IEC 17025:2017.

We requested the honorable authority to take lenient view in the subject case as there is a very minor difference in Dissolution results, all other parameters are well within limits.

CAPA # 1

Description:

Testing of retain sample of Axifen-SR 100mg performed and results were found satisfactory.

Action plan	Status of Actions taken	Evidence attached
Retain sample of Axifen-SR 100mg (Batch No. 381) to be tested on 14th June 2019 & on 17th June 2019.	Retained sample was tested on **14th June 2019** and results were found satisfactory as stated below: v. 1st hour 0.1N HCl: NMT 10% Results: complies avg. 2.10% v. 3rd hour (in water including 1 hour in 0.1NHCl) between 10-30% Result: Complies avg. 24.33% v. 5th hour (in water including 1 hour in 0.1NHCl) between 20-50% Result: Complies avg. 45.22% v. 10th hour (in water including 1 hour in 0.1NHCl) NLT 80% Result: Complies None of the tablet fell below avg. 85.16% Retained sample was tested on **17th June 2019** and results were found satisfactory as stated below: v. 1st hour 0.1N HCl: NMT 10% Results: complies avg. 2.04% v. 3rd hour (in water including 1 hour in 0.1NHCl) between 10-30% Result: Complies avg. 24.93% v. 5th hour (in water including 1 hour in 0.1N HCl) between 20-50% Result: Complies avg. 46.65% v. 10th hour (in water including 1 hour in 0.1NHCl) NLT 80% Result: Complies None of the tablet fell below avg. 85.07%	Both reports submitted

CAPA # 02

Description:

In DTL test Report average results are 77% which after 10th hour (limit: NLT 80%) this minor difference can be achieved at another 1 Hour as the release profile of product is satisfactory.

Action plan	Status of Actions taken	Evidence attached
We have reviewed our standard Analytical Procedure according to BP and specification to be revised as below: v. 1st hour 0.1NHCl NMT 10.0% v. 3rd hour (in water including 1 hour in 0.1N HCl) between 10-30% v. 5th hour (in water including 1 hour in 0.1N HCl) between 30-70% v. 12th hour (in water including 1 hour in 0.1N HCl) NLT 80%	Standard Analytical Procedure has been revised according to BP specification with the following limits: v. 1st hour 0.1NHCl NMT 10.0% v. 3rd hour (in water including 1 hour in 0.1N HCl) between 10-30% v. 5th hour (in water including 1 hour in 0.1N HCl) between 30-70% v. 12th hour (in water including 1 hour in 0.1N HCl) NLT 80%	Approved copy of SAP submitted

CAPA # 03

Description:

Testing of retain sample of Axifen-SR 100mg performed and results were found satisfactory**.**

Review of results of other batches included in Annual Product Review 2021.

Action plan	Status of Actions taken	Evidence attached
APR review of Dissolution results of 2021	Annual product review of Axifen SR 100mg tablet has been carried out from Batch # 544 to 580 (total batches: 36) and Dissolution results found satisfactory.	report submitted

4. Personal Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD

9. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Mujeeb ur Rehman, Secretary DQCB Okara was present. Among the nominated accused persons G. Murtaza (G.M/warrantor) along with Representative Rana Fakhar (GM-CRC) of M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5km Khurrianwala, Sahianwala Road, Faisalabad Pakistan was present.

10. The Board after due deliberation and discussion unanimously decided to **left over case** due to time constraints.

11. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

CURRENT PROCEEDINGS & DECISION BY THE BOARD

ITEM No. 2

ADJOURNED CASES OF 257 AND 258 CASES (CASE 19 - 23)

Case No. 1

PQCB/R-596/2021

Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat

Sub-Standard (Assay

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi through** its Chief Executive Officer Humza Obaid Naviwala 2. Humza Obaid Naviwala — Chief Executive Officer 3. Zia ur Rehman — Deputy GM/ Head of Production 4. Hamna Faizan Khan — Deputy Manager/ Quality Control Operations 5. Dr. Waseem Shahzad — Warrantor of **M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi.**

BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat reported that:-

i. He, on 08-03-2021, inspected the premises of Main Medicine Store of Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat and took sample of seven different types of drugs on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Faisalabad vide memo number 86519 dated 08-03-2021.

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

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Injection Ferris [Each ampoule contains: 100mg of elemental iron as iron sucrose] **Mfg. Date 02-2021** **Expiry Date: 02-2023** **Reg No. 086898**	21B001	M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan.	TRA No. 01-68007685/DTL Dated: 05-05-2021	**Analysis with specifications applied:** BP 2021 **Description:** Reddish brown liquid filled in plastic ampoule sealed with twist off cap, packed in plastic tray of 5 units, packed in outer hard carton. **Identification:** Iron is identified. **Assay:** Stated: 100 mg/ 5ml Determined: 80.565 mg/ 5ml Percentage: 80.565**%** Limit: 95-105% (BP-2021) **pH:** Stated: 10.5-11.0 (BP-2021) Determined: 10.52 (Complies) Extractable Volume: Stated: Not less than nominal volume (BP 2021) Determined: 5.0 ml (Average of 03 ampoules) (Complies) Sterility: Stated: Must be sterile (BP 2021) Determined: Sterile (Complies) **RESULT:** Given sample is **"Substandard"** with regards to Assay.

iii. Store keeper of Main Medicine Store of Aziz Bhatti Shaheed DHQ Teaching Hospital, Gujrat, provided invoice/ warranty/ no. INPQ/2021/2010 dated 25-02-2021 issued by M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample was sent to M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan.

v. A copy of test report of the drug sample was sent to M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan with directions to provide the requisite information and to explain their position in this regard. In response, firm requested for re-test/ analysis of their drug sample from Appellate Laboratory, National Institute of Health Sciences, Islamabad.

vi. Pursuant to their request, the PQCB portion of the drug sample was sent to Appellate Laboratory, National Institute of Health Sciences, Islamabad for the purpose of retest/ analysis. The drug sample was declared Substandard from National Institute of Health Sciences, Islamabad as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Report No. & Date	NIH Test Report Results
Injection Ferris 5 ml (Iron Sucrose… 10mg)	21B001	M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan.	036-P/2022 dated 20th July, 2022	**Analysis with specifications applied:** BP-2017 **Assay:** **Stated:** 100 mg/5ml **Found: 56.24 mg/5ml** **Limit: 95-105%** **Percentage :56.24%** **Does not comply with BP 2017** **RESULT:** The sample is of **"Substandard"** quality on the basis of tests performed.

vii. A copy of NIH test report of the drug sample was sent **to** M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan with directions to provide the requisite information and to explain their position in this regard.

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

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

3. Show cause notice(s) issued to the accused persons dated 21-10-2022

4. Personal Hearing notice(s) issued to accused person(s) dated 09-01-2023

PREVIOUS PROCEEDINGS BY THE BOARD:

PQCB 256th meeting dated 19-01-2023:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **256th meeting** held on **19-01-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Amtiaz Aslam Secretary DQCB District Gujrat and Ms. Saba Ghalib Drug Inspector Aziz Bhatti Shaheed Teaching Hospital, Gujrat were present along-with original case record. No-one among the nominated accused persons was present, however, representative from the firm Rana Arsalan (RSM) was present on behalf of **M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi 75020, Pakistan.** No-one appeared before the Board at the time of hearing. Keeping in view the facts of the case, the Board after due deliberation and detailed discussion unanimously decided to **adjourn the case** in best interest of justice. The Board further decided to provide another/ final opportunity of personal hearing to the accused persons.

PQCB 258th meeting held on **05-04-2023:**

13. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Imtiaz Aslam, Secretary DQCB, Gujrat joined the meeting through zoom link. No-one among the nominated accused appeared before the Board on behalf of M/S Hudson Pharma (Pvt.) Ltd. D93, North Western Industrial Zone Port Qasim, Karachi however, counsel of the firm, Syed Muneeb Zaidi (Advocate) was present. No-one appeared before the Board at the time of hearing. Keeping in view the facts of the case, the Board after due deliberation and detailed discussion unanimously decided to **adjourn the case** in best interest of justice. The Board further decided to provide another/ final opportunity of personal hearing to the accused persons

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

Summary:

Manufacturing Date: 02-2021

Expiry Date: 02-2023

Sampling Date (Form 4): 08-03-2021

Sent to DTL (Form 6): 08-03-2021

Date of receipt in DTL: 13-03-2021

DTL Report Date: 05-05-2021

Time Extension: N/A

1ST DI Communication with firm on dated: 14-06-2021

Date of Retesting Request of Firm: 22-06-2021

Fate of retesting Request: Allowed (NIH Substandard)

Investigation Report Dated: 18-08-2022

Case is placed before the Board

PROCEEDING & DECISIONS BY THE BOARD:

Case No. 2

PQCB/R-259/2022

Central Medical Store Depot Pessi, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan** through its Director/Proprietor Salman Anwar Malik 2. Salman Anwar Malik Director/Proprietor 3. Safder Ali Bhatti Production Manager 4. Muhammad Fiaz Quality Control Manager 5. Shahid Mashhood Warrantor of M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Central Medical Store Depot, Pessi reported that: -

i. He, on 05-10-2022 inspected the Central Medical Store Depot, Pessi, Lahore, took 14 different drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 143424 dated 05-10-2022.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report</th><th>DTL Test Report Result</th></tr>
<tr><td>Film coated Tablet Tenovir 300mg [Tenofovir disoproxil Fumarate 300mg]

Mfg. Date:
09-2022
Exp. Date:
08-2024
Regn. No: 065743</td><td>QJ20</td><td>M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan</td><td>01-10097000531/DTL dated: 30-11-2022</td><td>
Result of test/ analysis with specifications applied: IP 2020
<u>COMPOSITION:</u> Each film coated tablet contains:
Tenofovir Disoproxil Fumarate (MS)…….…..300mg
<u>DESCRIPTION</u>: Sea green color biconvex tablet, which is plain on both sides. packed in Alu-Alu blister pack (primary packing) of 10 tablets. three blisters are packed in outer hard carton. (Secondary Packaging)
Note: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states that “All registration holders shall follow official pharmacopeial specifications for all such formulation for which official monographs of drug product is available in the most recent edition of such pharmacopoeia”. Product specification of given sample is “Product specification: CCL pharmaceuticals specification.” and it is manufactured after the expiration of timeline to apply such specifications despite the availability of “Tenofovir Disoproxil Fumarate tablets (Tenofoviri disoproxili Fumerati compressi)” monograph in International Pharmacopoeia, Tenth Edition 2020. So, the manufacturer’s claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drug Act 1976.
Therefore, the product is Misbranded
<u>Wt. VARIATION (IP):</u> Limit: Avg. weight ± 5%
Determined: 97.27-102.96%
<u>DISSOLUTION TEST (IP</u>): Tolerance limit: NLT 80% release of Tenofovir disproxil Fumarate in 45 mins.
<table>
<tr><th colspan="7">ACCEPTANCE CRITERIA</th><th>Avg</th></tr>
<tr><td colspan="7">Each unit is not less than 80% (Q) Tenofovir disproxil Fumarate in 45 mins</td><td></td></tr>
<tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td></td></tr>
<tr><td>97.26%</td><td>99.42%</td><td>107.65%</td><td>107.51%</td><td>102.51%</td><td>99.82%</td><td>100.70%</td></tr>
</table>
<u>IDENTIFICATION (IP):</u> Tenofovir disproxil Fumerate is identified
<u>ASSAY (IP):</u> Tenofovir disproxi Fumarate
Stated: 300mg/tab
Determined: 323.13mg/tab
Percentage: 107.71%
Limit: 90-110%
<u>RESULT:</u> The sample is declared Misbranded as per Section 3 (s) (iv) of Drug Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) Human import dated 7th February, 2022.
</td></tr>
</table>

iii. CMSD, Pessi, provided invoice/ warranty No. 22091703 dated 30-09-2022 issued by M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan.

iv. Warrantor Portion of subject drug sample was sent to M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan dated 10-10-2022.

v. A Copy of Test/ Analysis report was sent to M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan and they were directed to provide requisite information in this regard.

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

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

3. Show-cause notice(s) issued to the accused dated 08-02-2023

Firm submitted reply of Show cause vide letter ref no. CCL/23/R-244 dated 17-02-2023

Please refer to your letter no. PQCB/R-259/2022 dated 8h February 2023 on the captioned subject wherein DTL Bahawalpur report declares Tenovir tab 300mg batch no. QJ20 as MISBRANDED on account of Pharmacopeial specs as not mentioned on the product pack, however, the said product COMPLIES with the quality parameters in terms of Dissolution tests, identification and Assay, as specified in USP 2022.

1. Reference to the letter, point 3. It is humbly submitted that:

The DTL has tested the product against USP 2022 and the product complies, the packaging component alignment w.r.t. Pharmacopeia, Drug labelling Rules 1986 and DRAP order No. F.3-5/2020-I & V.I (M-297) of 7th Feb 2022 ***has already been established in CCL whose synchronization with CCL's export orders is very critical, CCL being the 2nd largest exporter of drug products from Pakistan with its footprint in 22 countries.***

We solicit that this sequential completion/implementation of product art work in local and international Regulatory perspectives will soon be completed, a humble review in this regard may please be considered by the competent authority and oblige as the product is entirely satisfactory as per USP standards tested by DTL Bahawalpur. we hereby verify the names of person nominated in showcause notice.

4**.** Personal Hearing notice(s) issued to accused person(s) 29-03-2023

Case is placed before the Board for Decision

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD;

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Hassan Saeed, Secretary DQCB Lahore Mr. H.M Nouman Provincial Inspector of Drugs, CMSD, Pessi, Lahore was present along with the original case record. No one among the nominated accused persons of M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan appeared before the Board.

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

7. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-270/2022

Central Medical Store Depot Pessi, Lahore

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case:** 1. **M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan** through its Director/Proprietor Salman Anwar Malik 2. Salman Anwar Malik Director/Proprietor 3. Safder Ali Bhatti Production Manager 4. Muhammad Fiaz Quality Control Manager 5. Shahid Mashhood Warrantor of M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan

BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Central Medical Store Depot, Pessi reported that: -

i. He, on 05-10-2022 inspected the Central Medical Store Depot, Pessi, Lahore, took 14 different drug samples on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memo no. 143423 dated 05-10-

2022.

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

<table>
<tr><th>Name of Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report</th><th>DTL Test Report Result</th></tr>
<tr><td>Film coated Tablet Tacavir 0.5mg [Entecavir 0.5mg]

Mfg. Date:
08-2022
Exp. Date:
07-2024
Regn. No: 055321</td><td>J178</td><td>M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan</td><td>01-10097000532/DTL dated:
03-12-2022</td><td>
Result of test/ analysis with specifications applied: USP 2022
<u>COMPOSITION:</u> Each film coated tablet contains:
Entecavir monohydrate eq. to Entecavir ……..0.5mg
<u>DESCRIPTION</u>: Ligh pink color, round, biconvex film coated tablets, which is plain on both sides. packed in Alu-Alu blister pack (primary packing) of 10 tablets. three blisters are packed in outer hard carton. (Secondary packaging).
Note: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states that “All registration holders shall follow official pharmacopeial specifications for all such formulation for which official monographs of drug product is available in the most recent edition of such pharmacopoeia”. Product specification of given sample is “Product Spec.: CCL pharmaceuticals” and it is manufactured after the expiration of timeline to apply such specifications despite the availability of “Entecavir tablets” monograph in USP 2022. So, the manufacturer’s claim regarding the product specification is in contradiction to DRAP circular and also in violation to Drug Act 1976. Therefore, the product is Misbranded
<u>DISSOLUTION TEST (USP)</u>:
Tolerance limit: NLT 80% release of Entecavir in 30 mins.
<table>
<tr><th colspan="6">ACCEPTANCE CRITERIA</th><th>Avg</th></tr>
<tr><td colspan="6">Each unit is not less than 80% (Q) Entecavir in 30 mins</td><td></td></tr>
<tr><th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>6</th><td></td></tr>
<tr><td>94.69%</td><td>95.05%</td><td>96.66%</td><td>96.49%</td><td>96.49%</td><td>96.592%</td><td>95.99%</td></tr>
</table>
<u>IDENTIFICATION (USP):</u> Entecavir is identified
<u>ASSAY (USP):</u> Entecavir
Stated: 0.5mg/tab
Determined: 0.46875mg/tab
Percentage: 93.75%
Limit: 90-105%
<u>RESULT:</u> The sample is declared Misbranded as per Section 3 (s) (iv) of Drug Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) Human import dated 7th February, 2022.
</td></tr>
</table>

iii. CMSD, Pessi, provided invoice/ warranty No. 22091703 dated 30-09-2022 issued by M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan.

iv. Warrantor Portion of subject drug sample was sent to M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan.

v. A Copy of Test/ Analysis report was sent to M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan and they were directed to provide requisite information in this regard.

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

i. **Manufacture for sale/Sale of Misbranded Drug.**

ii. **Issuance of false warranty.**

3. Showcause notice(s) issued to the accused dated 20-01-2023

Firm submitted reply of Show cause notice vide ref: CCL/23/R-213 dated 25-01-2023

Please refer to your letter no. PQCB/R-270/2022 dated 20th January, 2023 on the captioned subject wherein DTL Bahawalpur report declares TACAVIR tab 0.5mg batch no. J178 as MISBRANDED on account of Pharmacopeial specs as not mentioned on the product pack, however, the said product COMPLIES with the quality parameters in terms of Dissolution tests, identification and Assay, as specified in USP 2022.

1. Reference to the letter, point 3. It is humbly submitted that:

The DTL has tested the product against USP 2022 and the product complies, the packaging component alignment w.r.t. Pharmacopeia, Drug labelling Rules 1986 and DRAP order No. F.3-5/2020-I & V.I (M-297) of 7h Feb 2022 **has already been established in CCL whose synchronization with CCL's export orders is very critical, CCL being the 2nd largest exporter of drug products from Pakistan with its footprint in 22 countries**. We solicit that this sequential completion/implementation of product art work in local and international Regulatory perspectives will soon be completed, a humble review in this regard may please be considered by the competent authority and oblige as the product is entirely satisfactory as per USP standards tested by DTL Bahawalpur.

4**.** Personal Hearing notice(s) issued to accused person(s) dated 29-03-2023

Case is placed before the Board for Decision

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD;

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **258th meeting** held on **05-04-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Hassan Saeed, Secretary DQCB Lahore Mr. H.M Nouman Provincial Inspector of Drugs, CMSD, Pessi, Lahore was present along with the original case record. No one among the nominated accused persons of M/s CCL Pharmaceuticals Pvt Ltd., 62 Industrial Estate Kot Lakhpat, Lahore Pakistan appeared before the Board.

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

7. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023

Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD;

Case No. 3

PQCB R-658/2020

Tehsil & District Vehari

ATTENDANCE:

Secretary DQCB Drug Inspector	**Accused Persons involved in the subject case** 1. **M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan** through Managing Director (MD) Muhammad Raza Jawa 2. Muhammad Raza Jawa — Managing Director (MD) 3. Kalb-e- Muhammad Abbas — Warrantor 4. Uzma Gul — Production Incharge 5. Shaukat Hayat — Quality Control Incharge of **M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan.**

BRIEF FACTS OF THE CASE:

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

i. He, on 21-11-2019 inspected the business premises of M/s Hamdard Medical Store club Road Vehari, and took subject drug sample on Form No. 4 for the purpose of test/analysis.

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

<table>
<tr><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>TRA No & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>Film coated Tablet Cardat [Atenolol 50mg]</td><td>1997</td><td>M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-
Pakistan</td><td>No. 01-74000201 dated 16th Jan, 2020.</td><td>
<u>Results of test/analysis with specifications applied:</u> BP 2018
<u>DESCRIPTION:</u> White color small round tablet engraved “JAWA” on one side and plain on the other side packed in ALU-PVC blister of 10 units in an outer carton.
<u>IDENTIFICATION:</u> Atenolol identified
<u>ASSAY:</u>
Analysis Method: UV-Spectrophotometer
<table>
<tr><th>Assay</th><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td>Atenolol</td><td>50mg/tab</td><td>48.74mg/tab</td><td>92.5-107.5%</td><td>97.47%</td></tr>
</table>
Comply
<u>Weight Variation:</u>
Limit: ±7.5 NMT 2 Tablets
Average: 181.10mg
Comply
<u>Disintegration:</u> Time: 30minutes
Not fewer than 16 of the total of 18 tablets tested disintegrate completely. Does not comply
RESULT: The sample is Substandard on the basis of Disintegration Test performed.
</td></tr>
</table>

iii. M/s Hamdard Medical Store club Road Vehari provided Invoice/ warranty No. 2420 dated 11-11-2019 issued by M/s Pakistan Distributors 9-11/WB Vehari.

iv. Warrantor Portion was sent to M/s Pakistan Distributors 9-11/WB Vehari.

v. M/s Pakistan Distributors 9-11/WB Vehari provided invoice/warranty no. 3132-1819 dated 08-03-2019 issued by M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan as a proof of its purchase.

vi. A copy of Test/ Analysis report was sent to M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan and they were directed to provide requisite information in this regard. In response, Firm requested retesting of the sample from NIH, Islamabad. Pursuant to Firm’s request, sample was sent to NIH, Islamabad.

vii. That Chief, Appellate Laboratory/ NIH Islamabad also declared the sample drug in question as **Substandard** vide Test Report No. 0159-P/2020 Dated 13th Nov, 2020. The detail is as follow: -

<table>
<tr><th>Name of drug</th><th>Batch no.</th><th>Name of manufacturer</th><th>NIH Test Report No. & Date</th><th>NIH Test Report Results</th></tr>
<tr><td>Cardat Tablets 50mg</td><td>1997</td><td>M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-
Pakistan</td><td>No. 0159-P/2020 dated 13th Nov, 2020</td><td>
<u>DESCRIPTION:</u>
White circular, film coated tablets having inscription “JAWA” on one side whereas plain from other side packed in blister packing further packed in an outer carton.
<u>IDENTIFICATION:</u>
Atenolol identified
<u>WT VARIATION:</u>
Complies with BP-2017
<u>DISINTEGRATION TIME:</u>
Determined: 45minutes
Limit: NMT 30mins
Does not comply with BP-2017
<u>ASSAY:</u>
<table>
<tr><th>Assay</th><th>Stated</th><th>Found</th><th>Limit</th><th>Percentage</th></tr>
<tr><td>Atenolol</td><td>50mg/tab</td><td>52.1mg/tab</td><td>92.5-107.5%</td><td>104.2%</td></tr>
</table>
Complies with BP-2017
<u>CONCLUSION:</u> The sample is Substandard quality on the basis of tests performed.
</td></tr>
</table>

viii. A copy of Test/ Analysis NIH report was sent to M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan.

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

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

<u>Summary:</u>

Manufacturing Date: 02-2019

Expiry Date: 02-2021

Sampling Date: 21-11-2019

Sent to DTL (Form 6): 23-11-2019

Date of receipt in DTL: 27-11-2019

DTL Report Date: 16-01-2020

1ST DI Communication with firm on dated: 11-02-2020

Date of Retesting Request of Firm: 18-10-2020

Fate of Retesting Request: Allow (Substandard from NIH on Disintegration test)

Sample received in NIH: 17-09-2020

NIH report dated: 13-11-2020

Investigation Report Dated: 31-03-2022

3. Showcause notice(s) issued to the accused person (s) dated 13-05-2022

Firm submitted written Reply of show cause notice vide letter ref no. JPPL/QCM/0100 dated 26-05-2022

It is to be stated as follow:

1. Our tablet/product i.e., Cardat 50 mg is a film coated tablet so the protocol of testing to be apply must be of "COATED TABLETS" described in detail in Pharmacopoeias under Chapter of "GENERAL MONOGRAPHS".
2. For coated Tablets the time specified is although 30 minutes but very clearly it is mentioned that if the film coated tablet fail to comply then repeat the test on a further 6 tablets without using disc.
3. Definitely this specific measure is to be taken when the tablets stick to discs.
4. NIH in its purported alleged report fail to point out that whether tablets adhere to discs or not during
5. tests.
6. It is mandatory under DRAP ACT 2012 and revised Punjab Drugs Rules that the protocol of test performed by any Laboratory in case of substandard drug is to be mentioned in the report.
7. So here the report given by NIH lacks the mandatory requirements, hence the report cannot be relied
8. as conclusive evidence.

So it is hereby requested to drop the case. Meanwhile we are submitting the test report (In-house) of the retention portion of said batch.

4. Personal Hearing notice(s) issued to accused person(s) dated 08-06-2022

Case is placed before the Board for Decision

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

245th meeting dated 16-06-2022

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **245th meeting** held on **16-06-2022** under the chairmanship of Vice Chairperson in the presence of Board Members mentioned above. Mr. Imran Rashid, Secretary DQCB, Vehari was present along with original case record. Among the nominated accused persons Muhammad Raza Jawa (Director) along with Muhammad Ali (Assistant Manager Quality Control) of M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan was present.

6. The Board after due deliberation and discussion unanimously decided to **left over** due to time constraints.

7. Personal Hearing notice(s) issued to accused person(s) dated 24-06-2022

246th meeting dated 05-07-2022:

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **246th meeting** held on **05-07-2022** under the chairmanship of Vice Chairperson. Mr. Imran Rashid, Secretary DQCB, Vehari and Provincial Inspector of Drugs, Miss Robina Taj, Tehsil Vehari was present along with original case record. Among the nominated accused persons Kalb-e-Muhammad Abbas (Warrantor) along with Muhammad Ali Farrukh (Assistant Manager Quality Control) of M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore, Pakistan appeared before the Board.

9. Representatives of the firm submitted that Tab Cardat 50mg is a film coated tablet so the protocol of testing to be applied must be of “coated tablets” described in detail in BP Pharmacopoeia under Chapter of “General Monograph”. For coated tablets the time specified is although 30mins but very clearly it is mentioned that if the film coated tablet fails to comply then repeat the test on further 6 tablets without using discs. Definitely, this specific measure is to be taken when the tablets stick to discs. NIH in its purported alleged report fail to point out that whether tablets adhere to disc or not during test. The NIH report given by NIH, Islamabad lacks the mandatory requirements and protocol, hence the report cannot be relied as conclusive evidence. So, requested to drop the case.

10. Government analyst apprised the Board that according to BP *the tablets comply with the test using water R as liquid medium. Add a disc to each tube. Operate the apparatus for 30 mins for film coated tablets. If any of the tablets has not disintegrated, repeat the test on further 6 tablets, replacing water R with 0.1M hydrochloric acid…. If fail to comply because of adherence to the discs, the results are invalid. Repeat the test on further 6 tablets, omitting discs.*

11. Keeping in view the above facts and statements by the representatives of the firm observed that National Institute of Health Sciences tested drug film coated tablet Cardat 50mg according to BP monograph. The NIH report reflected the use of water as fluid but according to BP Monograph if any of the tablets has not disintegrated then repeat the test on further 6 tablets replacing water media with 0.1M hydrochloric acid. So, the Board after due deliberation and discussion unanimously decided to **pend** the case and **seek clarification from National Institute of Health Sciences, Islamabad** regarding the proper BP testing protocol followed for disintegration time of the subject drug product.

12. In response, **National Institute of Health, Islamabad, submitted letter no. F.141-160/0159-P/2020-DC&TMD dated 04-10-2022**

Corrigendum of Test Report No. 0159-P/2020 Dated 13-11-2020

Reference your letter No. PQCB/R-658/2020 dated 13-09-2022.

2. It is submitted that in protocol a typographic error has been noticed in the report of sample

No. 0159-P/2020 batch No.1997. In this regard the complete protocol for the disintegration is below:

"**Reference:** British Pharmacopoeia-2017.

Procedure:

Place 1 dosage unit in each of the six tubes of the basket and add a disc. Operate the apparatus using water as the fluid, maintained at 37°C. Lift the baskets after the specific time and observe the physical condition of the tablet. All the tablet fails to disintegrate within the time limit.

After that repeated the test on the further 6 tablet replacing water R with 0.1M hydrochloric acid.

All the tablet fails to disintegrate within the specified time limit

Time of disintegration for all the six tablets in both tests = 45 minutes.

Limit: Not more than 30 minutes.

3. This inadvertent typographic error is highly regretted. The other contents of the report remain the same.

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

255th meeting dated 29-12-2022:

14. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **255th meeting** held on **29-12-2022** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Imran Rashid, Secretary DQCB Vehari, Mst. Robina Taj, Provincial Inspector of Drugs, Tehsil Vehari was present along with the original case record. Among the nominated accused persons Shaukat Hayat (Quality control Manager) along with Muhammad Ali Farrukh (Assistant Manager Quality) of M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore, Pakistan appeared before the Board. Representative of the firm submitted letter no. P-27-01/2020 dated 16-02-2021 according to which the subject drug sample was declared standard and case was dropped.

15. The Board after careful scrutiny of the NIH report and letter submitted by the firm observed that subject drug sample Film coated Tablet Cardat (Atenolol 50mg) Batch No. 1997 was declared of Substandard quality vide Test Report No. 0159-P/2020 dated 13-11-2020. There was typographical mistake in the letter (P-27-01/2020 dated 16-02-2021) for which substituted letter No. P-27-01/2020 dated 23-02-2021 was issued to the Drug Inspector as well as to the firm M/s Jawa Pharmaceuticals mentioning substandard NIH Test report.

16. The Board after due deliberation and discussion unanimously decided to **pend** the case to present in next meeting after verification from the record.

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

257th meeting dated 07-02-2023

18. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **257th meeting** held on **07-02-2023** under the chairmanship of Secretary, Primary & Secondary Healthcare, Department. Mr. Imran Rashid, Secretary DQCB Vehari, Miss Robina Taj, Provincial Inspector of Drugs, Tehsil Vehari was present along with the original case record. No one among the nominated accused persons of M/s Jawa Pharmaceuticals Pvt Ltd.,112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan appeared before the Board. Secretary PQCB apprised the Board that the case is fourth time placed before the Board and the firm has submitted written request for adjournment vide letter no. JPPL/CEO/23/092 dated 01-02-2023 that Manager Regulatory Affairs, Sheikh Manzoor Saeed is on Umrah Holidays from 4th -24th February, 2023. Therefore, requested to adjourn the case.

19. The Board after due deliberation and discussion unanimously decided to **adjourn the case** in the best interest of justice. The Board further decided to provide final/last opportunity of hearing to the accused.

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

Case is placed before the Board

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 4

DISTRICT LODHRAN

PQCB/R-549/2021

Tehsil Kahror Pacca, District Lodhran

ATTENDANCE:

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Nawabsons Laboratories (Pvt) Ltd, T-13, Rukhshanda Heights, 4th Floor 8-Km Multan Road, Lahore-Pakistan** through its Chief Executive Officer Akhtar Hussain Bhutta 2. Akhtar Hussain Bhutta — Chief Executive Officer 3. Arjumand Akhtar Bhutta — Production Incharge 4. Nadeem Akhtar Bhutta — Quality Control Incharge 5. Riaz Ahmad — Manager/ Warrantor Of **M/S Nawabsons Laboratories (Pvt) Ltd, T-13, Rukhshanda Heights, 4th Floor 8-Km Multan Road, Lahore-Pakistan.**

BRIEF FACTS OF THE CASE

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

i. His Predecessor, on 30-04-2021, inspected the business premises M/S Khan Pharmacy situated at Old Bahawalpur Road near MCB bank Kahror Pacca, and took samples of drugs on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Multan vide memorandum no. 0000091728 dated 06-05-2021.

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

iii. M/S Khan Pharmacy situated at Old Bahawalpur Road near MCB bank Kahror Pacca submitted Invoice/warranty no. 14510 dated 03-02-2021 issued by Nauman Akbar, M/S A.S Corporation 753-C Satelite Town Bahawalpur as a proof of its purchase of the said drug.

iv. Warrantor portion of the drug sample and a copy of test report of the drug sample were sent to Mr. Nauman Akbar (Warrantor) M/S A.S Corporation 753-C Satelite Town Bahawalpur who in turn submitted invoice/ warranty no. 20-1414 dated 31-10-2020 issued by M/S Nawabsons Laboratories (Pvt) Ltd, T-13, Rukhshanda Heights, 4th Floor 8-Km Multan Road, Lahore-Pakistan as a proof of its purchase of the said drug.

v. A copy of test/analysis report was sent to M/S Nawabsons Laboratories (Pvt) Ltd, T-13, Rukhshanda Heights, 4th Floor 8-Km Multan Road, Lahore-Pakistan and they were asked to provide the requisite information in this regard.

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>Bisacodyl (Dia Cetoxy-Diphenyl Pyridyl Methane 5 mg) Tablet.
Mfg.date:
Sep-2020
Exp. date:
Sep-2022
Regn No.
006329</td><td>214</td><td>M/S Nawabsons Laboratories (Pvt) Ltd, T-13, Rukhshanda Heights, 4th Floor 8-Km Multan Road, Lahore-Pakistan</td><td>TRA No. 01-89003708/DTL

Dated:-03-07-2021</td><td><u>Analysis with specifications applied:</u>
Manufacturer Specifications (MS)
<u>Description:</u>
Yellow to lemon color, round, biconvex tablet plain on both sides packed in ALU-PVC blister of 20 units in a labeled outer carton.
Each outer carton contains 5 blisters of 20 units each (5*20= 100 Tablets).
<u>Assay:</u>
Analysis method: UV-Spectrophotometer
Dia Cetoxy- Diphenyl pyridyl methane
<table>
<tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr>
<tr><td>5mg/Tablet</td><td>5.91 mg/Tablet</td><td>118.22%</td><td>90-110%</td></tr>
</table>
(<u>DOES NOT COMPLY</u>)
<u>Disintegration Test:</u>
<u>Stated:</u>
<u>First Stage:</u> 1 hour in 0.1 N HCL. No tablet shows any Disintegration.
<u>Final Stage:</u> 1 hour in 1.5% w/ v Sodium hydrogen carbonate medium. All Tablets Should Disintegrate within 1 Hour.
<u>Determined:</u> All Tablets disintegrated during first stage. (DOES NOT COMPLY)
RESULT:
The above sample is Sub-standard, on the basis of Tests performed.</td></tr>
</table>

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

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

b. **Issuance of false warranty**

3. Show cause Notice (s) issued to the accused person(s) Dated 29-09-2022.

Reply of the firm to Show cause notice vide letter no. NSL/2022/9064 dated 07-10-2022:

1. That we supplied Bisacodyl Tablets Batch No. 214 to M/S A.S. Corporation
Bahawalpur.
2. That M/S A.S Corporation Bahawalpur supplied the Bisacodyl 5mg Tablets Batch No. 214 to M/S Khan Pharmacy situated at old Bahawalpur road near MCB Bank Kahror Pacca, from where Drug Inspector Tehsil Kahror Pacca District Lodhran took sample of said drug on Form No. 4 for the purpose of Test and Analysis.
3. That M/S A.S Corporation also supplied the same product i.e. Bisacodyl Tablet 5mg Batch No. 214 out of the same stock supplied by us as reported by the firm M/S A.S Corporation to M/S Sardar Bukhari Medical Store chowk Abbasia, Tehsil Ahmad Pur East District Bahawalpur.
4. That sample of Bisacodyl 5mg Batch No. 214 was picked by Provincial Drug Inspector Tehsil Ahmad Pur East, Bahawalpur for the purpose of Test and Analysis.
5. That both samples were declared of Sub-standard Quality by Drugs Testing Laboratories. Astonishingly results of both tests were contradictive of same product batch of Bisacodyl Tablet i.e. 214, which clearly indicates that drug was not properly stored as required on the label of the product and concerned quarters also failed to give notice u/s 32 of Drugs Act 1976. Without notice u/s 32 of Drugs Act 1976, liability cannot be shifted to manufacturer. Further violations of laws are observed.

6. That our company M/S Nawabsons Laboratories (Pvt) Ltd disagreed the Report of Drug Testing Laboratory and requested for Re-testing as required under law. On our request PQCB allowed the Re-testing of the sample of Bisacodyl Tablets 5mg Batch No. 214.
7. That N.I.H declared the sample of our product Bisacodyl 5mg Batch No. 214 of standard quality vide Test Report No. 02-P/2022 10TH March 2022.(Attested copy enclosed) Annex-A
8. PQCB discussed the matter in its 214th meeting dated 14.12.2019 and decided that all such cases in which the Appellate laboratory produces a "Standard Quality result, the Drug Inspector may close the case, as the appellate lab report is CONCLUSIVE EVIDENCE of the facts stated therein. Copy of the directions to Drug Inspector was also endorsed to our Firm M/S Nawabsons Laboratories (Pvt) Ltd, which is attached
herewith for perusal and record) Annex-B.
9. That we have already informed the directions of PQCB with copy of directions to Drug Inspector Tehsil Kahror Pacca (copy of our reply attached) Annex-C.
10. That our product Bisacodyl tablet 5mg Batch No. 214 has been declared of standard quality in appellate lab and PQCB has already directed Drug Inspector to close the case, it is requested to close the case under reply in supreme interest of justice fair
play, and to maintain rule of consistency.
11. It is requested to drop the name of our Chief Executive officer, as he is an old person of 90 years suffering from many diseases and not involved in any companies activities from many years, especially in this case, and Mr. Arjumand Akhtar Bhutta is working as acting chief executive officer/Director.

12. Other requisite information are described as hereunder.

Name of qualified persons and directors.

1. Mr. Arjumand Akhtar Bhutta

Acting chief officer/ Director/ Production Incharge

2. Nadeem Akhtar Bhuuta

Quality Control Incharge

3. **Riaz Ahmad (Late) Manager/warrantor**

4. Copy of drug manufacturing license

5. Valid drug registration certificate

6. Copy of NIC of all concerned

Under the circumstances, it is most respectfully prayed to withdraw the show cause notice under reply and file the proceedings initiated in the supreme interest of justice, fair play and to maintain rule of consistency.

We would like to be heard in person.

4. Personal Hearing notice(s) issued to accused person(s) dated 26 -01-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **257th** meeting held on **07-02-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Dr. Misbah-ud-Din, Secretary DQCB, District Lodhran and Mr. Arif Shahzad, Drug Inspector Tehsil Kahror Pacca, District Lodhran were present along with the original case record. No one among the nominated accused persons of **M/s Nawabsons Laboratories (Pvt) Ltd, T-13, Rukhshanda Heights, 4th Floor 8-Km Multan Road, Lahore-Pakistan** appeared before the Board. However, M.Akeel, Reulatory Manager appeared before the Board on behalf of the firm and submitted a written request for adjournment vide letter no. NSL/2023/9137 dated 07-02-2023.

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

7. Personal Hearing notice(s) issued to accused person(s) dated 10-04-2023.

Case is placed before the Board for Decision

Summary:

- **Manufacturing Date: 09-2020**
- **Expiry Date: 09-2022**
- **Sampling Date (Form 4): 30-04-2021**
- **Sent to DTL (Form 6): 06-05-2021**
- **Date of receipt in DTL: 06-05-2021**
- **DTL Report Date (Form 7): 03-07-2021**
- **Time Extension: Not applicable**
- **1ST DI Communication with firm on dated: 14-07-2022**
- **Date of Retesting Request of Firm: NA**
- **Fate of Retesting: Not applicable.**
- **Investigation Report Dated: 29-07-2022**

CURRENT PROCEEEDINGS & DECISION BY THE BOARD:

Case No. 5

PQCB/R-778/2019

Tehsil Kamalia & District Toba Tek Singh

Sub-Standard (Assay

ATTENDENCE

Secretary DQCB **Drug Inspector**	**Accused Persons involved in subject case** 1. **M/S Siza International (Pvt) Ltd, 18km, Ferozepur Road, Lahore-Pakistan** through its Director Muhammad Galib Raazee. 2. Muhammad Galib Raazee — Director 3. Muhammad Imran Khalid — Production Manager 4. Muhammad Yaqoob — Quality Control Manager/ Warrantor of **M/S Siza International (Pvt) Ltd, 18km, Ferozepur Road, Lahore-Pakistan.**

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Kamalia, District Toba Tek Singh reported that: -

i. His Predecessor, on 31-07-2019, inspected the business premises of M/S Humayun Pharmacy Situated at Iqbal Bazar Kamalia and took subject drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo. No.0000046773, dated. 03-08-2019.

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

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Tablet. AMRX [Each Tablet contains: Amlodipine (Besilate) BP……..5mg] **Mfg Date:** Feb-2019 **Exp Date:** Jan-2021 **Registration No.** 024046	02-19	M/S Siza International (Pvt) Ltd, 18km, Ferozepur Road, Lahore-Pakistan	01-56004692/DTL Dated. 08-10-2019	**Analysis with specifications applied:** **USP 2019.** **Description:** Small round, off-white, Biconvex Tablets, plain from one side and engraved with "SIZA" on other side, packed in ALU-PVC 1X 20's blister, contained in outer hard carton. **Identification:** Amlodipine (Besilate) is identified. **Assay:** Stated: 5mg Amlodipine/Tablet **Determined: 4.368mg Amlodipine/ Tablet** **Percentage: 87.365%** Limit: 90-110% (USP 2019) **Does not comply.** **Dissolution Test:** **Facility not available.** **Result:** Given sample is declared **Substandard** on the basis of **Assay**.

iii. M/S Humayun Pharmacy Situated at Iqbal Bazar Kamalia provided Invoice/warranty No 8801, dated 21-07-2019 issued by M/S Al-Abbas Medicine Company Housing Colony Toba Tek Singh who in turn provided invoice/warranty No. 19-09293, dated. 30-04-2019 issued by M/S Siza International (Pvt) Ltd, 18km, Ferozepur Road, Lahore-Pakistan as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Al-Abbas Medicine Company Housing Colony Toba Tek Singh and they were asked to explain their position in this regard.

v. A copy of test/analysis report was sent to M/S Siza International (Pvt) Ltd, 18km, Ferozepur Road, Lahore-Pakistan and they were asked to provide the requisite information in this regard.

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

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

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

Reply of Show Cause Notice:

1. This is in reference to the Show Cause Notice No. PQCB/R-778/2019 dated 15-11-2022 whereunder you have directed M/s Siza International (Pvt.) Ltd. (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 license may not be taken against the Company for the alleged violation of the provisions of the Drug Laws and the rules framed thereunder.

2. At the very outset, it is submitted that the Company is engaged in the manufacturing of high quality, efficacious and safe pharmaceutical products at its state-of-the-art manufacturing unit of the Company. As a result, thereof, the pharmaceutical products manufactured by the Company are increasingly being prescribed across the country by health practitioners and no complaint vis-à-vis the quality of the same has been received from any quarter what-so-ever. It is in this context that the Company seeks to categorically refute the absolutely erroneous and inaccurate findings rendered by the Government Analyst Drug Testing Laboratory Faisalabad rendered vide TRA No. 56004692/DTL dated 08-10-2019 (the "DTL Report") whereby Tablet AMRX Batch No. 02-19 (the "Product") has allegedly been declared as Substandard on the basis of the results of the Assay Test.

3. A perusal of the DTL Report reveals that the Government Analyst has miserably failed to test the Product in accordance with the testing procedure provided under the official compendia. The foregoing submission is substantiated by the fact that the uniformity of dosage units and dissolution test has not been performed by the Government Analyst. As such, it is essential for the testing protocols employed by the Government Analyst to be provided to the Company so as to allow it to conduct a detailed investigation. Even otherwise, no testing method has been obtained from the Company. As a result, thereof, it is clear that no reliance can be placed upon the inaccurate findings given by the Government Analyst since the same have been rendered without following proper and appropriate testing protocols.

4. It is pertinent to submit that the results of all tests conducted at the time of release of the Product were found to be satisfactory and in compliance with the parameters defined under USP Specifications. The Company was able to obtain such optimum results due to the proper maintenance and storage of the Product in a controlled environment. In this regard, it is essential to highlight that the label claim of the Product expressly and unequivocally mentions that the same is to be stored below 30 C and should be kept away from light. Since the Product is both light and heat resistant it is essential to maintain and store the same in accordance with the specific storage conditions as non-compliance with the same may potentially cause the degradation of the Active Pharmaceutical Ingredient.

5. Since, the results of all tests conducted at the time of release were in compliance with the specifications, the alleged deviation observed in the DTL Report has solely occurred due to the inability of the third party i.e., store keeper and staff of the pharmacy to store and maintain the Product in accordance with the storage conditions listed on the label claim of the Product. Please note that the in-process batches of the Product have also been critically examined and no such deviation has been observed by the Company which affirms that it is the negligence of the store keeper/staff of the pharmacy which has resulted in the alleged disparity in the DTL Report. As such, it shall be great travesty of justice to penalize the Company and its officials on the basis of the negligence exhibited by a third party.

6. In view thereof, it is evident that the entire manner in which the Product has been obtained and tested is riddled with glaring discrepancies and infirmities. The Government Analyst and the Drug Inspector have failed to adhere with the principles enshrined under the Drug Laws and the rules framed thereunder, hence, it shall be against the tenets of justice to penalize the Company and its officials on the basis of a faulty investigation. Even otherwise, please note that the Product has already expired.

7. Without prejudice to the foregoing and despite the absolute innocence of the Company and its officials, please find the following information as per your requirement:

1- Muhammad Yaqoob (Quality Control In-charge

2- Imran Khalil (Production In-charge)

8. Accordingly, it is reiterated that the Company and its officials have not contravened the provisions of the Drug Laws and the rules framed thereunder rather the Company has taken extensive measures to ensure the manufacturing and sale of high-quality and safe pharmaceutical products. As such, it is kindly requested that the titled Show Cause Notice and

subsequent proceedings may kindly be withdrawn in the interest of justice, equity and fair-play.

4. Personnel Hearing notice(s) issued to accused person(s) dated 26-01-2023 and 10-04-2023

Summary:

Manufacturing Date:02-2019

Expiry Date:01-2021

Sampling Date (Form 4): 31-07-2019

Sent to DTL (Form 6): 03-08-2019

Date of receipt in DTL: 10-08-2019

DTL Report Date (Form 7): 08-10-2019

Time Extension: N/A

1ST DI Communication with firm on dated: 30-12-2019.

Date of Retesting Request of Firm: Nil

Fate of Retesting Request: N/A

Investigation Report Dated:09-11-2022

Case is placed before the Board for Decision.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, Under Section 11 of the Drug Act 1976 in its 2**57th meeting held on 07-02-2023** under the chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. M. Arfan Secretary DQCB District Toba Tek Singh and Mr. Zaheer-ud-Din Babar Drug Inspector Tehsil Kamalia District Toba Tek Singh were present. No-one among the nominated accused were present, however, counsel of the firm Fatima Zahid (Advocate) appeared before the Board on behalf of M/S Siza International (Pvt.) Ltd, Ferozepur Road, Lahore Pakistan and submitted written request for adjournment. The Board after due deliberation and discussion unanimously decided the **adjourn the case** in best interest of justice. The Board further decided to provide another/ final opportunity of persona hearing to the accused persons.

CURRENT PROCEEDINGS & DECISION BY THE BOARD: