

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

284 Meeting of PQCB

Date: 05-09-2024

Time: 11:00 AM

Venue

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

TABLE OF CONTENTS

- **Item No. 1**
- **REGULAR CASES**
 - **Case No. 1**
 - R-22/2021 (Case Id: 0000052572)
 - **Case No. 2**
 - PQCB/R-674/2021 (Case Id: 0000054657)
 - **Case No. 3**
 - R-675/2021 (Case Id: 0000065942)
 - **Case No. 4**
 - R-583/2022 (Case Id: 0000072626)
 - **Case No. 5**
 - R-584/2022 (Case Id: 0000072552)
 - **Case No. 6**
 - No. PQCB/R-299/2022 (Case Id: 0000076938)
 - **Case No. 7**
 - No. PQCB/R-606/2022 (Case Id: 0000083968)
 - **Case No. 8**
 - R-789/2022 (Case Id: 0000095195)

- **Case No. 9**
- No. PQCB/R-741/2022 (Case Id: 0000085794)
- **Case No. 10**
- No. PQCB/ R-716/2022 (Case Id: 0000093593)
- **Case No. 11**
- No. PQCB/ R-359/2022 (Case Id: 0000084145)
- **Case No. 12**
- R-541/2022 (Case Id: 0000087335)
- **Case No. 13**
- R-398/2023 (Case Id: 0000115297)
- **Case No. 14**
- R-413/2023 (Case Id: 0000116085)
- **Case No. 15**
- R-443/2023 (Case Id: 0000113706)
- **Case No. 16**
- R-444/2023 (Case Id: 0000114673)
- **Case No. 17**
- No. PQCB/ R-397/2023 (Case Id: 0000114064)
- **Case No. 18**
- R-121/2023 (Case Id: 0000114524)
- **Case No. 19**
- No. PQCB/R-110/2023 (Case Id: 0000113364)
- **Case No. 20**
- No. PQCB/R-590/2022 (Case Id: 0000086351)
- **Case No. 21**
- PQCB/R-808/2019 (Case Id: 0000035104)
- **Case No. 22**
- R-610/2021, R-611/2021 (Case Id: 0000065516)
- **Case No. 23**

- R-712/2021 (Case Id: 0000065713)
- **Case No. 24**
- R-608/2021 (Case Id: 0000062834)
- **Case No. 25**
- R-615/2021 (Case Id: 0000066375)
- **Case No. 26**
- R-793/2021 (Case Id: 0000068814)
- **Case No. 27**
- PQCB/R-812/2021 (Case Id: 0000065857)
- **Case No. 28**
- R-146/2022 (Case Id: 0000072531)
- **Case No. 29**
- R-367/2022 (Case Id: 0000071761)
- **Case No. 30**
- R-726/2022 (Case Id: 0000092671)
- **Case No. 31**
- R-778/2022 (Case Id: 0000096739)
- **Case No. 32**
- R-749/2022 (Case Id: 0000079633)
- **Case No. 33**
- MSS-176662/2023 (Case Id: 0000129149)
- **Case No. 34**
- MSS-178849,178850/2023 (Case Id: 0000131002)
- **Case No. 35**
- R-885/2019 (Case Id: 0000028567)
- **Case No. 36**
- R-886/2019 (Case Id: 0000028571)
- **Case No. 37**
- R-887/2019 (Case Id: 0000028587)

- **Case No. 38**
- R-888/2019 (Case Id: 0000028568)
- **Case No. 39**
- R-889/2019 (Case Id: 0000031219)
- **Case No. 40**
- R-890/2019 (Case Id: 0000031235)
- **Case No. 41**
- R-891/2019 (Case Id: 0000031226)
- **Case No. 42**
- R-892/2019 (Case Id: 0000031237)
- **Case No. 43**
- R-893/2019 (Case Id: 0000031229)
- **Case No. 44**
- R-894/2019 (Case Id: 0000031222)
- **Case No. 45**
- R-895/2019 (Case Id: 0000033182)
- **Case No. 46**
- R-109/2022 (Case Id: 0000076060)
- **Case No. 47**
- PQCB/SM-30-12/2022, R-267/2023 (Case Id: 0000105252)
- **Case No. 48**
- PQCB/R-750/2020 (Case Id: 0000048529)
- **Case No. 49**
- R-617/2021 (Case Id: 0000068758)
- **Case No. 50**
- R-411/2022 (Case Id: 0000078720)
- **Case No. 51**
- No. PQCB/ R-497/2022 (Case Id: 0000076715)
- **Case No. 52**

- R-449/2022 (Case Id: 0000089626)
- **Case No. 53**
- R-905/2021 (Case Id: 0000118401)
- **Case No. 54**
- R-414,415,416/2023 (Case Id: 0000106130)
- **Case No. 55**
- R-772/2019 (Case Id: 0000037439)
- **Case No. 56**
- R-777/2020 (Case Id: 0000041296)
- **Case No. 57**
- R-775/2020 (Case Id: 0000041301)
- **Case No. 58**
- R-633/2020 (Case Id: 0000043042)
- **Case No. 59**
- R-792/2022 (Case Id: 0000089573)
- **Case No. 60**
- MSS-176736/2023 (Case Id: 0000129188)
- **Case No. 61**
- MSS-180554/2024, MSS-180544/2024 (Case Id: 0000132618)
- **Case No. 62**
- R-657/2022 (Case Id: 0000083326)
- **Case No. 63**
- R-569/2022 (Case Id: 0000085712)
- **Case No. 64**
- R-319/2023 (Case Id: 0000117458)
- **Case No. 65**
- R-249/2022 (Case Id: 0000156612)
- **Case No. 66**
- PQCB/R-576/2022 (Case Id: 0000088243)

- **Case No. 67**
- R-437/2023 (Case Id: 0000108320)
- **Case No. 68**
- MSS-162794/2023 (Case Id: 0000115451)
- **Case No. 69**
- R-662/2019 (Case Id: 0000033571)
- **Case No. 70**
- R-266/2023 (Case Id: 0000107624)
- **Case No. 71**
- R-747/2019 (Case Id: 0000037580)
- **Case No. 72**
- R-790/2022 (Case Id: 0000091504)
- **Case No. 73**
- MSS-174932/2023 (Case Id: 0000127220)
- **Case No. 74**
- MSS-188771/2024 (Case Id: 0000141387)
- **Case No. 75**
- MSS-181101/2024 (Case Id: 0000133285)

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result												
Injection Cintox [Oxytocin 10- I.U/ml	041	M/s Epoch Pharmaceuticals, 83- 85, Sector, 15 Korangi Industrial area Karachi-Pakistan	01-77002408/DTL Dated. 04-02-2021	<p><u>Analysis with specifications applied:</u> USP 2020.</p> <p><u>Composition:</u></p> <p>Each ml contains:</p> <p>Oxytocin U.S.P.....10 I.U</p> <p><u>Description:</u></p> <p>Colorless liquid in amber glass sealed vial with grey stopper and silver metallic seal, packed in outer carton. (Stated volume 50ml).</p> <p><u>Volume (USP):</u></p> <table border="1" data-bbox="928 927 1402 1133"> <thead> <tr> <th data-bbox="928 927 1157 1032">Limit</th> <th data-bbox="1157 927 1402 1032">NLT nominal volume</th> </tr> </thead> <tbody> <tr> <td data-bbox="928 1032 1157 1133">Determined</td> <td data-bbox="1157 1032 1402 1133">51ml</td> </tr> </tbody> </table> <p><u>Sterility (USP):</u></p> <p>The product is sterile.</p> <p><u>Identification (USP):</u></p> <p>Oxytocin is not identified.</p> <p>(Does not comply with the specifications.)</p> <p><u>Assay (USP): Oxytocin</u></p> <table border="1" data-bbox="928 1615 1345 2024"> <tbody> <tr> <td data-bbox="928 1615 1145 1720">Stated</td> <td data-bbox="1145 1615 1345 1720">10IU/ml</td> </tr> <tr> <td data-bbox="928 1720 1145 1825">Determined</td> <td data-bbox="1145 1720 1345 1825">0.00 IU/ml</td> </tr> <tr> <td data-bbox="928 1825 1145 1930">Percentage</td> <td data-bbox="1145 1825 1345 1930">0.00%</td> </tr> <tr> <td data-bbox="928 1930 1145 2024">Limit</td> <td data-bbox="1145 1930 1345 2024">90.0-110.0%</td> </tr> </tbody> </table> <p><u>Result:</u></p>	Limit	NLT nominal volume	Determined	51ml	Stated	10IU/ml	Determined	0.00 IU/ml	Percentage	0.00%	Limit	90.0-110.0%
Limit	NLT nominal volume															
Determined	51ml															
Stated	10IU/ml															
Determined	0.00 IU/ml															
Percentage	0.00%															
Limit	90.0-110.0%															

				The sample is declared Spurious as defined under section 3 (zb)(i) of the drugs act 1976.
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- iii. M/s Abbas Medical Store Madni Bazar Feroza, Tehsil Liaqatpur, District Rahim Yar Khan provided Invoice/warranty No 12197 dated 25-07-2020 issued by M/s Ruman Medicine House No. 7, Malik Street, West Street, 111/P West Rahim Yar Khan who in turn provide invoice/warranty No. 074, dated 18-07-2020 issued by M/S Osman & Company Jamlana Mansion Katchi Gali # 2, Marriot Road, Karachi who in turn provide invoice/warranty No.538, dated 14-05-2020 issued by M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/s Ruman Medicine House No. 7, Malik Street, West Street, 111/P West Rahim Yar Khan and they were asked to explain their position in this regard.
- v. A copy of test/analysis report was sent to M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan and they were asked to provide the requisite information in this regard.

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

Accused Persons	Offences
1. Ghulam Abbas S/O Muhammad Ismail Proprietor Of M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur	a. Stocking/Selling for sale of Spurious drug
1. Muhammad Tahir Nadeem Proprietor/Warrantor Of M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan.	a. Selling/Stocking for sale of Spurious drug b. Issuance of false warranty
2. Salman Warrantor Of M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi.	a. Selling/Stocking for sale of Spurious drug b. Issuance of false warranty
1. M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Industrial Area Karachi-Pakistan through its Managing Partner Muhammad Saleem. 2. Muhammad Saleem Managing	a. Manufacturing/selling/Stocking for sale of Spurious drug b. Issuance of false warranty

<p>Partner 3. Farhat Begum Production Incharge 4. Zeenat Quality Control Incharge/Warrantor</p> <p>of M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Industrial Area Karachi-Pakistan.</p>	
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3. Show cause notice issued to accused person(s) vide dated 05-11-2021

Reply of the firm:

1- In this regard your kind attention is invited to your earlier show cause notice no. POCB/R-22/2021 dated 31-03-2021 (received on 05-04-2021) on the said subject and we responded vide our letter no. nil dated 07-04-2021

2- That on the receipt of personal hearing letter no. POCB/R-22/2021 dated 15-06-2021, we appear in the 232 meeting of POCB Lahore held on 24-06-2021 through our council Mr. Rana M. Maqsood Afzal khan and defended the said case by way of oral discussion as well as submitted our written arguments vide letter no. nil dated 24-06-2021. After arguing the case, we were told that the decision will be conveyed later on. But so far no such decision has been conveyed to us till date. (At agenda of the meeting the serial no. of the case was 70 of item-2 regular cases.)

3- That instead of receiving the decision of the Board, we received a letter from the Drug Inspector vide no. DI-LQP/2036 dated 03-07-2021, asking for some in formations, which we responded the same under intimation to POCB vide our letter no. nil dated 12-07-2021, wherein in lieu of 232 meeting of POCB dated 24-06-2021, we requested the Drug Inspector to inform us about the decision of the Board for further correspondence in the matter. 4- That again we received a letter from the Drug Inspector vide no. DI-LQP/2085 dated 17-07-2021 (received on 24-07-2021) and again this letter was silent regarding the decision of the meeting of the POCB dated 24-06-2021. A comprehensive reply to this letter was sent to DI vide our letter no. nil dated 27-07-2021 and Drug Inspector was asked that since the case has been heard by the Board after the completion of your investigation and you requested for prosecution against the accused persons, then under what authority who authorized you to initiate further correspondence with us before decision of the Board. Our request for the provision of decision of 232 meeting of Board dated 24-06-2021 was repeated for further correspondence.

5- That surprisingly your fresh revised show cause notice is also silent on previous proceedings of the case and still we are un-aware about the decision taken by the Board in its 232d meeting held on 24-06-2021.

6- That after completion of the investigation of the case and subsequently hearing of the case in 232 meeting of the Board held on 24-06-2021, then under what law & grounds fresh and revised show cause notice has been issued to us.

7-That in view of above submissions your good offices are requested to provide us the copy of decision taken by the Board on the subject case in its 232n meeting held on 24-06-2021.

Reply of the Osman & Company

Purchased invoice by M/s Epoch bill # 538 dated 14th May 2020 along with Drug Sale license. It is reiterated that the purchase and sale of drug was as per law and I have not done anything against the provision of the Drugs Act 1976 and rues framed there under. Hence it is requested that I may please be acquitted of the case.

Reply of Ruman Medicine

Ruman medicine authorized Distributor of Pharmaceutical products under the license No. 03-313-0156-049150D. We have purchased Inj Cintox from M/s Osman & Company Jamlana Mansion Katchi. We have provided warranty to the

chemist with warranty No. 074 dated 18-7-2020. Mr. Salman is warrantor of Osman & Company who is the sole agent of the M/s Epoch Pharmaceutical Karachi who in turn provided invoice/warranty of Epoch and the firm own the said product. It is requested that we have purchased above aid product from authorized sole agent and also provided warranty chain. So, please take sympathetic view.

Reply of Abbas Medical Store:

I (Ghulam Abbas) took medicine Inj. Cintox from M/s Ruman Medicine and provided warranty/invoice No. 12197 issued by Ruman medicine who in turn provided warranty issued from Osman & Company to Drug Inspector Liaqatpur. So, please exclude my name from this case.

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **232rd meeting held on 24-06-2021**. Mr. Mazhar Shabeer Provincial Inspector of Drugs, Tehsil Liaqatpur, district Rahim Yar Khan was present along with original case record. No one among nominated accused persons of **M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan** was present. However, Rana Maqsood Afzal Khan, (Advocate) appeared on behalf of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan.

6. During proceedings of the meeting of the Board, the Drug inspector requested for reinvestigation and resubmission of complete investigation report. The Board after keen perusal of the case record, allowed to Drug Inspector to submit reinvestigation Report.

7. Revised Showcause notice issued to accused person (s)

8. Personal Hearing Notice issued to accused persons

PQCB 236th meeting held on 15-12-2021:

9. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **236th meeting held on 15-12-2021** under the chairmanship of Mr. Imran Sikandar Baloch Secretary Primary & secondary Healthcare Department Punjab, in the presence of Board members as mentioned above. Mr. Amjad Farooq Secretary District Quality Control Board, Rahim Yar Khan and Mr. Arfan Ali Provincial Inspector of Drugs, Tehsil Liaqatpur, District Rahim Yar Khan were present along with original case record. No one among nominated accused persons of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan was present. However, Muhammad Salman S/O Muhammad Saleem along with counsel, Rana Maqsood Afzal Khan, (Advocate) appeared before the Board on behalf of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan. M. Salman CNIC 42000-9472060-1, warrantor of M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi was present. Muhammad Tahir Nadeem (Proprietor) of M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan and Ghulam Abbas (Proprietor) of M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur appeared before the Board along with their counsel Sh. Irfan Saeed.

10. Ghulam Abbas (Proprietor) of M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur submitted that he took medicine Inj. Cintox from M/s Ruman Medicine and provided warranty/invoice No. 12197 dated 25-7-2020 issued by M/s Ruman Medicine to the drug inspector which was verified. He requested a lenient view.

11. Counsel of M/s Ruman Medicine House no. 7, Malik Street, west Street, 111/P West Rahim Yar Khan submitted that he is an authorized Distributor of Pharmaceutical products under the license No.

03-313-0156-049150D. He has purchased Inj. Cintox Batch No. 041 from M/s Osman & Company Jamlana Mansion Katchi and also provided warranty to the chemist with invoice/warranty No. 074 dated 18-7-2020. Mr. Salman was warrantor of M/s Osman & Company who is the sole agent of the M/s Epoch Pharmaceutical Karachi who in turn provided invoice/warranty of Epoch and the firm owned the said product. He requested that they have purchased above said product from authorized sole agent and also provided warranty which is linked up to the manufacturer chain, which was also verified. So, he requested for sympathetic view from the Board.

12. Counsel of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan submitted that they appeared in the 232nd meeting of PQCB Lahore held on 24-06-2021 through their counsel Mr. Rana Maqsood Afzal Khan and defended the case in detail discussion as well as submitted their written arguments vide letter no. nil dated 24-06-2021. After detailed argument of the case, they were told that the decision of the Board will be conveyed later on. So far, no such decision of the Board has been conveyed to them till date. He further argued that as the case has been submitted in the Board by the concerned Drug Inspector then under what authority and whose authorization the Drug Inspector concerned, initiated further correspondence with the firm before the decision of the Board. Moreover, they received fresh revised show cause notice which was also silent on previous proceedings of the case and still they are un-aware about the decision taken by the Board in its 232nd meeting held on 24-06-2021. He further added that after completion of the investigation of the case and subsequent hearing of the case in 232nd meeting of the Board held on 24-06-2021, under which law & grounds fresh and revised show cause notice has been issued to them. He further submitted that a licensed manufacturer cannot take risk of making spurious drugs when he has invested millions of rupees in making manufacturing unit. So, it is requested to retest the sample in the best interest of justice as the expiry of Inj. Cintox Batch No. 041 is April 2022.

13. The Board, thoroughly scrutinized complete case record and observed that the stance of the firm regarding revised showcause notice without any authority is invalid as the Drug Inspector in compliance of the orders of PQCB dated 25-06-2021, reinvestigated the case and submitted detailed investigation report vide letter no DI-LQP/2014. In the light of investigation report, PQCB issued revised showcause of even no. dated 05-11-2021. The Board after thorough screening of the documents provided by M/s Osman & Company, Karachi observed that two different authority letters dated 01-01-2020 and 01-07-2020 have been provided by them. The authority letter dated 01-01-2020 states that:

“We, M/s Epoch Pharmaceuticals, Karachi has authorized M/s Osman & Company, Jamlana Mansion, Katchi Gali No. 02, Marriot Road, Karachi as our appointed sole agent them to supply offer our registered products all over the Pakistan. The authorized sole agent M/s Osman & Company, Karachi are further authorized to issue their invoice & warranty onward to their dealer M/s Ruman Medicine 111/P west House # 7 Malik Street Rahim Yar Khan”.

While the authority letters issued on dated 01-07-2020 states that:

“This is to certify that M/s Osman & Company, Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi is our authorized distributor. This authorization letter is valid till 30-06-202. However, company reserves right to amend change the validity at any time by giving one-month notice.

14. The Board observed that the authority letters dated 01-01-2020 and 01-07-2020 are contradictory with two different statements, format and signatures of the firm. The Board asked Salman warrantor of M/S Osman & Company to explain his position in this regard. However, he refused to give any statement and submitted that he is presenting M/S Epoch at the moment and he cannot answer any question as warrantor of M/s Osman & Company. The Board showed serious concern that Salman bearing CNIC 42000-9472060-1 despite of his presence and appearance before the Board refused to clarify and explain this matter and submitted a copy *Drug Sale License by way of Wholesale* No. DHSKDK(Drug)/-254 Licence No. 3193 dated 19-2-2020 of M/s Osman & Company being authorized agent of M/s Epoch Pharmaceuticals issued

by Government of Sindh.

15. Drug Inspector briefed about the facts of the case and requested for permission of registration of FIR against all the nominated accused persons. The Board after detailed scrutiny of the case record, statement of the accused and Drug Inspector was of the view that the two authority letters issued by the firm M/s Epoch Pharmaceuticals, Karachi in favour of M/s Osman & Company, Karachi shows that both the distributors *i.e.*, M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi and M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan are beneficiaries, involved in selling/stocking for sale of spurious drug. Furthermore, the firm has the right to apply for retesting of the sample in writing, to Drug Inspector or the Provincial Quality Control Board, Punjab within 10 days after the intimation of DTL Report. The firm did not show any such intention. However, during hearing of the case, the firm requested the Provincial Quality Control Board, Punjab for retesting of its product therefore, violating the time limit of ten days as prescribed in the Drug Acts 1976 (as amended). The Board was of the unanimous view that a detailed police investigation is required in subject case regarding statements and contradictory documents provided by the accused and such elements must be dealt with iron hands to curb the menace of spurious drugs which is a cognizable offence under Drugs Act 1976/DRAP Act 2012 and rules framed there under. Keeping in view the facts of the case, the Board after due deliberation and discussion at length unanimously decided to **grant permission of registration of FIR** at the concerned police station, against the following below mentioned accused persons under Section 11 (5) (b) & (e) of Drug Act 1976 for the offences of:

<p>1. M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan through its Managing Partner Muhammad Saleem.</p> <p>2. Muhammad Saleem Managing Partner</p> <p>3. Farhat Begum Production Incharge</p> <p>4. Zeenat Quality Control Incharge/Warrantor</p> <p>of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi- Pakistan.</p>	<p>a. Manufacturing/selling/Stocking for sale of Spurious drug</p> <p>b. Issuance of false warranty</p>
<p>5. Salman Warrantor</p> <p>Of M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi.</p>	<p>a. Selling/Stocking for sale of Spurious drug</p> <p>b. Issuance of false warranty</p>
<p>6. Muhammad Tahir Nadeem Proprietor/Warrantor</p> <p>Of M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan.</p>	<p>a. Selling/Stocking for sale of Spurious drug</p> <p>b. Issuance of false warranty</p>

9. The Board further decided to exonerate the name Ghulam Abbas (Proprietor) of M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur under section 32 (3) of Drug act 1976 as the warranty provided by him was verified and owned by M/s Ruman Medicine House Rahim Yar Khan.

10. Review petition submitted by M/s Epoch Pharmaceuticals, Karachi vide letter no. nil dated

24-01-2022 received in the office of PQCB dated 27-01-2022. In the light of Honorable Drug Court, Lahore Orders dated 25.08.2021 the review petition submitted by M/s Epoch Pharmaceuticals dated 24-01-2022 against PQCB Order dated 15-12-2021, cannot be entertained vide letter No. PQCB/R-22/2021 dated 31-01-2022. The operative part of the order is;

11. *“There is no provision or section which empowers the Board to review or revision so that illegal practice which was started since 2002 till date has no legal cover rather the same is based on unlawful Orders passed by the Board under the shadow of notification dated 03.05.2002 is without legal authority in these cases and the same is declared illegal and unlawful...”*
12. ***Firm vide letter no. Ref: 67 dated 08-02-2022 received in office of PQCB dated 10-02-2022***
13. *It is requested that as the order has been passed by the honorable court in W.P No. 895/2022 dated 04-02-2022 for not to take any further action against the petitioner till pending decision of review petition of petitioner.*

Form No. HCJD/C-121

ORDER SHEET

IN THE LAHORE HIGH COURT,

BAHAWALPUR BENCH, BAHAWALPUR

JUDICIAL DEPARTMENT

Writ Petition No.895 of 2022

Date of Order: 04-02-2022

Farhat Begum Vs Chairman Provincial Quality Control Board, Lahore etc.

Learned counsel for the petitioners contends that review petition against order dated 15.12.2021 filed by the present petitioner is pending before respondent/Chairman Provincial Quality Control Board (Health Department) Punjab Lahore which is still pending without any meaningful hearing and remedy i.e., provided in law will become infructuous if the order impugned in the said review petition is implemented.

2. It is contended by learned counsel that no heed is being paid in the matter despite repeated visits and requests to review the application and also contends that he will be satisfied if a direction is given to respondent No.1 to decide the review application, expeditiously.

3 Learned Law Officer has not opposed this request.

4. The instant petition is **disposed** of with the direction to respondent No. 1 to decide the review application, if still pending, strictly in accordance with law, after providing an opportunity of hearing to the concerned parties, **preferably within two weeks from the date of receipt** of certified copy of this order. The Respondent-Department is expected not to take any further adverse action against the petitioner, before deciding the aforementioned review application.

PQCB 239th meeting held on 24-02-2022

14. In compliance to Lahore High court order, the issue was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **239th** meeting held on **24-02-2022** under the chairmanship of Secretary Health Primary & Secondary Healthcare Department, Punjab, in the

presence of Board members as mentioned above. Mr. Amjad Farooq, Secretary DQCB, Rahim Yar Khan and Mr. Arfan Ali, Provincial Inspector of Drugs, Tehsil Liaquatpur, District Rahim Yar Khan was present along with the original case record. Muhammad Saleem (Managing Partner) along with counsel, Ch. Mahmood Ali (Advocate) of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan appeared before the Board. Counsel for the firm raised the argument as stated in the writ petition and requested to accept the same. He further added that report is time barred and requested for retesting of the sample of the subject drug and submitted that the warrantor portion was not sent to the company till now.

15. The Board after careful scrutiny of the case record observed that argument of the petitioner regarding warrantor portion is not correct as the warrantor portion was sent to M/s Ruman Medicine company vide letter no. DI/LQP/459 dated 10-10-2020 and time extension as required under section 22(2) of the Drugs act 1976 was granted by the Board. Provincial Inspector of Drug apprised the Board that FIR has been registered against the accused persons vide F.I.R No. 17/22 dated 14-01-2022 in concerned police station.
16. In the light of the above forgoing facts, as the Board does not have any **application of Review Petition of M/s Epoch Pharmaceuticals, 83-85, Sector, 15 Korangi Industrial area Karachi-Pakistan pending before Provincial Quality Control Board.**
17. **Lahore High Court Bahawalpur Bench, Bahawalpur Crl. Rev.No. 62 of 2022 order dated 06-06-2022 Operative part is**

..... *The learned counsel for the petitioner has failed to point out any illegality or irregularity in impugned order, as the same is well-reasoned and calls for no interference by this Court, consequently the instant petition having no substance is **dismissed.***

18. Drug Inspector submitted Investigation report vide letter no. 810 dated 16-06-2022 for grant permission for prosecution against the accused
19. SCN issued to the accused dated 29-07-2022
20. **Firm filed writ petition No. 30570/Writ dated 27-06-2023 Lahore High Court, Bahawalpur Bench, Bahawalpur Crl. Org. No. 389-W/2022 in W.P No. 895/2022 Order dated 13-06-2023**

ORDER SHEET

IN THE LAHORE HIGH COURT,

BAHAWALPUR BENCH, BAHAWALPUR

JUDICIAL DEPARTMENT

Crl.Org. No. 389-W of 2022 BWP.

Muhammad Saleem Vs Imran Sikandar Baloch etc

Date of Order: 13-06-2023

It is apprised by learned Law Officer that pursuant to direction passed by this Court, speaking order dated 11-03-2022 on review petition of petitioner has been passed copy of which is annexed with reply submitted by respondents.

2. When confronted, learned counsel for petitioner submits that order passed by this Court in previous round of litigation has not been complied with in letter and spirit and the matter has been disposed of with observation that no review petition was pending.
3. In this view of the matter, petitioner is directed to file review petition before respondent

No. 1 and if it is filed, the same shall be dealt with and decided on merits strictly in accordance with law, after hearing petitioner and all concerned, through speaking order **within a period of seven days**, failing which petitioner shall be at liberty to move an appropriate application for revival of this contempt petition.

4. The instant petition is *disposed of accordingly*.

PQCB 24th Committee Meeting held on 10-08-2023

21. The issue was considered by the Committee of the Board in **24th Committee Meeting** held on **10-08-2023** under the Convenorship of Director General, Drugs Control. Issue was considered by the Committee of Provincial Quality Control Board, as empowered by Board under section 11 (6) & (7) of the Drugs Act 1976 in its 258th meeting. Secretary PQCB apprised the Committee about the details of the case. The Committee after due deliberation and discussion unanimously decided to place the case on direction of Lahore High Court orders in upcoming Board meeting.
22. Personal Hearing Notice issued to accused persons vide dated 11-08-2023.
23. Case is placed before the Board for Decision.

PQCB 266th meeting held on 24-08-2023

24. The subject review petition was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **266th meeting held on 24-08-2023** under the Chairmanship of Vice-Chairperson. Mr. Rafaqat Ali Secretary DQCB District Rahim Yar Khan and Mr. Arfan Ali Drug Inspector Tehsil Liaqatpur were present along with original record of the case. Among the nominated accused persons Muhammad Saleem (Managing Partner) was present of **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Industrial Area Karachi-Pakistan** along with Representative of the firm Khan Muhammad (Current Quality Control Manager) and counsel person Hafiz Ahsan (Advocate) and Noor Mehar (Advocate).

25. Hafiz Ahsan (Advocate) appeared on the behalf of **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Industrial Area Karachi-Pakistan** and stated that the technical persons was engaged with the petition on 23-08-2023, therefore due to lack of time, proper consultation cannot be made with my client. Serious legal question is involved in the present case i.e to continue with the petition or to withdraw the same, Therefore, it is in the best interest of justice that give time to the technical persons for detailed discussion. Therefore it is requested to kindly adjourn the case in the next meeting of PQCB in the best interest of justice.

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

27. Personal Hearing Notice issued to accused persons vide dated 12-09-2023.

PQCB 268th meeting held on 21-09-2023:

28. The subject review petition was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **268th meeting held on 21-09-2023** under the Chairmanship of Vice-Chairperson. Mr. Rafaqat Ali Secretary DQCB District Rahim Yar Khan appeared via zoom link and Mr. Arfan Ali Drug Inspector Tehsil Liaqatpur was present along with case record. Counsel person of the firm Asim Malik (Advocate) and Hafiz Ahsan Naseer Aslam (Advocate) appeared before the Board on the behalf of **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Industrial Area Karachi-Pakistan** and submitted that the said titled review petition is filed before the Honourable Board on 21-09-2023 in compliance of directions of Honourable High Court Bahawalpur Bench passed in writ petition No. 29737/2023. In addition, the said time being is not intended to file review petition and submit before the honorable Board that we would defend our case on merit at the time of arguments in the main case.

However, it is requested to decide the application of the firm dated. 31-08-2023 for providing the protocol of tests according to its merit.

29. Keeping in view the facts of the case, the Board, thoroughly scrutinized complete case record and decided that the stance of the firm regarding **withdrwal of its review petition is hereby accepted** and further directed to place the said case as regular case in Board meeting.

30. Personal Hearing Notice issued to accused persons vide dated 11-12-2023.

PQCB 274th meeting held on 21-12-2023

31. Case was considered by the Provincial Quality Control Board, under section, 11 of the Drugs Act 1976 in its **274th meeting** held on **21-12-2023** under the Chairmanship of Vice-Chairperson. Secretary Provincial Quality Control Board apprised the Board that Show Cause and Personal Hearing notice was duly served to accused persons. Mr. Razaqat Ali Secretary DQCB District Rahim Yar Khan attended the meeting via zoom link and Mr. Arfan Ali Drug Inspector Tehsil Liaqatpur was present along with record of the case. No one among the nominated accused persons appeared before the Board on the behalf Of **M/s Osman & Company Jamlana Mansion Katchi gali # 2, Marriot Road, Karachi.** Among the nominated accused persons Muhammad Tahir Nadeem (Proprietor/Warrantor) appeared before the Board on the behalf of **M/s Ruman Medicine House no. 7, malik street, west Street, 111/P West Rahim Yar Khan** and Ghulam Abbas S/O Muhammad Ismail (Proprietor) appeared before the Board on the behalf Of **M/s Abbas Medical store Madni Bazar Feroza, Tehsil Liaqatpur.** Counsel of the firm Asim Malik (Advocate) and Noor Muhammad Mehar (Advocate) appeared before the Board on the behalf of **M/s Epoch Pharmaceuticals. 83-85, Sector, 15 Korangi Indusrtrial Area Karachi-Pakistan** and submitted that we did not obtain the final FIR report of Police under section 173 Cr.PC and the statements of the witnesses and other evidence which got recorded by the investigation officer during the course of investigation. He further submitted that it would be appropriate to give the accused persons an opportunity to examine the entire record for assisting the Board to reach logical, reasonable, fair and just decision and in such like cases, FIR is registered to dig out the actual facts, the accused persons are unable to defend the case due to non-availability of police record. He further submitted that the said request may kindly be accepted and directed the drug inspector concerned and the investigation officer of police to provide the entire record of police investigation to proceed and defend it further.

32. The Board after discussion decided to **pend the case** and directed the concerned drug inspector for provision of FIR copy and also directed to get complete 173 police challan from concerned police station and submit complete investigation report for the consideration by the Board.

32. Case is placed before the Board for Decision.

Sr. No.	SUMMARY OF THE CASE	
1	Sampling Date (Form 4)	30-09-2020
2	Sample Sent to DTL (Form-6)	03-10-2020
3	Receipt Date in DTL	08-10-2020

4	Issuance of DTL Report	04-02-2021
5	Time Extension	Not Time Barred (Extension granted in 232M)
6	DI First Communication with Firm	26-02-2021
7	Retesting Request	No (told verbally in 236th meeting held on 15-12-2021)
8	Investigation Report by DI	25-06-2021
10	Show Cause Notice Issued	Show Cause Issued
11	History (3 years)	1 case reported.
12	Manufacturing Date	04-2020
13	Expiry Date	04-2022

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 2

PQCB/R-674/2021

(Tehsil Mankera, District Bhakkar)

ATTENDANCE

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Stanley Pharmaceutical (Pvt.) Ltd 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan through its Chief Executive Officer/Warrantor Abdullah Shah. 2. Abdullah Shah Chief Executive Officer/Warrantor 3. Imran Khan Production In Charge 4. Umar Kamran Marwat Quality Control In Charge Of M/s Stanley Pharmaceutical (Pvt.) Ltd 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan.
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BRIEF FACTS OF THE CASE

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

- i. His predecessor, on 27-11-2020 inspected the business premises of M/S Punjab Pharmacy near Iqbal Gate Mankera, Tehsil Mankera, District Bhakkar and took sample of the subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo No.0000078724 dated 27-11-2020.
- ii. The following drug sample, after test/analysis was declared as Substandard by Government Analyst, Drug Testing Laboratory, Rawalpindi as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tablet RID-ALL [Orphenadrine Citrate 35mg, Paracetamol 450mg] Mfg Date: 07-2020 Exp. Date: 07-2023 Reg. # 069786	A-868	M/s Stanley Pharmaceutical (Pvt.) Ltd 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan.	01- 75000192/DTL dated: 29 Jan 2021	Result of test/ analysis with specifications applied: MS <u>PHYSICAL DESCRIPTION</u> White coloured, round shaped, flat tablets having beveled edges, engraved with "STANLEY" on one side and plain from other side, packed in Alu-PVC blister of 1x10's tablets, further packed in outer labelled carton containing 10 blisters (100 Tablets). <u>DISINTEGRATION TEST:</u> Result: All units comply the disintegration test Limit: NMT 15min <u>ASSAY:</u>

				<p>Orphenadrine Citrate:</p> <p>Stated: 35mg/Tablet</p> <p>Determined: 33.094mg/Tablet</p> <p>Percentage: 125.98% (DOES NOT COMPLY)</p> <p>Limit 90-110%</p> <p><u>Paracetamol:</u></p> <p>Stated: 450mg/Tablet</p> <p>Determined: 461.457mg/Tablet</p> <p>Percentage: 102.55%</p> <p>Limit 90-110%</p> <p><u>RESULT</u></p> <p><u>The above sample is Substandard on the basis of Assay test performed.</u></p>
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- iii. The proprietor of M/S Punjab Pharmacy near Iqbal Gate Mankera, Tehsil Mankera, District Bhakkar provided invoice/ warranty bearing No. 4760 dated 26-11-2020 issued by M/s Al-Shafi Distributors Bhakkar, who in turn provided invoice/warranty bearing No. 157 dated 10-08-2020 issued by M/s Stanley Pharmaceutical (Pvt.) Ltd 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan.
- iv. Warrantor Portion was sent to M/s Al-Shafi Distributors, Bhakkar .
- v. A copy of Test/ Analysis report was sent to M/s Stanley Pharmaceutical (Pvt.) Ltd 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan and they were directed to provide requisite information in this regard. In Response, the firm challenged the test/analysis reports and requested to re-test the above-mentioned drug sample from Appellate laboratory NIH, Islamabad which was allowed in 246th meeting of Provincial Quality Control Board dated 05-07-2022.
- vi. Pursuant to the firm's request, the subject drug sample was sent to National Institute of Health, Islamabad, from where the sample was declared as **Sub-standard** as detailed below:

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results														
Tablet RID-All	A-868	M/s Stanley Pharmaceutical (Pvt.) Ltd 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan	No. 0186-P/2022 dated 7 th September, 2022	<p>Result of test/ analysis with specifications applied: Manufacturer's Specifications.</p> <p><u>Assay:</u></p> <table border="1"> <thead> <tr> <th></th> <th><u>Stated</u></th> <th><u>Found</u></th> <th><u>Limit</u></th> <th><u>Percentage</u></th> </tr> </thead> <tbody> <tr> <td>Paracetamol</td> <td>450mg/Tablet</td> <td>439.30mg/Tablet</td> <td>95-105%</td> <td>97.62%</td> </tr> </tbody> </table>						<u>Stated</u>	<u>Found</u>	<u>Limit</u>	<u>Percentage</u>	Paracetamol	450mg/Tablet	439.30mg/Tablet	95-105%	97.62%
	<u>Stated</u>	<u>Found</u>	<u>Limit</u>	<u>Percentage</u>														
Paracetamol	450mg/Tablet	439.30mg/Tablet	95-105%	97.62%														

				Orphenadrine Citrate	35mg/Tablet	58.15mg/Tablet	90-110%	166.14%
<p>Does not comply with manufacturer's specification.</p> <p>RESULT: The sample is of Sub-standard quality on the basis of test performed.</p>								

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

a. Manufacturing for sale/ sale of Substandard Drug

b. Issuance of false warranty

3. The Show-Cause Notice was issued to the accused person (s).

Reply of SCN by Frim:

We have received your Kind letter No.POCB/R-674/2021 dated 23.01.2023 received on 30-01-2023, along with Test Report No. TRA 01-75000192/DTL dated 29.01.2021 issued by Government Analyst Drugs Testing Laboratory Rawalpindi regarding our product namely Rid-All Tablets bearing Batch No. A-868 Mfg. Date 07-2020 and Expiry Date 07-2023. The said laboratory analyst has declared drug sample as Substandard on the basis of Assay test performed. Moreover retested by NIH Islamabad declared Substandard vide Test Report No.0186-P/2022 on dated 07.09.2022 In this regards we have drawn your attention on following

points.

1. The government analyst DTL Rawalpindi has determined Orphenadrine Citrate 125.98% & NIH 166.14% which does not comply the specification that is 90-110%. This showed that in this the analyst has made some mistake during analysis. Both Assay results have differed i.e. 40.16% from each other, which clearly shows the mistakes have done during analysis.

2. As you know that our product is Mfg Stanley Specification. The Assay of Orphenadrine Citrate on Non-Aqueous Titrations.

Following Points must be considered during the Assay of Orphenadrine Citrate on Non-Aqueous

Titration.

- Naphthol Benzein 0.2% w/v must be standardized before titration
- 0.1M Perchloric Acid must be standardized with Potassium Dihydrogen Phthalate with following manner.
- Take 0.35gm of Potassium Dihydrogen Phthalate previously dried at 120' C for 2 hours.
- Dissolve it in 50ml glacial acetic acid
- Add 0.1ml of crystal violet 0.5% w/v
- Titrate with 0.1M perchloric Acid solution until the violet color change to green.
- Perform the blank and make necessary actions.
- Weigh and Powdered 20 tablets .Add a quantity of the powder equivalent to 100mg of Orphenadrine Citrate in 30ml glacial acetic acid and the filter through 0.45um .after filtration add indicator 1-Naphthol Benzein 0.2% w/v and titrate with 0.1M perchloric Acid.
- Closely observe the end point when green color persists is very important factor in Non-Aqueous Titration.

- Filtration is also important factor before titrate with 0.1 M Perchloric Acid.
- Proper Crushing of 20 Tablets is very important step during assay.
- Human error must be consider in this case

3. We always assure our products quality of each batch and each product during manufacturing in our premises under the supervision of qualified staff and with strict drug act rules, and in-process control. Each prepared batch is transferred to packing section after receiving passed analysis certificate from quality control department. After packing the finish pack again tested by quality control department and issue release certificate for marketing when all tests protocol qualified.

4. Every step of each batch of each product (including weighing of raw materials, preparation, sample for analysis and batch release) is performed under the supervision of qualified staff. There is no chance for any mistake or to manufacture a drug of substandard.

S/No	Name/ Designation	Address
1	Mr.Abdullah Shah (warrantor/CEO)	House No 363 Street No 6Sector E7 Phase 7 Hayatabad Peshawar
2	Imran Khan (Production Incharge)	Sirmustkhel PO Kohi Hassan khel Buddabair FR Peshawar
3	Umar kamran Marwat(QC Incharge)	House No 350 Street No 15Sector F7 Phase6 Hayatabad Peshawar

Kindly consider our justification on the basis of above said reasons during analysis of Orphenadrine Citrate on Non-Aqueous titration and may warned us in this regard.

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

Summary:

Manufacturing Date: 07.2020

Expiry Date: 07.2023

Sampling Date (Form 4): 27.11.2020

Sent to DTL (Form 6): 27.11.2020

Date of receipt in DTL: 30.11.2020

DTL Report Date (Form 7): 29.01.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 18.03.2021

Date of Retesting Request of Firm: 26.03.2021

Fate of Retesting: Allowed in 246th meeting dated 05.07.2022 (Substandard by NIH)

Investigation Report Dated: 10.11.2022

Permission of SCN:

SCN issued: 23.01.2023

Reply of firm: 30.01.2023

History (Last 03 Years): Product: 01 subject case reported, Firm: 52 cases reported.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 3

PQCB/R-675/2021

Tehsil Khairpur Tamewali District Bahawalpur

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/s Stanley Pharmaceuticals (Pvt) Ltd. 84-B, Industrial Estate, Hayatabad Peshawar-Pakistan through its Chief Executive Officer, 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 (Pvt) Ltd. 84-B, Industrial Estate, Hayatabad Peshawar-Pakistan
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BRIEF FACTS OF THE CASE:

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

- i. He, on 23-06-2021, inspected the business premises of M/s Hafiz Medical Store, Ward No. 3, Kachi Abadi Chak No. 24, Sharaf Shah Khairpur Tamewali, District Bahawalpur, took samples of four different types of drugs on Form No.04 for the purpose of test/analysis and sent to Drugs Testing Laboratory Bahawalpur vide memorandum no. 99173 dated 24-06-2021.
- ii. The subject drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report No. & Date	DTL Test Report Result
Suspension. Pedrol [Paracetamol 120mg/5ml, 60ml] Mfg Date: Apr 2021 Expiry Date: Apr 2023	E-297	M/S Stanley Pharmaceuticals (Pvt) Ltd. 84-B, Industrial State, Hayatabad Peshawar-Pakistan.	01- 77004729/DTL dated 23-08-2021	Analysis with Specifications Applied: BP 2020 COMPOSITION: Each 5ml contains: Paracetamol (B.P.) 120mg DESCRIPTION: Yellow colored suspension in sealed amber glass bottle with <i>visible sedimented crystals that are not re-dispersed on shaking.</i> (Stated Volume: 60ml). (Observed upon Physical Inspection). (Does not comply with specs.) IDENTIFICATION: Paracetamol Is Identified.

Regn No. 001719				<p><u>ASSAY OF PARACETAMOL:</u></p> <p>Stated: 120 mg/ 5 ml</p> <p>Determined: 104.064 mg/ 5 ml</p> <p>Percentage: 86.72%</p> <p>Limit: 95.0% - 105.0%</p> <p>(Does not comply with specs.)</p> <p><u>RESULT:</u> The sample is declared <u>SUB-STANDARD</u> on the basis of <u>ASSAY</u> and <u>PHYSICAL DESCRIPTION</u> Test.</p>

- iii. M/s Hafiz Medical Store, Ward No. 3, Kachi Abadi Chak No. 24, Sharaf Shah Khairpur Tamewali, District Bahawalpur provided warranty bearing No. 46470 dated 09-06-2021 issued by M/s Khushi Pharma, 76-C, Block Z, Model Town-C, Bahawalpur as a proof of its purchase of the subject drug sample.
- iv. Warrantor portion of drug sample was sent to M/s Khushi Pharma, 76-C, Block Z, Model Town-C, Bahawalpur who provided invoice/warranty bearing No. 3382 dated 25-05-2021 issued by M/s Stanley Pharmaceuticals (Pvt) Ltd. 84-B, Industrial Estate, Hayatabad Peshawar-Pakistan as a proof of its purchase.
- v. A copy of test/analysis report was sent to M/S Stanley Pharmaceuticals (Pvt) Ltd. 84-B, Industrial Estate, Hayatabad Peshawar-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 240th meeting held on 15-03-2022 **allowed** to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result
Suspension. Pedrol 60ml [Paracetamol 120mg/5ml]	E-297	M/s Stanley Pharmaceuticals (Pvt) Ltd. 84-B, Industrial State, Hayatabad Peshawar- Pakistan.	068-P/2022 dated 27-06- 2022	<p>Analysis with specifications applied: BP-2017</p> <p><u>DESCRIPTION:</u> Yellow coloured suspension contained in amber coloured labeled glass bottle packed in an outer carton having undissolved particles which did not disperse even on shaking. (Does not comply with manufacturer's specifications which states that A yellow homogeneous suspension with a characteristic odour of banana. Filled in amber colour glass bottle sealed with PP aluminium cap label packed in unit carton.)"</p>

				<p><u>ASSAY:</u></p> <p>Stated: 120 mg/ 5 ml</p> <p>Determined: 120.94 mg/ 5 ml</p> <p>Limit: 95-105%</p> <p>Percentage: 100.78%</p> <p>Complies with BP-2017</p> <p><u>CONCLUSION:</u> The sample is of <u>Sub-Standard</u> quality on the basis of tests performed.</p>
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2. Drug Inspector requested for grant of permission for prosecution against the above- mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

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

3. Personal hearing notice(s) issued to accused person(s) dated 26-08-2024.

Reply of the firm to show cause notice

Kind references your letter no. POCB/R-675/2021 dated 06.02.2023 received on 14.02.2023, along with NIH Test Report No. 068-P/2022 issued by NIH Appellate Testing Laboratory Islamabad regarding our product namely Pedrol Suspension 120mg/5ml bearing batch No. E-297 Mfg. Date 04-2021 and Expiry Date 04-2023. The said laboratory analyst has declared drug sample as Substandard on the basis of description. While declared Paracetamol Assay Results 100.78% which is within BP limits i.e. 95-105%

We have drawn your attention on following points

Determined Amount Paracetamol.....120.94mg/5ml

Stated Amount Paracetamol.....120mg/5ml 100.78%

Percentage..... 100.78%

Limits.....95-105%

NIH Test report is self-explanatory shows Paracetamol Assay Results 120.94mg/5ml i.e. 100.78% (Limit 95-105%) and mentioned remarks in the report that the above said Product complies BP 2017. Moreover BP specification is mentioned on both Unicarton and inner most Labels. The question is that when once the Product complies BP why they declared substandard on the basis of description (Physical Appearance).

Our Product is BP Specifications not Manufacturer Specification and how it is possible when undissolved particles observed and still assay results of Paracetamol within limits i.e. 100.78%

Hope You will consider our above said justifications on Technical ground and kindly may close the File in our Favor in this regard.

Summary:

Date of sampling: 23-06-2021

Date of DTL: 24-06-2021

Date of receipt in DTL: 25-06-2021

Issuance date of DTL Report: 23-08-2021

Time Extension: Not Time Barred

1st DI Communication with firm on dated: 06-09-2021

Retesting Request of Firm: Firm requested for Retesting Request dated 09-09-2021

Fate of Retesting Request: Sample sent to NIH in 240 meeting dated 15-03-2022

Investigation Report Dated: 19-11-2022

Permission of Show cause notice: 256-M

Show Cause Notice Date: 06-02-2023

Reply of the firm: Received

History of the firm of last 3 years:

Firm: 52 cases of the subject firm

Product: 02 cases of the subject product including subject product

Manufacturing Date: 04-2021

Expiry Date: 04-2023

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 4

PQCB R-583/2022

Tehsil Murree, and District Rawalpindi

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, 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 (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan .
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BREIF FACTS OF THE CASE:

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

- He, on 01-12-2021 inspected the premises of Main Medicine Store, Syed Muhammad Hussain Government T.B Sanitorium, Samil Tehsil Murree, District Rawalpindi and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 0000112052 dated 01-12-2021.
- The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Suspension Pedrol 60ml [Each ml contains Paracetamol 120mg] Mfg. Date: 10-2021 Exp. Date: 10-2023 Reg# 001719	E-661	M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	01-74003283/ DTL dated: 17 Mar 2022	Result of test/ analysis with specifications applied BP 2022 <u>PHYSICAL DESCRIPTION:</u> Visibly clear, light-yellow coloured, viscous liquid, filled in amber coloured glass bottle with affixed label, sealed with metallic screw cap imprinted with "STANLEY", further packed in outer labelled carton. <u>IDENTIFICATION:</u> Paracetamol identified. <u>ASSAY:</u> Stated: 120mg/5ml Determined: 109.969 mg/5ml

				<p>Percentage 91.64% (DOES NOT COMPLY)</p> <p>LIMIT: 95-105%</p> <p><u>RESULT:</u></p> <p><u>The above sample is "Substandard" with respect to Assay test performed.</u></p>
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- iii. Medical Superintendent, Syed Muhammad Hussain Government T.B Sanatorium, Samli Tehsil Murree, District Rawalpindi provided invoice/warranty No. 1324 dated 15-10-2021 issued by M/S Pharma Surge Distributor, House No. B/516, Block B near Government Degree College for Women, Satellite Town, Rawalpindi.
- iv. Warrantor Portion was sent to M/S Pharma Surge Distributor, House No. B/516, Block B near Government Degree College for Women, Satellite Town, Rawalpindi.
- v. M/S Pharma Surge Distributor, House No. B/516, Block B near Government Degree College for Women, Satellite Town, Rawalpindi provided invoice/warranty No. 196 dated 30-09-2021 issued by M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar.
- vi. Store keeper was directed *not to dispose of stock* on Form 3.
- vii. A copy of Test/ Analysis report was sent to M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar and they were directed to provide requisite information in this regard. In response the firm requested for retesting of subject drug sample from Appellate Laboratory, National Institute of Health (NIH), Islamabad.
- viii. Pursuant to the firm's request, the sample was sent to Appellate Laboratory National Institute of Health (NIH), Islamabad from where the sample was declared substandard.

Name of Drug	Batch No.	Name of Manufacturer	Test Report No.	Details of Result of Test/analysis (With protocols of test applied)										
Suspension Pedrol 60ml	E-661	M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	023-P/2023 dated: 5th April 2023	<p>Reference: BP 2017</p> <table border="1"> <thead> <tr> <th><u>ASSAY:</u></th> <th><u>Stated</u></th> <th><u>Found</u></th> <th><u>Limit</u></th> <th><u>%age</u></th> </tr> </thead> <tbody> <tr> <td>Paracetamol</td> <td>120mg/5ml</td> <td>61.09mg/5ml</td> <td>95- 105%</td> <td>50.91%</td> </tr> </tbody> </table> <p>Does not comply with BP-2107</p> <p><u>RESULT:</u></p> <p><u>The above sample is SUB-STANDARD on the basis of test performed.</u></p>	<u>ASSAY:</u>	<u>Stated</u>	<u>Found</u>	<u>Limit</u>	<u>%age</u>	Paracetamol	120mg/5ml	61.09mg/5ml	95- 105%	50.91%
<u>ASSAY:</u>	<u>Stated</u>	<u>Found</u>	<u>Limit</u>	<u>%age</u>										
Paracetamol	120mg/5ml	61.09mg/5ml	95- 105%	50.91%										

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

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

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

Sr.	Summary of the case	
1.	Date of sampling	01-12-2021
2.	Sent to DTL	01-12-2021
3.	Date of receipt in DTL	02-12-2021
4.	Issuance of DTL Report	17-03-2022
5.	Time Extension	PQCB 238 Meeting dated 09-02-2022
6.	DI 1st communication with firm	21-11-2022
7.	Retesting Request	23-11-2022
8.	Fate of retesting request	Allowed 256 th meeting dated 19-01-2023. NIH Substandard (65 days)
9.	Investigation Report of DI	12-06-2023
10.	Permission of SCN	267 th meeting dated 07-09-2023
11.	SC Notice Issued	23-11-2023
12.	Reply of the firm	Not received
13	History (3 years)	52 cases of the firm 02 case of the product (Subject case)

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 5

PQCB R-584/2022

Tehsil Murree, and District Rawalpindi

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, 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 (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan .
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BREIF FACTS OF THE CASE:

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

- i. He, on 30-11-2021 inspected the premises of Main Medicine Store, Syed Muhammad Hussain Government T.B Sanitorium, Samli, Tehsil Murree, District Rawalpindi and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 0000111908 dated 01-12-2021.
- ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Suspension Riam 90ml [Metronidazole Benzoate eq. to Metronidazole 200mg/5ml] Mfg. Date:09-2021 Exp. Date:09-2023 Reg# 027907	E-610	M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	01-74003278/ DTL dated: 12 Jan 2022	Result of test/ analysis with specifications applied BP 2021 <u>PHYSICAL DESCRIPTION:</u> Light yellow colored, viscous suspension with medicinal odour, filled in amber coloured glass bottle with affixed label, sealed with metallic screw cap imprinted with "STANLEY", further packed in labelled outer carton. <u>pH</u> Observed: 4.39 at 25.2 C (Does not comply) Limit: 5.0-6.5 <u>ASSAY:</u> Stated: 200mg/5ml

				Determined: 199.366mg/5ml Percentage 99.68% LIMIT: 95-105% <u>RESULT:</u> <u>The above sample is Substandard on the basis of pH test performed.</u>
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- iii. Medical Superintendent, Syed Muhammad Hussain Government T.B Sanitorium, Samli, Tehsil Murree, District Rawalpindi provided invoice/warranty No. 4568 dated 20-10-2021 issued by M/S Pharma Surge Distributor, house No. B/516, Block B near Govt. Degree College for Women, Satellite Town, Rawalpindi who in turn provided invoice/warranty No.196, dated 30-09-2021 issued by M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan .
- iv. Warrantor Portion was sent to M/S Pharma Surge Distributor, house no. B/516, Block B near Govt. Degree College for Women, Satellite Town, Rawalpindi.
- v. A copy of Test/ Analysis report was sent to M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar and they were directed to provide requisite information in this regard. In response the firm requested for retesting of subject drug sample from Appellate laboratory, National Institute of Health (NIH), Islamabad.
- vi. Pursuant to the firm's request, the sample was sent to Appellate laboratory, National Institute of Health (NIH), Islamabad, from where it was declared **Sub-standard**.

Name of Drug	Batch No.	Name of Manufacturer	Test Report No.	Details of Result of Test/analysis (With protocols of test applied)
Suspension Riam 90ml	E-610	M/s Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	021-P/2023 dated: 16th Feb 2023	Reference: BP 2017 pH: Determined: 4.1 + 0.06 Limit: 5.0-6.5 Does not comply with BP 2017 <u>CONCLUSION:</u> <u>The above sample is SUB-STANDARD quality on the basis of tests performed.</u>

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

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

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

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/s Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar submitted written reply vide reference number nil dated 21-12-2023 as follows:

Reference your kind Letter No:PQCB/R-584/2022 dated 11.12.2023 received on dated 21/12.2023. Please refer to the subject cited above, it is stated that PQCB Board decided to issue Warning to M/S Stanley Pharma 84-B Industrial Estate Hayatabad Peshawar and moreover decided that the subject Drug Sample Riam Suspension 90ml is an oral suspension and slight decrease in pH would have lesser/no clinical impact on the absorption of the product and would not harm to the patients. (PQCB Detailed order report PQCB/R-495/2021) attached.

Moreover We M/S Stanley Pharma Peshawar has rectified the problem of decrease in pH by revising the master Formulation and adjusting the buffering agents like citric acid 0.125mg/5ml (0.0025%) and sodium Citrate 12mg/5ml (0.24%) and now pH remains stable within BP Specification upto its shelf life. We M/S Stanley Pharma Peshawar hereby informed you that previously PQCB Lahore Board considered the case under the section 11 of Drug Act, 1976 in its 255th meeting held on dated 29.12.2022 under the Chairmanship of Secretary Primary & Secondary Healthcare department regarding to cases Reference No's PQCB/R-457,455,456,606,605,619,495,494,496/2021.

Moreover the above said Riam Suspension 90ml Batch No: E-610 Mfg Date 09.2021 & Exp.Date 09.2023 already expired in September 2023 and no more available in market for use.

PQCB Board keeping in view the remedial measures taken by the Firm and lesser clinical impact, the Board after due deliberation and discussion unanimously decided to issue Warning to M/S Stanley Pharma 84-B Industrial Estate Hayatabad Peshawar and moreover decided that the subject Drug Sample Riam Suspension 90ml is an oral suspension and slight decrease in pH would have lesser/no clinical impact on the absorption of the product and would not harm to the patients.

So kindly considered above said opinion of PQCB Board about subject sample that not harm to the patients.

Therefore humble request to may warned us in this regard as per previous PQCB Orders.

Sr.	Summary of the case	
1.	Date of sampling	30-11-2021
2.	Sent to DTL	01-12-2021
3.	Date of receipt in DTL	02-12-2021
4.	Issuance of DTL Report	12-01-2022
5.	Time Extension	N/A
6.	DI 1 st communication with firm	21-11-2022

7.	Retesting Request	23-11-2022
8.	Fate of retesting request	Allowed 256 th meeting dated 19-01-2023. NIH Substandard
9.	Investigation Report of DI	03-03-2023
10.	Permission of SCN	267 th meeting dated 07-09-2023
11.	SC Notice Issued	11-12-2023
12.	Reply of the firm	21-12-2023
13	History (3 years)	52 cases of the firm 16 case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 6

No. POCB/R-299/2022

Tehsil Jand, District Attock

ATTENDANCE

Secretary DQCB Drug Inspector	<p>1. M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar through Chief Executive Officer (CEO), Abdullah Shah</p> <p>2. Abdullah Shah Chief Executive Officer (CEO)/Warrantor</p> <p>3. Imran Khan Production Incharge</p> <p>4. Umar Kamran Marwat Quality Control Incharge</p> <p>of M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar.</p>
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Tehsil Jand, District Attock reported that:-

- i. He, on 23-02-2022 inspected the premises of M/S Zakria Pharmacy, Jhamat Chowk, Tehsil Jand, District Attock and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 0000119638 dated 25-02-2022.
- ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Suspension Riam 90ml [Metronidazole Benzoate eq. to Metronidazole 200mg/5ml] Mfg. Date: 12-2021 Exp. Date: 12-2023 Reg# 027907	E-799	M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	01-74004100/ DTL dated: 28 Apr 2022	Result of test/ analysis with specifications applied BP 2022 <u>PHYSICAL DESCRIPTION:</u> Light yellow colored, viscous suspension with medicinal odour, filled in amber coloured glass bottle with affixed label, sealed with metallic screw cap imprinted with "STANLEY", further packed in labelled outer carton.. pH Observed: 4.68 (Does not comply) Limit: 5.0-6.5 <u>ASSAY:</u>

				<p>Stated: 200mg/5ml</p> <p>Determined: 206.678mg/5ml</p> <p>Percentage 103.34%</p> <p>LIMIT: 95-105%</p> <p><u>RESULT:</u></p> <p><u>The above sample is Substandard on the basis of pH test performed.</u></p>
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- iii. M/S Zakria Pharmacy, Jhamat Chowk, Tehsil Jand, District Attock provided invoice/warranty No. 6625 dated 16-02-2022 issued by M/S Rabbani Traders Attock, who in turn provided invoice/warranty No.2296, dated 06-01-2022 issued by M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan
- iv. Warrantor Portion was sent to M/S Rabbani Traders Attock.
- v. A copy of Test/ Analysis report was sent to M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar and they were directed to provide requisite information in this regard. In response the firm requested for retesting of subject drug sample from Appellate laboratory, National Institute of Health (NIH), Islamabad.
- vi. The firm then appealed for withdrawal of its request for re-testing. The Provincial Quality Control Board accepted the firm's withdrawal request in its 251st meeting dated 22-09-2022.

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

- i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
- ii. **Issuance of false warranty**

3. Showcause was issued to accused person(s) vide dated 15/05/2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 22-05-2023 stating that:

Reference your kind Letter No: PQCB/R-299/2022 dated 15.05.2023 received on dated 22.05.2023.

WS Stanley Pharma Peshawar withdrawal retest request in its meeting dated 22.09.2022 due to the reason that PQCB Board decided to issue Warning to WS Stanley Pharma 84-B Industrial Estate Hayatabad Peshawar and moreover decided that the subject Drug Sample Riam Suspension 90ml is an oral suspension and slight decrease in pH would have lesser/no clinical impact on the absorption of the product and would not harm to the patients. (PQCB Detailed order report PQCB[R-456/2021) attached.

Moreover We M/S Stanley Pharma Peshawar has rectified the problem of decrease in pH by revising the master Formulation and adjusting the buffering agents like citric acid and sodium Citrate 12mg/5ml (0.24%) and now pH remains stable within BP Specification up to its shelf life.

We M/S Stanley Pharma Peshawar hereby informed you that previously PQCB Lahore Board considered the case under the section I I of Drug Act, 1976 in its 255th meeting held on dated 29.12.2022 under the Chairmanship of Secretary

Primary & Secondary Healthcare department regarding to cases Reference No's PQCWR-457,455,456,606,605,619,495,494,496/2021.

PQCB, board keeping in view the remedial measures taken by the Firm and lesser clinical impact, the Board after due deliberation and discussion unanimously decided to issue warning to M/s Stanley Pharma 84-B industrial estate Hayatabad Peshawar and moreover decided that the subject drug sample Riam Suspension 90ml is an oral suspension of the product and would not harm to the patients.

So, kindly considered above said opinion of PQCB board about subject sample that not harm to the patients. Therefore humble request to may warned us in this regard. We have verified the names of accused persons.

Hope you will give positive expeditious response.

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	23-02-2022
2	Sample Sent to DTL (Form-6)	25-02-2022
3	Receipt Date in DTL	01-03-2022
4	Issuance of DTL Report	28-04-2022
5	Time Extension	N/A
6	DI First Communication with Firm	22-06-2022
7	Retesting Request	18-07-2022
8	Investigation Report by DI	31-12-2022
9	SCN Permission	257 th meeting dated 07-02-2023
10	Show Cause Notice Issued	15-05-2023

12	History (3 years)	Firm's Reported: 79
		Product's Reported: 22

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 7

No. POCB/R-606/2022

Madina Town Faisalabad

ATTENDANCE

<p>Secretary DQCB</p> <p>Drug Inspector</p>	<p>1. M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar through Chief Executive Officer (CEO), Abdullah Shah</p> <p>2. Abdullah Shah Chief Executive Officer (CEO)/Warrantor</p> <p>3. Imran Khan Production Incharge</p> <p>4. Umar Kamran Marwat Quality Control Incharge</p> <p>of M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar.</p>
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Madina Town, District Faisalabad reported that: -

- i. He, on 17-06-2022, inspected the business premises of M/s Stanley Pharmaceuticals situated at House No. 1 B/2, Madina Town District Faisalabad, took five different types of drug sample on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Faisalabad vide memorandum no. 130512 dated 18-06-2022.
- ii. The subject 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	TRA No. & Date	DTL Test Report Result												
Capsule Ferfolic [Each capsule contains: Ferrous Sulphate (U.S.P) ... 200mg, Folic Acid (B.P) 0.1mg]	F-865	M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar.	01-68016545/DTL dated: 19-08-2022	<p>Analysis with specifications applied: MS</p> <p>DESCRIPTION: Off-white colored powder encapsulated in red colored hard gelatin capsules, contained in PVC/Alu blister of 10 units packed in outer hard carton.</p> <p>IDENTIFICATION Ferrous Sulphate and Folic Acid are identified.</p> <p>ASSAY:</p> <table border="1"><thead><tr><th>Generic</th><th>Stated Potency</th><th>Determined Potency</th><th>Percentage</th><th>Reference Limit (MS)</th><th>Remarks</th></tr></thead><tbody><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></tbody></table>	Generic	Stated Potency	Determined Potency	Percentage	Reference Limit (MS)	Remarks						
Generic	Stated Potency	Determined Potency	Percentage	Reference Limit (MS)	Remarks											

Mfg Date: Dec-2021				Ferrous Sulphate	200 mg / Capsule	211.066 mg / Capsule	105.533 %	90 - 110%	Complies
				Folic Acid	0.1 mg / Capsule	0.0736 mg/Capsule	73.6 %	90-115%	Does Not Comply
Expiry Date: Dec-2024				RESULT: Given sample is declared Sub-Standard with regards to Assay.					
Regn No. 004340									

- iii. Proprietor of M/s Stanley Pharmaceuticals situated at House No. 1 B/2, Madina Town District Faisalabad provided warranty bearing No. 3460 dated 29-03-2022 issued by M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to 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 with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis reports of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to firm's request, the Provincial Quality Control Board in its 255th Meeting held on 29-12-2022, decided to turn down the firm's request for retesting of the subject sample.

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

- i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
- ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 30-08-2023

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 06-09-2023 stating that:

Dear Sir.

We have received your Kind letter No.R-606/2022 dated 30.08.2023 received on 06.0 .20

PQCB decided to turn down the Retest Request in its 255th meeting held on dated 29.12.2022 on the basis that the Firm has been observed that the Limits of Assay Test of Folic Acid is 90-130% which is Typographical mistake in Finished Products Analysis report. but in data (Manufacturer Specifications) provided to DTL by firm the Limits of Assay of Folic Acid is 90-115%

Therefore we requested to review the case & please provide us re-test chance from National

institute of Health as per drugs laws rules framed under.

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	17-06-2022
2	Sample Sent to DTL (Form-6)	16-06-2022
3	Receipt Date in DTL	23-06-2022
4	Issuance of DTL Report	19-08-2022
5	Time Extension	N/A
6	DI First Communication with Firm	20-09-2022
7	Retesting Request	26-09-2022
8	Investigation Report by DI	06-07-2023
9	SCN Permission	265-M meeting
10	Show Cause Notice Issued	30-08-2023
11	History (3 years)	Firm's Reported: 79
		Product's Reported: 01

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 8

PQCB-R-789/2022

Benazir Bhutto Hospital, Rawalpindi

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/S Stanley pharmaceuticals (Pvt.) Ltd., 84-B, Industrial Estate, Hayatabad, Peshawar, Pakistan. Through its Chief Executive Officer 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 (pvt) ltd., 84-b, industrial estate, Hayatabad, Peshawar, Pakistan.
Drug Inspector	

BREIF FACTS OF THE CASE:

Provincial Inspector of Drugs, Benazir Bhutto Hospital, Rawalpindi reported that:-

- i. She on 26-09-2022 inspected the premises of Main Medical store Benazir Bhutto hospital took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory Punjab, Rawalpindi vide memo No.0000141707 Dated 26-09-2022 .
- ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory Punjab, Rawalpindi as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result					
Suspension Manacid 120ML (Each 5ML Contains: Aluminium Hydroxide:215 MG, Magnesium Hydroxide: 80 MG, Simethicone (Polydimethylsiloxane):25MG Mfg. Date: 09-2022 Exp. Date: 09-2024 Reg # 001425	P-443	M/S Stanley pharmaceuticals (Pvt.) ltd., 84-b, industrial estate, Hayatabad, Peshawar, Pakistan.	01- 74005887/DTL Dated:30-11- 2022 (Rawalpindi)	Specification applied: USP 2022 <u>PHYSICAL DESCRIPTION:</u> Off-white colored viscous liquid filled in Ambered colored glass bottle with affixed label, sealed with silver aluminium screw cap on which company name is printed, further packed in outer labeled carton. pH: Observed:8.88 at 25.0 °C (DOES NOT COMPLY) Limit:7.0-8.6 <u>ASSAY:</u>					
				<table border="1"><thead><tr><th>Name</th><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr></thead></table>	Name	Stated	Determined	Percentage	Limit
Name	Stated	Determined	Percentage	Limit					

				Aluminium Hydroxide	215 mg/5ml	198.332 mg/5ml	92.25 %	90-115%
				Magnesium Hydroxide	80 mg/5ml	75.406 mg/5ml	94.26 %	90-115%
				Simethicone	25 mg/5ml	24.115 mg/5ml	96.46 %	85-115%
<p>RESULT: The above sample is "Substandard" with respect to pH Test Performed.</p>								

- iii. The Drug Inspector of Main Medicine store Benazir Bhutto Hospital, Rawalpindi provided the invoice/Warranty No. SA22092110 dated 21-09-2022 issued by M/S Sudais Associates Street no. 07, house no. A1 Khan Bahadar Colony Duran Pur Peshawar-Pakistan.
- iv. Warrantor Portion was sent to M/S Sudais Associates Street no. 07, house no. A1 Khan Bahadar Colony Duran Pur Peshawar-Pakistan.
- v. M/s Sudais Associates Street no. 07, house no. A1 Khan Bahadar Colony Duran Pur Peshawar-Pakistan provided warranty/invoice No.1323 Dated 20-09-2022 issued by M/s Stanley pharmaceuticals (Pvt.) ltd., 84-b, industrial estate, Hayatabad, Peshawar, Pakistan.
- vi. A copy of Test/ Analysis reports was sent to M/S Stanley pharmaceuticals (Pvt.) ltd., 84-b, industrial estate, Hayatabad, Peshawar, Pakistan. In response, the firm challenged the report and requested for re-testing of the sample from Appellate Laboratory.
- vii. Pursuant to the retesting request of the firm, sample was sent to Appellate Laboratory, National Institute of Health (NIH), Islamabad from where the sample was declared **substandard**.

Name of Drug	Batch No.	Name of Manufacturer	Test Report No.	Details of Result of Test/analysis (With protocols of test applied)
Suspension Manacid 120ML	P-443	M/S Stanley pharmaceuticals (pvt) ltd., 84-b, industrial estate, Hayatabad, Peshawar, Pakistan.	0156-P/2023	<p>Reference: USP-39</p> <p>pH:</p> <p>Determined: 8.9 ± 0.06</p> <p>LIMIT: 7.0-8.6</p> <p>(Does not comply with USP-39)</p> <p>RESULT:</p> <p>The above sample is SUB-STANDARD on the basis of tests performed.</p>

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

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

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

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/S Stanley pharmaceuticals (pvt) Ltd., 84-b, industrial estate, Hayatabad, Peshawar, Pakistan submitted written reply vide letter dated 25-06-2024 as follows:

We have received your Kind letter pqcb/r-789/2022 dated 10.06.2024 received on 25.06/2024 regarding our product namely Manacid Suspension 120ml bearing Batch No.P-443 Mfg. Date 09-2022 and Expiry Date 09- 2024. The DTL Rawalpindi & NIH analyst has declared drug sample as Substandard on the basis of PH test 775 result.

The government analyst has determined PH 8.88 which does not complies the specification that is

7.0-8.6 USP NIH analyst has determined PH 8.90 which does not complies the specification that is

27.0-8.6 USP.

In this regards we have drawn your attention on following points.

Manacid Suspension is Nonsystemic antacid Manacid suspension having Active Pharmaceutical Ingredients like Aluminium Hydroxide 215mg/Magnesium Hydroxide 80mg and Simethicone 25mg per 5ml. All three API's are usually alkaline substances and are used for neutralizing excess acid n the stomach of patients suffering from hyperacidity. Slightly more alkaline PH helps to neutralize the stomach acid and prevents hyperacidity more effectively. We have checked PH of both warrantor portion and Retain sample of same Batch No P-443, confirmed PH 8.45.

It is requested to accept our justification/ clarification and release the product for consumption as there is no patient risk involved in this case.

Sr.	Summary of the case	
1.	Date of sampling	26-09-2022
2.	Sent to DTL	26-09-2022
3.	Date of receipt in DTL	01-10-2022
4.	Issuance of DTL Report	30-11-2022
5.	Time Extension	N/A
6.	DI 1st communication with firm	17-12-2022
7.	Retesting Request	19-12-2022
8.	Fate of retesting request	Allowed (NIH Substandard)
9.	Investigation Report of DI	03-05-2024

10.	Permission of SCN	280 th meeting dated 16-05-2024
11.	SC Notice Issued	10-06-2024
12.	Reply of the firm	25-06-2024
13	History (3 years)	52 cases of the firm 02 cases of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 9

No. POCB/ R-741/2022

Lyallpur Town Faisalabad

ATTENDANCE

Secretary DQCB Drug Inspector	<p>1. M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar through Chief Executive Officer (CEO), Abdullah Shah</p> <p>2. Abdullah Shah Chief Executive Officer (CEO)/Warrantor</p> <p>3. Imran Khan Production Incharge</p> <p>4. Umar Kamran Marwat Quality Control Incharge</p> <p>of M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar.</p>
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Lyallpur Town, District Faisalabad reported that: -

- i. The then drug inspector, on 04-07-2022 inspected the premises of Medicine Store of Punjab Health Facilities Management Company, situated at Civil Lines near Deputy Commissioner Office, District Faisalabad, took fifteen different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 132579 dated 05-07-2022.
- ii. The subject drug sample, 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 No. & Date	DTL Test Report Result				
Uncoated Tablet Bendazol [Each uncoated tablet contains: (Albendazole USP) 200mg] Mfg. Date:	H-395	M/s Stanley Pharmaceuticals (Pvt.) Ltd., 84-B Industrial Estate Hayatabad, Peshawar.	01-68016929/DTL dated 01-09-2022	<p>Results of test/analysis with specifications applied: MS</p> <p>DESCRIPTION: White coloured, round shaped, flat tablets engraved STANLEY plain from other side, contained in ALU-PVC packing of 02 units, packed in outer ha</p> <p>IDENTIFICATION: Albendazole is identified.</p> <p>ASSAY:</p> <table border="1"><tr><td>Stated</td><td>200mg / Tablet</td></tr><tr><td>Determined</td><td>217.561 mg / Tablet</td></tr></table>	Stated	200mg / Tablet	Determined	217.561 mg / Tablet
Stated	200mg / Tablet							
Determined	217.561 mg / Tablet							

May-2022	Exp. Date: May-2026	Regn. No: 006095	Percentage	108.781 % (Complies)							
			Limit	90 – 110% (Manufacturer's Specifications)							
			<p>DISSOLUTION TEST: Does not comply with Manufacturer's acceptance criteria. Test as detailed below:</p> <p>Tolerance Limit: Not less than 80% of the stated amount is dissolved in 30 minutes.</p>								
			Level	Unit Tested	Acceptance Criteria						Average
			S1	6	Each unit is not less than Q+5%						
				Time	UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6	
				After 30 minutes	70.6%	<u>50.9%</u>	70.6%	<u>58.1%</u>	68.8%	71.1%	
			S2	6	Average of 12 units (S1+S2) is \geq Q and no unit is $<$ Q-15%						70.22%
				Time	UNIT 7	UNIT 8	UNIT 9	UNIT 10	UNIT 11	UNIT 12	
				After 30 minutes	77.0%	79.9%	<u>59.2%</u>	78.8%	84.1%	73.5%	
			<p>NOTE: Percentage release of drug among all six units tested at first level is found (Q+5%) of the stated amount of Albendazole. Furthermore, Average of 12 units is found (75%) and drug release among three units is found less than Q-15%. Therefore, Dissolution test is stopped at second stage. (Does Not Comply)</p> <p>RESULT: Given sample is Sub-Standard with regards to Dissolution Test.</p>								

- iii. The District Manager, Punjab Health Facilities Management Company, District Faisalabad provided warranted Delivery Challan No. PHFMC 019-22 dated 24-06-2022 issued by M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar as a proof of its purchase.
- iv. Warrantor portion of the subject drug sample was sent to 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 with directions to explain their position and provide requisite

information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

- vi. Pursuant to the request of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar, the retesting request of the subject drug sample was considered in 20th Committee Meeting of the Board held on 17-05-2023 and the retest request of the subject drug sample was allowed. Moreover, in the light of letter no. F. No. 1-20/2-Misc/2023-DCTMD dated 13-04-2023 by National Institute of Health, Islamabad it was observed by the Board in its 261st meeting held on 25-05-2023 that the subject batch no. H-395 has already been declared **Sub-standard** from NIH, Islamabad twice, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result
Tablet Bendazole 200mg	H-395	M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	0280-P/2022 dated: 4th January 2023	<p>Reference: Manufacturer Specification</p> <p><u>DISSOLUTION TEST:</u></p> <p>Determined: All the six tablets are deviated from the limit</p> <p>Limit: Not less than 80% of the stated amount is dissolved in 30 minutes.</p> <p>Does not comply with manufacturer specification.</p> <p><u>RESULT:</u></p> <p>The sample is of Sub-Standard quality on the basis of test performed.</p>
Tablet Bendazole 200mg	H-395	M/s Stanley Pharmaceuticals (Pvt) Ltd., 84-B Industrial Estate Hayatabad, Peshawar.	015-P/2023 dated 24-03-2023	<p>Reference: Manufacturer Specification</p> <p><u>DISSOLUTION TEST:</u></p> <p>Determined: All the six tablet deviated from the limit.</p> <p>Limit: Not less than 80% (Q) of the stated amount is dissolved in 30 minutes.</p> <p>Does not comply with manufacturer specification.</p> <p><u>REMARKS:</u> Percentage release of drug among all six units tested at first level is found less than 85% (Q+5%) of the stated amount of albendazole. Moreover, drug release in two unit are found less than Q-25% at S1 level. Therefore, Dissolution test is stopped at first stage.</p> <p><u>CONCLUSION:</u> The sample is of Sub-Standard quality on the basis of test performed.</p>

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

- i. Manufacturing for Sale / Sale of Sub-standard Drug.
- ii. Issuance of false warranty.

3. Showcause was issued to accused person(s) vide dated 28-02-2024

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 07-03-2024 stating that:

Dear Sir.

We have received your kind letter No: PQCB/R-741/2022 dated 28.02.2024 received on dated 07.03.2024.

We M/S Stanley Pharma Peshawar hereby explain our position regarding the subject, that we have the capacity manufactured Bendazol Tablets Batch No H-395 at once not in portion wise, there is no chance of unequal distribution of API (Albendazole) in Finished product with strong evidence that the Product Bendazole 200mg Tablets (Albendazole) of same Batch No: H-395 declared STANDARD QUALITY by DTL Lahore Bahawalpur & Multan (Reports attached).

We M/S Stanley Pharma Peshawar hereby informed you that the same Product Tablet Bendazol

200mg(Albendazole 200mg) Batch No H-395 declared Standard Quality more than three DTLs like DTL Lahore, DTL Multan & DTL Bahawalpur of samples received from different stations(Medical Store Depot/PHFMC Rajanpur/PHFMC DG Khan/DHA Lodhran & Sahiwal) reports attached.

Name /Designation

Mr. Abdullah Shah (warrantor)

Imran Khan (Production In charge)

Umar kamran Marwat(QC Incharge)

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	04-07-2022
2	Sample Sent to DTL (Form-6)	05-07-2022
3	Receipt Date in DTL	06-07-2022
4	Issuance of DTL Report	01-09-2022

5	Time Extension	N/A
6	DI First Communication with Firm	30-01-2023
7	Retesting Request	06-02-2023
8	Investigation Report by DI	11-10-2023
9	SCN Permission	271- Meeting
10	Show Cause Notice Issued	28-02-2024
12	History (3 years)	Firm's Reported: 58
		Product's Reported:20

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 10

No. PQCB/ R-716/2022

Lyallpur Town Faisalabad

ATTENDANCE

<p>Secretary DQCB</p> <p>Drug Inspector</p>	<p>1. M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar through Chief Executive Officer (CEO), Abdullah Shah</p> <p>2. Abdullah Shah Chief Executive Officer (CEO)/Warrantor</p> <p>3. Imran Khan Production Incharge</p> <p>4. Umar Kamran Marwat Quality Control Incharge</p> <p>of M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar.</p>
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Lyallpur Town, District Faisalabad reported that: -

- i. The then drug inspector, on 10-09-2022 inspected the premises of Main Medicine Store Chief Executive Officer, District Health Authority, District Faisalabad, took sixteen different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 139867 dated 12-09-2022.
- ii. The subject drug sample, 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 No. & Date	DTL Test Report Result				
Uncoated Tablet Bendazol (Each uncoated tablet contains: (Albendazole USP) 200mg)	H-395	M/s Stanley Pharmaceuticals (Pvt) Ltd., 84-B Industrial Estate Hayatabad, Peshawar.	01-68018536/DTL dated 24-10-2022	<p>Results of test/analysis with specifications applied: MS</p> <p>DESCRIPTION: White colored, round shaped, flat tablets engraved STANLEY on one side and plain from other side, contained in ALU-PVC packing of 02 units, packed in outer hard carton.</p> <p>IDENTIFICATION: Albendazole is identified.</p> <p>ASSAY:</p> <table border="1"><tr><td>Stated</td><td>200mg / Tablet</td></tr><tr><td>Determined</td><td>210.673 mg / Tablet</td></tr></table>	Stated	200mg / Tablet	Determined	210.673 mg / Tablet
Stated	200mg / Tablet							
Determined	210.673 mg / Tablet							
Mfg Date: May-2022								

Exp. Date:
May-2026

Regn. No:
006095

Percentage	105.336 % (Complies)
Limit	90 – 110% (Manufacturer's Specifications)

DISSOLUTION TEST: Does not comply with Manufacturer's acceptance criteria of Dissolution Test as detailed below:

Tolerance Limit: Not less than 80% (Q) of the stated amount is dissolved in 30 minutes.

Level	Unit Tested	Acceptance Criteria						Remarks	
S1	6	Each unit is not less than Q+5%						Does Not Comply	
		Time	UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5		UNIT 6
		After 30 minutes	12.6%	22.3%	11.1%	10.3%	21.4%		12.5%

NOTE: Percentage release of drug among all six units tested at first level is found less than 80% (Q+5%) of the stated amount of Albendazole. Furthermore, percentage of drug release among all six units is found less than Q-25%. Therefore, Dissolution test is stopped at first stage. **(Does Not Comply)**

RESULT: Given sample is **Sub-Standard** with regards to Dissolution Test.

- iii. Storekeeper Main Medicine Store Chief Executive Officer, District Health Authority, District Faisalabad provided Invoice/ warranty No. 1900777 dated 30-08-2022 issued by M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar as a proof of its purchase.
- iv. Warrantor portion of the subject drug sample was sent to 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 with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to firm's request, the Provincial Quality Control Board in its 20th committee meeting held on 17-05-2023, after due deliberation and discussion unanimously decide to turn down the firm's request for retesting of the subject drug sample. Firm's review petition against retesting request orders, has also been turned down in 267th meeting held on 07-09-2023.

2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned

accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

- i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
- ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) **vide dated**. 01-03-2024

REPLY OF SHOW CAUSE NOTICE

*Firm replied to the show cause notice vide letter **Reference no. nil dated** 07-03-2024 stating that:*

Dear Sir,

We have received your kind letter No: PQCB/R-716/2022 dated 01.03.2024 received on dated 07.03.2024.

We M/S Stanley Pharma Peshawar hereby explain our position regarding the subject, that we have the capacity to manufactured Bendazol Tablets Batch No H-395 at once not in portion wise, there is no chance of unequal distribution of API (Albendazole) in Finished product with strong evidence that the Product Bendazole 200mg Tablets (Albendazole) of same Batch No: H-395 declared STANDARD QUALITY by DTL Lahore Bahawalpur & Multan (Reports attached)

We M/S Stanley Pharma Peshawar hereby informed you that the same Product Tablet Bendazol

200mg (Albendazole 200mg) Batch No H-395 declared Standard Quality more than three DTLs like DTL Lahore, DTL Multan & DTL Bahawalpur of samples received from different stations (Medical Store Depot/PHFMC Rajanpur/PHFMC DG Khan/DHA Lodhran & Sahiwal) reports attached.

Name /Designation

Mr.Abdullah Shah (warrantor)

Imran Khan (Production In charge)

Umar kamran Marwat(QC Incharge)

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	10-09-2022
2	Sample Sent to DTL (Form-6)	12-09-2022

3	Receipt Date in DTL	14-09-2022
4	Issuance of DTL Report	24-10-2022
5	Time Extension	N/A
6	DI First Communication with Firm	26-11-2022
7	Retesting Request	23-01-2023 (turned down, Time barred)
8	Investigation Report by DI	05-07-2023
9	SCN Permission	276 th meeting
10	Show Cause Notice Issued	01-03-2024
11	History (3 years)	Firm's Reported: 58
		Product's Reported: 20

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 11

No. PQCB/ R-359/2022

Tehsil and District Jhelum

ATTENDANCE

Secretary DQCB Drug Inspector	<p>1. M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar through Chief Executive Officer (CEO), Abdullah Shah</p> <p>2. Abdullah Shah Chief Executive Officer (CEO)/Warrantor</p> <p>3. Imran Khan Production Incharge</p> <p>4. Umar Kamran Marwat Quality Control Incharge</p> <p>of M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar.</p>
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BRIEF FACTS OF THE CASE

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

- i. His predecessor, on 20-06-2022 inspected the premises of Main Medicine Store, Office of the CEO/DHA, District health Authority Office, Jhelum and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 0000130682 dated 20-06-2020.
- ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tablet Bendazole 200mg [Albendazole 200mg] Mfg. Date: 05-2022 Exp. Date: 05-2026 Reg# 006095	H-395	M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	01-74004801/ DTL dated: 20 Aug 2022	Result of test/ analysis with specifications applied MS <u>PHYSICAL DESCRIPTION:</u> White to off-white coloured, round shaped, flat tablets with beveled edges, engraved "STANLEY" on one side and plain from other side, packed in Alu/PVC blister of 1x2 tablets, further packed in labelled outer carton. <u>UNIFORMITY OF WEIGHT:</u> Result: All 20 units comply with the Test. Limit: \pm 7.5% <u>DISSOLUTION TEST:</u> Tolerances: NLT 80% of the stated amount is dissolved in 30 minutes.

S1	U1	U2	U3	U4	U5	U6
	69.05	69.35	68.61	69.05	73.02	72.73

(Does not Comply)

S2	U7	U8	U9	U10	U11	U12	Av (S1+S2)
	73.07	52.94	60.99	59.38	48.71	70.86	65.65

(Does not Comply)

S3	U13	U14	U15	U16	U17	U18	Av (S1+S2+S3)
	73.19	53.12	69.43	51.65	62.53	53.95	64.70
	U19	U20	U21	U22	U23	U24	
	70.05	69.84	50.61	78.21	66.08	66.29	

(Does not Comply)

ASSAY:

Stated: 200mg/Tablet

Determined: 213.437 mg/Tablet

Percentage 106.72%

LIMIT: 90-110%

RESULT:

The above sample is Substandard as it failed to comply with the Dissolution Test.

- iii. Storekeeper, Main Medicine Store, Office of the CEO/DHA, District Health Authority Office, Jhelum provided invoice/warranty No. 1500038 dated 10-06-2022 issued M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan
- iv. Warrantor Portion was sent to M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar-Pakistan.
- v. A copy of Test/ Analysis report was sent to M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar and they were directed to provide requisite information in this regard. In response the firm requested for retesting of subject drug sample from Appellate Laboratory, National Institute of Health (NIH), Islamabad.

vi. Pursuant to the firm's request, the sample was sent to Appellate Laboratory National Institute of Health (NIH), Islamabad from where the sample was declared substandard.

Name of Drug	Batch No.	Name of Manufacturer	Test Report No.	Details of Result of Test/analysis (With protocols of test applied)
Tablet Bendazole 200mg	H-395	M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	0280-P/2022 dated: 4th January 2023	<p>Reference: MS</p> <p><u>DISSOLUTION TEST</u></p> <p>Determined:</p> <p>All the six tablets deviated from the limit</p> <p>Limit:</p> <p>Not less than 80% of the stated amount is dissolved in minutes. <u>(DOES NOT COMPLY WITH MANUFACTURERS' SPECIFICATIONS)</u></p> <p><u>RESULT:</u></p> <p><u>The above sample is SUB-STANDARD on the basis of tests performed.</u></p>

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

- i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
- ii. **Issuance of false warranty.**

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

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	20-06-2022
2	Sample Sent to DTL (Form-6)	20-06-2022
3	Receipt Date in DTL	22-06-2022
4	Issuance of DTL Report	20-08-2022

5	Time Extension	N/A
6	DI First Communication with Firm	30-08-2022
7	Retesting Request	05-09-2022
8	Investigation Report by DI	04-02-2023
9	SCN Permission	258 th meeting dated 05-04-2023
10	Show Cause Notice Issued	01-06-2023
11	History (3 years)	Firm's Reported: 79
		Product's Reported: 38

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 12

PQCB/R-541/2022

Tehsil & District Gujrat

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">1. M/S Stanley Pharmaceuticals Pvt. Ltd. Plot No. 84-B Industrial Estate Jamrud Road, Hayatabad Peshawar through its Chief Executive Officer Abdullah Shah2. Abdullah Shah Chief Executive Officer/ Warrantor3. Imran Khan Production Incharge4. Umar Kamran Marwat Quality Control Incharge <p>of M/S Stanley Pharmaceuticals Pvt. Ltd. Plot No. 84-B Industrial Estate Jamrud Road, Hayatabad Peshawar.</p>
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BRIEF FACTS OF THE CASE:

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

- He, on 23-07-2022, inspected the premises of Medicine Store CEO DHA Gujrat Fawara Chowk, Gujrat and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo. No. 134234, dated 23-07-2022.
- 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
Uncoated Tablet, Bendazol [Each uncoated tablet contains: (Albendazole USP)...200mg] Mfg Date: Jun 2022 Exp Date: Jun 2026 Registration No. 006095	H-399	M/S Stanley Pharmaceuticals Pvt. Ltd. Plot No. 84-B Industrial Estate Hayatabad Peshawar.	01-68017558/DTL Dated. 29-09-2022
DTL Test Report Result			

Analysis with specifications applied: MS

Description:

White colour round shaped, flat tablets engraved STANLEY on one side and plain from other side, contained in ALU-PVC packing of 02 units, packed in outer hard carton.

Identification:

Albendazole is identified.

Assay:

Stated: 200mg/ Tablet Determined: 208.776 mg/ Tablet

Percentage: 104.388% (Comply) Limit: 90-110% (Manufacturer's Specifications)

Dissolution Test:

Does not comply with the BP and Manufacturer's acceptance criteria of Dissolution Test as detailed below:

Tolerance Limit: Not less than 80% of the stated amount is dissolved in 30 minutes.

Level	Unit Tested	Acceptance criteria						Remarks
S1	6	Each Unit is not less than Q + 5%						Does not Comply
	Time	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	
	After 30 minutes	11.8%	15.2%	12.5%	12.4%	7.3%	13.2%	

NOTE: Percentage release of drug among all six units tested at first level is found less than 80% (Q + 5) of the stated amount of Albendazole. Furthermore, percentage of drug release among all six units is found less than Q-25%. Therefore, Dissolution test is stopped at first stage. **(Does not comply)**

Result: Given sample is **Sub-standard** on the basis of **Dissolution Test**.

- iii. Medicine Store CEO DHA Gujrat Fawara Chowk, Gujrat provided Invoice/warranty/ bill no. 1500704, dated 04-07-2022 issued by M/S Stanley Pharmaceuticals Pvt. Ltd. Plot No. 84-B Industrial Estate Jamrud Road, Hayatabad Peshawar as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S Stanley Pharmaceuticals Pvt. Ltd. Plot No. 84-B Industrial Estate Jamrud Road, Hayatabad Peshawar.
- v. A copy of test report was sent to M/S Stanley Pharmaceuticals Pvt. Ltd. Plot No. 84-B Industrial Estate Jamrud Road, Hayatabad Peshawar with directions to explain their position and provide requisite information in this regard.

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

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

3. Show cause notice(s) issued to accused person(s) on 08-06-2023.

Reply of the firm to show cause notice vide letter dated 06-03-2023:

Dear Sir,

We have received your kind letter No: PQCB/R-541/2022, dated 08.06.2023 received on Please refer to the subject cited above, it is stated that we M/S Stanley Pharma Peshawar have requested for Retest chance From National institute of Health as per drugs laws rules framed under on dated 06.03.2023 regarding to Muhammad Akram Rana (Drug Controller Gujrat) Reference Letter No:36/DS dated 02.03.2023 received on dated 06.03.2023 applied for retest chance on the same day (Photocopy of Letters attached). PQCB Lahore still not issue us letter regarding to adduced Evidence S under section 22(4) of the Drugs Act, 1976. Our retest chance from National institute of Health as per drugs laws rules framed under still pending for entertained.

We M/S Stanley Pharma Peshawar hereby explain our position regarding the subject, that we have the capacity to manufactured Bendazol Tablets Batch No H-399 at once not in portion wise, there is no chance of unequal distribution of API(Albendazole) in Finished product.

DTL FAISALABAD regarding our product namely Bendazole Tablet 200mg(Albendazol 200mg) bearing Batch No. H-399 Mfg. Date 06-2022 and Expiry Date 06-2026. The said laboratory analyst has declared drug sample as Substandard on the basis of Dissolution Test.

We M/S Stanley Pharma Peshawar hereby informed you that the same Product Tablet Bendazol 200mg(Albendazole 200mg) Batch No H-399 declared Standard Quality more than three DTLs like DTL Bahawalpur, DTL. Rawalpindi, DTL Faisalabad & DTL Multan of samples received from different stations(Rahim Yar Khan, Chakwal,PHFMC, Toba Tek Singh) reports attached.

Therefore request you to may Warned us in this regard on the basis of above said reasons.

4. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 06-2022**
- **Exp. Date: 06-2026**
- **Sampling date (Form 4): 23-07-2022**
- **Sent to DTL (Form 6): 04-08-2022**
- **Date of receipt in DTL: 05-08-2022**
- **DTL Report Date (Form 7): 29-09-2022**
- **DI 1st intimation to firm: 10-10-2022**
- **Retesting request if any: 06-03-2023**
- **Fate of Retesting: Not Entertained**
- **Investigation report Dated: 13-03-2023**
- **Permission of SCN: 258th meeting dated 05-04-2023**
- **SCN Issued: 08-06-2023**
- **Reply of the firm: Yes**
- **History (3 years) Firm: 52 cases**

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Product: 20 cases

Flaws observed in case file: Date of Form-6 as investigation report is 23-07-2022. However, date of Form-6 as per DTL report is 04-08-2022.

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 13

[PQCB/R-398/2023](#)

Tehsil & District Mandi Bahauddin

ATTENDENCE

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

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

- i. He, on 01-04-2023, inspected the premises of Main Medicine Store Office of Chief Executive Officer District Health Authority Mandi Bahauddin, took different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 162589 dated 01-04-2023.
- ii. The subject drug sample, after test/ analysis was declared **Substandard & Misbranded** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report No. & Date	DTL Test Report Result
Uncoated Tablet. Bendazol [Each uncoated tablet contains: (Albendazole USP) 200mg) Mfg Date: March-2023	K-296	M/s Stanley Pharmaceuticals (Pvt) Ltd., 84-B Industrial Estate Hayatabad, Peshawar-Pakistan	01-68023587/ DTL dated 23-05-2023	<p><u>Results of test/analysis with specifications applied:</u> USP 2023</p> <p><u>DESCRIPTION:</u> White colored, round shaped, flat tablets engraved STANLEY on one side and plain from other side, contained in ALU-PVC packing of 02 units, packed in outer hard carton.</p> <p><u>NOTE:</u> As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states “all registration holders shall follow official pharmacopeial specifications for all such formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia”. Product specifications of the given sample is “(Mfg. Stanley Specifications)” and it is manufactured after the expiration of timeline to apply such specifications despite the availability of Albendazole tablet’s monograph in USP 2022 and 2023, so the manufacturer’s claim regarding product specifications is in contradiction to DRAP circular and in</p>

Exp. Date:
March-2027

Regn. No:
006095

violation to Drugs Act 1976. **(Does not Comply)**

UNIFORMITY OF DOSAGE UNIT (Weight Variation):

Complies the acceptance criteria of Uniformity of dosage unit (weight variation) as per USP 2023.

(Average weight of Tablet= 494.29 mg)

Acceptance Criteria: Acceptance value \leq L1%=15%

Determined: Acceptance value= 7.004% (Complies)

IDENTIFICATION: Albendazole is identified.

ASSAY:

Stated	200mg / Tablet
Determined	206.986 mg / Tablet
Percentage	103.493 % (Complies)
Limit	90 – 110% (USP 2023)

DISSOLUTION TEST: Does not comply with USP's acceptance criteria of Dissolution Test as detailed below:

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

Level	Unit Tested	Acceptance Criteria						Remarks
S1	6	Each unit is not less than Q+5%						Does Not Comply
	Time	UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6	
	After 30 minutes	<u>43.4%</u>	57.5%	65.7%	61.4%	60.0%	60.6%	

NOTE: Amount of Albendazole dissolved among all six units tested at first level is found less than 85% (Q+5%) of the labeled amount. Furthermore, Amount of Albendazole dissolved in one unit is found less than Q-25%. Therefore, Dissolution test is stopped at first stage. **(Does Not Comply)**

RESULT: Given sample is **Sub-Standard** with regards to Dissolution Test

and **Misbranded** as per Section 3 (s) (iv) of The Drug Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022.

- iii. Storekeeper of Main Medicine Store Office of Chief Executive Officer District Health Authority Mandi Bahauddin provided Invoice/ warranty No. 2300043 dated 13-03-2023 issued by M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar as a proof of its purchase.
- iv. Warrantor portion of the subject drug sample was sent to 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 with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to the request of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar, the retesting request of the subject drug sample was considered in 25th Committee Meeting of the Board held on 13-09-2023 and the subject drug sample was sent to NIH, Islamabad, from where the sample was declared **Sub-standard & Misbranded** as detailed below.

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Bendazol Tablet 200mg	K-296	M/s Stanley Pharmaceuticals (Pvt) Ltd., 84-B Industrial Estate Hayatabad, Peshawar-Pakistan	0187-P/2023 dated 30-10-2023	<p><u>LABELING:</u></p> <p><u>Determined:</u> Product specification of given sample is “Manufacturer Specifications” and it is manufactured after the expiration timeline to apply such specification despite the availability of “Albendazole Tablet” monograph in USP, so the manufacturer’s claim regarding product specification is in contradiction to DRAP circular and in violation to Drugs Act 1976.</p> <p><u>Limit:</u> As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states “all registration holders shall follow official pharmacopeia specification for all such formulation for which official monograph of the drug product is available in the most recent edition of such pharmacopoeia”.</p> <p>Does not comply with labeling rules (Section 3 (s) (iv) of Drugs Act 1976) in compliance to DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022.</p> <p><u>DISSOLUTION TEST:</u></p> <p><u>Determined:</u> All the six tablet deviated from the limit.</p> <p><u>Limit:</u> Not less than 80% (Q) of the labeled amount of (C₁₂H₁₅N₃O₂S) is dissolved in 30 minutes.</p> <p>Does not comply with USP-43.</p>

				<p>REMARKS: Percentage release of drug among all six units tested at first level is found less than 85% (Q+5%) of the stated amount of albendazole. Moreover, drug release in all six units is found less than Q-25% at S1 level. Therefore, Dissolution test is stopped at first stage</p> <p>RESULT: The sample is of Sub-standard quality on the basis of test performed and Misbranded, as defined under Section 3 (s) (iv) of Drugs Act 1976) in compliance to DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022.</p>
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vii. A copy of NIH test/ analysis report was sent to M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar with directions to explain their position and provide requisite information in this regard

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

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

3. Show cause notice(s) issued to accused person(s) on 21-03-2024.

Reply of the firm to show cause notice vide letter dated 29-03-2024:

Dear Sir,

We have received your Kind letter No: PQCB/R-398/2023 dated 21.03.2023 received on 29.03.2024 Please refer to the subject cited above, it is stated that we M/S Stanley Pharma Peshawar hereby justify our position & drawn your attention on the following points.

1. NIH(Appellate Laboratory) declared substandard our Product namely Tablet Bendazol Batch # K-296 on the basis of Dissolution Test, in NIH report is self explanatory i.e. deviates the DRAP Order No.F 3-5/2020-1 & V- II (M-297) dated 07.02.2022 by applying most recent edition of official Pharmacopeia.

NIH(Appellate Laboratory) applied the Method of Dissolution Test as mentioned in USP Monograph 2020 instead of most recent edition of USP Monograph 2023.

NIH(Appellate Laboratory) applied the formula to calculate the quantity in mg of Albendazole dissolved by the formula $22.5C(Au/As)$ as mentioned in USP Monograph 2020 instead of most recent edition of USP Monograph 2023 formula i.e to calculate the quantity in in mg of Albendazole dissolved by the formula Result: $(Au/As) \times (Cs/L) \times V \times D \times 100$

Where Au: Absorbance of Sample solution at about 308nm-Absorbance of Sample solution at about 350nm

As: Absorbance of Standard solution at about 308nm- Absorbance of Standard solution at about 350nm

Cs: Concentration of USP Albendazole RS in the standard solution(mg/ml)

L: Label claim(mg/Tablet)

V: Volume of medium 900ml

D: Dilution factor of sample solution, 25

The Formula mentioned in most recent edition of USP Monograph 2023 may have great impact on dissolution test result of Albendazole instead of applying formula of USP Monograph 2020.

Moreover for your kind information Albendazole is a low soluble drug & belong to BCS Class II/IV, on above said reason on the basis of solubility of Albendazole USP have revised their Dissolution test in most recent edition of USP Monograph 2023 & 2021-2022 and also mentioned Test 2 where RPM changed from 50RPM to 75RPM. So briefly NIH (Appellate Laboratory) did not follow the most recent edition of USP Monograph 2023.

2. We M/S Stanley Pharma Peshawar hereby also informed you that the same Product Tablet Bendazol 200mg (Albendazole 200mg) Batch No: K-296 declared Standard Quality by DTL Lahore from from two different stations like Data Gunj Baksh Town & CEO Office Sheikhpora (reports attached)

3. Moreover We M/S Stanley Pharma have the capacity to manufactured Bendazol Tablets Batch No K-296 Batch Size 300000 Tablets at once not in portion wise, there is no chance of unequal distribution of API (Albendazole) in Finished product.

PQCB Lahore already decided to issue Warning after rectification of both innermost packing of Unitcarton & Aluminium Foil of Bendazol Tablets Batch #K-296 where USP Specifications (Reports attached) mentioned.

Hope you will consider our justification and may warned us in this regard.

4. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 03-2023**
- **Exp. Date: 03-2027**
- **Sampling date (Form 4): 01-04-2023**
- **Sent to DTL (Form 6): 01-04-2023**
- **Date of receipt in DTL: 05-04-2023**
- **DTL Report Date (Form 7): 23-05-2023**
- **DI 1st intimation to firm: 10-06-2023**
- **Retesting request if any: 14-06-2023**
- **Fate of Retesting: Allowed in 25th Committee Meeting held on 13-09-2023. NIH Substandard & Misbranded**
- **Investigation report Dated: 19-12-2023**
- **Permission of SCN: 275th (S) meeting dated 31-01-2024**
- **SCN Issued: 21-03-2024**
- **Reply of the firm: Yes**
- **History (3 years) Firm: 52 cases**
- **Product: 20 cases**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 14

PQCB/R-413/2023

Tehsil & District Gujrat

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <p>1. M/S Stanley Pharmaceutical Pvt, Ltd. Situated at 84-B Industrial Estate, Hayatabad Peshawar, Pakistan through its Chief Executive Officer Abdullah Shah.</p> <p>2. Abdullah Shah Chief Executive Officer/Warrantor CNIC No. 17301-1568978-9</p> <p>3. Imran Khan S/O Awal Zada Production Incharge CNIC No. 17301-1415834-9</p> <p>4. Umar Kamran Marwat S/O Atta Ullah Kamran Marwat Quality Control Incharge CNIC No. 11101-6142018-9</p> <p>of M/S Stanley Pharmaceutical Pvt, Ltd. Situated at 84-B Industrial Estate, Hayatabad Peshawar, Pakistan.</p>
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BRIEF FACTS OF THE CASE:

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

- i. His Predecessor, on 11-04-2023, inspected the premises of Main Medicine Store of CEO, DHA Gujrat Situated at Fawara Chowk Gujrat and took fifteen drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo no. 0000163583, dated. 11-04-2023.
- ii. Following Drug sample after test/analysis were declared as **Substandard & Misbranded** 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
Uncoated Tablet. Bendazol [Each uncoated tablet contains: (Albendazole USP).....200mg]	K-316	M/S Stanley Pharmaceutical Pvt, Ltd. Situated at 84-B Industrial Estate, Hayatabad Peshawar,	01-68023762/DTL Dated. 23-05-2023	<p><u>Analysis with specifications applied:</u> USP 2023.</p> <p><u>Description:</u> White colored round shaped, flat tablets engraved STANLEY on one side and plain from other side, contained in ALU-PVC packing of 02 units, packed in outer hard carton.</p> <p><u>NOTE:</u> As per DRAP Order No. F.3-5/2020- I & V-II (M-297), dated 7th February, 2022 stated</p>

Mfg Date:

March-2023

Exp Date:

March-2027

Registration No.

006095

Pakistan

“all registration holders shall follow official pharmacopoeial specifications for all such formulations for which official monograph of the drug product is available in the most recent edition of such pharmacopoeia” Product Specification of the given sample is “(Mfg. Standard Specifications)” and is manufactured after the expiration of the timeline to apply such specifications despite the availability of Albendazole tablet’s monograph in USP 2022 and 2023 so, the manufacturer’s claim regarding product specifications is in contradiction to DRAP circular and in violation to Drugs Act 1976. (Does not comply).

Uniformity of Dosage Unit (Weight Variation):

Complies the acceptance criteria of uniformity of dosage unit (Weight variation) as per USP 2023.

(Average Weight of Tablet= 515.14mg)

Acceptance Criteria: Acceptance value $\leq L1\% = 15\%$

Determined: Acceptance value= 12.764% (Complies)

Identification:

Albendazole is identified.

Assay:

Stated	200mg/Tablet
Determined	211.346 mg/Tablet
Percentage	105.673% (Complies)
Limit	90-110% (USP 2023)

Dissolution Test:

Does not comply with USP’s acceptance criteria of Dissolution Test as detailed below:

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

<u>Level</u>	<u>Unit Tested</u>	<u>Acceptance Criteria</u>	<u>Remarks</u>							
S1	6	Each Unit is not less than Q+5%	Does not comply							
				Time	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6
					60.8%	58.6%	53.2%	52.4%	49.4%	60.9%

				After 30 minutes	
				<p>NOTE: Amount of albendazole dissolved among all six units tested at first level is found less than 85% (Q+5) of the labelled amount. Furthermore, Amount of albendazole dissolved in three units is found less than Q-25%. Therefore, Dissolution test is stopped at first stage. (Does not comply).</p> <p>Result:</p> <p>Given sample is Substandard, with regards to Dissolution test and Misbranded as per Section 3 (s)(i) of the Drugs Act 1976, in compliance to DRAP order No. F.3-5/2020- I & V-II (M-297), dated 7th February, 2022.</p>	

- iii. Store Keeper of Main Medicine Store of CEO, DHA Gujrat Situated at Fawara Chowk Gujrat provided Invoice/warranty No DHA GUJRAT-1047-23, dated. 13-03-2023 issued by M/S Stanley Pharmaceutical Pvt, Ltd. Situated at 84-B Industrial Estate, Hayatabad Peshawar, Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Stanley Pharmaceutical Pvt, Ltd. Situated at 84-B Industrial Estate, Hayatabad Peshawar, Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Stanley Pharmaceutical Pvt, Ltd. Situated at 84-B Industrial Estate, Hayatabad Peshawar, Pakistan and they were asked to provide the requisite information in this regard. In Response, the firm challenged the test/analysis report and requested to re-test the above-mentioned drug samples from Appellate laboratory NIH, Islamabad. Pursuant to the request of manufacturer, the said batch was placed in 25th committee meeting held on 13-09-2023 in which committee allowed to send the sample to NIH, Islamabad. the sample was sent to NIH, Islamabad, from where the same was declared as **Substandard and Misbranded** detailed below: -

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Bendazole Tablet 200mg	K-316	M/S Stanley Pharmaceutical Pvt, Ltd. Situated at 84-B Industrial Estate, Hayatabad Peshawar, Pakistan	0188-P/2023 dated: 30-10-2023	<p>Specifications Applied</p> <p>USP-43</p> <p>Labelling:</p> <p>Determined:</p> <p>Product specification of given sample is “Manufacturer Specification” and it is manufactured after the expiration timeline to apply such specification despite the availability of “Albendazole Tablet” monograph in USP so the manufacturer’S claim regarding product specification is in contradiction to DRAP circular and in violation to Drugs Act 1976.</p> <p>Limit:</p> <p>As per DRAP order No. F. 3-5/2020 & V-II (M-297) dated 7th February 2022 states, “All registration holders shall follow official Pharmacopoeia specification for all such formulations for which</p>

				<p>official monograph of the drug product is available in the most recent edition of such pharmacopoeia.</p> <p>Does not comply with labeling rules (Section 3 (s)(iv) of Drugs Act 1976) in compliance to DRAP order No. F.3-5/2020-I & V-II (M-297) Dated. 7th February 2022.</p> <p><u>Dissolution Test:</u></p> <p><u>Determined:</u></p> <p>All six tablets deviated from the limit.</p> <p><u>Limit:</u></p> <p>Not less than 80% of the labelled amount of (C₁₂H₁₅N₃O₂S) is dissolved in 30 minutes.</p> <p>Does not comply with USP-43.</p> <p><u>Remarks:</u></p> <p>Percentage release of drug among all six units tested at the first level is found less than 85% (Q+5%) of the stated amount of albendazole. Moreover, Drug release in all six units is found less than Q-25% at S1 level. Therefore, Dissolution test is stopped at first stage.</p> <p><u>Conclusion:</u> The sample is of substandard quality on the basis of test performed and Misbranded, as defined under section 3 (s) (iv) of Drugs Act 1976) in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297), Dated. 7th February 2022.</p>
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2. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of :-

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

3. Show cause notice(s) issued to accused person(s) on 09-04-2024.

Reply of the firm to show cause notice vide letter dated 22-04-2024:

Dear Sir,

We have received your Kind letter No: PQCB/R-413/2023 dated 09.04.2024 received on 22.04.2024

Please refer to the subject cited above, it is stated that we M/S Stanley Pharma Peshawar hereby justify our position & draw your attention on the following points.

1. NIH(Appellate Laboratory) declared substandard our Product namely Tablet Bendazol Batch #K-316 on the basis of Dissolution Test, in NIH report is self explanatory ie, deviates the DRAP Order No.F 3-5/2020-1 & V- II (M-297) dated 07.02.2022 by applying most recent edition of official Pharmacopoeia.

NIH(Appellate Laboratory) applies the Method of Dissolution Test as mentioned in USP Monograph 2020(USP-43) instead of most recent edition of USP Monograph 2023.

NIH(Appellate Laboratory) applied the formula to calculate the quantity in mg of Albendazole dissolved by the formula $22.5C(Au/As)$ as mentioned in USP Monograph 2020(USP-43) instead of most recent edition of USP Monograph 2023 formula i.e to calculate the quantity in mg of Albendazole dissolved by the formula Result: $(Au/As) \times (Cs/L) \times V \times D \times 100$

Where Au: Absorbance of Sample solution at about 308nm- Absorbance of Sample solution at about 350nm

As: Absorbance of Standard solution at about 308nm-Absorbance of Standard solution at about 350nm

Cs: Concentration of USP Albendazole RS in the standard solution(mg/ml)

L: Label claim(mg/Tablet)

V: Volume of medium 900ml

D: Dilution factor of sample solution, 25

The Formula mentioned in most recent edition of USP Monograph 2023 may have great impact on dissolution test result of Albendazole instead of applying formula of USP Monograph 2020(USP-43),

Moreover for your kind information Albendazole is a low soluble drug & belong to BCS Class II/IV, on above said reason on the basis of solubility of Albendazole USP have revised their Dissolution test in most recent edition of USP Monograph 2023/2024 & 2021-2022 and also mentioned Test 2 where RPM changed from 50RPM to 75RPM. So briefly NIH(Appellate Laboratory) did not follow the most recent edition of USP Monograph 2023.

We M/S Stanley Pharma have the capacity to manufactured Bendazol Tablets Batch No K-316 Batch Size 300000 tablets at once product not in portion wise, there is no chance of unequal distributopn of API (albendazole) in finished product.

POCB Lahore Order Nor PC272-M/MB/2023 dated 22.11.2023 already decided to issue Warning ster Petification of both innermost packing of Unitcaron & Aluminium Foil of Bendazol Tablets Batch #K-351 Mfg Date 03/2023 Exp Date 03/2027 & Bendazol Tablets Batch #K-407 Mfg Date 04/2023 Exp Da where USP Specifications (Reports attached) mentioned.

Hope you will consider our justification and may warned us in this regard.

4. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 03-2023**
- **Exp. Date: 03-2027**
- **Sampling date (Form 4): 11-04-2023**
- **Sent to DTL (Form 6): 11-04-2023**
- **Date of receipt in DTL: 14-04-2023**
- **DTL Report Date (Form 7): 23-05-2023**
- **DI 1st intimation to firm: 06-07-2023**
- **Retesting request if any: 10-07-2023**
- **Fate of Retesting: Allowed in 25th Committee Meeting held on 13-09-2023. NIH Substandard & Misbranded**
- **Investigation report Dated: 10-01-2024**
- **Permission of SCN: 276th meeting dated 29-02-2024**

- **SCN Issued: 09-04-2024**
- **Reply of the firm: Yes**
- **History (3 years) Firm: 52 cases**
- **Product: 20 cases**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 15

PQCB/R-443/2023

Mumtaz Abad Town, District Multan

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <p>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 Marwat Quality Control Incharge</p> <p>of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar</p>
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BRIEF FACTS OF THE CASE:

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

- i. He, on 15-03-2023, inspected the premises of Main Medicine Store, O/o Chief Executive Officer, (DHA), Multan, situated at BHU Jhooke Lashkarpur, Multan and took 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. 160702 dated: 15-03-2023, 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
BENDAZOL TABLET (ALBENDAZOLE 200mg) Mfg. Date: March-2023 Exp. Date: March-2027 Reg. No: 006095	K-296	M/S STANLEY PHARMACEUTICALS (PVT) LTD. 84-B, Industrial Estate Hayatabad, Peshawar-Pakistan.	01-105001812/DTL Dated:26-05-2023 (DTL Multan)
<p>Specification applied USP 2023</p> <p>DESCRIPTION: White colored, uncoated round tablet, plain on one side & engraved "STANLEY" on other side of tablet, in ALU-PVC blister of 02 units packed in a labeled outer hard carton. Each outer carton contains one blister i.e. (1x02=02) tablets per pack.</p> <p>Note: As per Drap Order No. F. 3-5/2020-I & V-II (M-297) dated 7th February 2022 states, "all registration</p>			

holders shall follow official Pharmacopeia Specifications for all such formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopeia. Product Specifications of given sample is “Manufacturer’s Specifications” and it is manufactured after the expiration timeline to apply such specifications despite the availability of “**Albendazole Tablet**” monograph in USP 2023, so the manufacturer’s claim regarding product specifications is in contradiction to Drap circular and in violation to Drugs Act 1976. **Mis-Branded (Does not Comply)**

UNIFORMITY OF DOSAGE UNIT (Weight Variation)

Max. AV=L1:15% **(Complies)**

IDENTIFICATION: Albendazole Identified.

Analytical Technique: By HPLC

ASSAY:

Albendazole: Stated: 200 mg/Tablet
 Determined: 195.8 mg/ Tablet
 Percentage: 97.9%
 Limit: 90-110% **(Complies)**

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

Tolerance Limit: NLT 80% (Q) of the labeled amount of Albendazole is dissolved in 30 minutes.

LEVEL	UNITS	% RELEASE						AVERAGE	REMARKS
S1	6	No Unit is less than 85% (Q+5)						S1	Does not comply
		U#1	U#2	U#3	U#4	U#5	U#6		
Determined	%	53.1%	64.5%	52.8%	61.8%	75.6%	59.9%		

* As the criteria of S3 i.e., NMT 2 units are < Q-15%, And no unit is <Q-25% is achieved. So, the results conform at S1 Stage. **The quantity Q, is specified amount of dissolved active substance, expressed as percentage on the label claim. **(Does Not Comply)**

RESULT: The above-mentioned sample is **Mis-Branded** as defined under section 3(s)(iv) of the Drugs Act, 1976, in compliance to DRAP Order No. F. 3-5/2020-I &V-II (M-297) dated 7th February 2022 & **Substandard** on the basis of Dissolution Test.

- iii. Storekeeper, Main Medicine Store, O/o Chief Executive Officer, (DHA), Multan, , situated at BHU Jhooke Lashkarpur, Multan provided invoice/ warranty No. 2300034 dated 08-03-2023 issued by M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar, as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to 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, and they were asked to explain their position and provide the requisite information in this regard.
- vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.
- vii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
BENDAZOL TABLET (ALBENDAZOLE 200mg)	K-296	M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar	0184-P/2023 dated: 30-10-2023	<p>Analysis with specifications applied: USP-43</p> <p>Labeling:</p> <p>Determined: Product specification of given sample is "Manufacturer Specification" and it is manufactured after the expiration timeline to apply such specification despite the availability of "Albendazole Tablet" monograph in USP, 50 the manufacturer's claim regarding product specification is in contradiction to DRAP circular and in violation to Drugs Act 1976.</p> <p>Limit: As per DRAP Order No. F. 3-5/2020-1 & V-II (M-297) dated 7th February 2022 states, "all registration holders shall follow official pharmacopoeia specification for all such formulation for which official monograph of the drug product is available in the most recent edition of such pharmacopoeia. Does not comply with labeling rules (Section 3 (s) (iv) of Drugs Act 1976) in compliance to DRAP Order No. F.3- 5/2020-1 & V-II (M-297) dated 7th February 2022.</p> <p>Dissolution Test:</p> <p>Determined: All six tablets deviated from the limit.</p> <p>Limit: Not less than 80% (9Q) of the labeled amount of (C₁₂H₁₅N₃O₂S) is dissolved in 30 minutes. (Does not comply with USP-43)</p> <p>Remarks:</p> <p>Percentage release of drug among all six units tested at first level is found less than 85% (Q+5%) of the stated amount of Albendazole. Moreover, drug release in all six units is found less than Q-25% at S1 level. Therefore, Dissolution test is stopped at first stage.</p> <p>Result: The sample is of Substandard quality on the basis of tests performed and Misbranded, as defined under section</p>

viii. Copy of NIH report was sent to M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar.

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. **Manufacturing for sale /sale of Substandard and Misbranded drugs**
- b. **Issuance of false warranty**

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

Reply to Show Cause Notice:

Dear Sir,

We have received your Kind letter No: PQCB/R-443/2023 dated 11-06-2024 received on 27-06.2024.

M/S Stanley Pharma Peshawar hereby justify our position regarding the subject, that we have the capacity to manufacture Bendazol Tablets Batch No K-296 at once not in portion wise, there is no chance of unequal distribution of API(Albendazole) in Finished product with strong evidence that the Product Bendazol 200mg Tablets (Albendazole) of same Batch No. K-296 declared **STANDARD QUALITY** by DTL Lahore.

Moreover, DTL Multan declared results of Bendazol Tablets Batch no. K-296 dissolution on stage 1 S1 (average 61.29%) , while NIH does not mentioned detail dissolution report Bendazol Tablets Batch no. K-296, which is clearly justify our position in this regard.

We M/S Stanley Pharma Peshawar hereby also informed you that the same Product Tablet Bendazol 200mg (Albendazole 200mg) Batch No: K-296 declared Standard Quality by DTL Lahore from two different stations like Data Gunj Baksh Town & CEO Office Sheikhpura (reports attached).

The firm further verified the names of technical staff of the firm.

Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:03-2023**
- **Exp. Date: 03-2027**
- **Sampling date (Form 4): 15-03-2023**
- **Sent to DTL (Form 6): 15-02-2023**
- **Date of receipt in DTL: 17-03-2023**
- **DTL Report Date (Form 7): 26-05-2023 (On 71st day)**
- **Time Extension to DTL: Yes, in 20th -CM, dated: 17-05-2023**
- **DI 1st intimation to firm: 03-06-2023**
- **Retesting request if any: Yes, allowed in 25th -CM, dated: 13-09-2023**
- **Fate of Retesting Request: NIH Substandard and Misbranded (Reported on 42nd Day)**

- **Investigation report Dated: 04-01-2024**
- **Permission of SCN: 275th meeting dated 31-01-2024**
- **SCN Issued: 11-06-2024**
- **Reply of the firm Yes**
- **History (3 years) Firm: 52 cases**
- **Product: 20 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 16

PQCB/R-444/2023

Tehsil and District Khanewal

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <p>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 Marwat Quality Control Incharge</p> <p>of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar</p>
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BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Tehsil and District Khanewal reported that:

- i. The then Drug Inspector, on 27-03-2023, inspected the premises of Main Medicine Store, O/o Chief Executive Officer, (DHA) Khanewal and took 13 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. 161841 dated: 27-03-2023, 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
BENDAZOL TABLET (ALBENDAZOLE 200mg) Mfg. Date: March-2023 Exp. Date: March-2027 Reg. No: 006095	K-296	M/S STANLEY PHARMACEUTICALS (PVT) LTD. 84-B, Industrial Estate Hayatabad, Peshawar-Pakistan.	01-105001998/DTL Dated:26-05-2023 (DTL Multan)

Specification applied USP 2023

DESCRIPTION: White colored, uncoated round tablet, plain on one side & engraved "STANLEY" on other side of tablet, in ALU-PVC blister of 02 units packed in a labeled outer hard carton. Each outer carton contains one blister i.e. (1x02=02) tablets per pack.

Note: As per DRAP Order No. F. 3-5/2020-I & V-II (M-297) dated 7th February 2022 states, "all registration holders shall follow official Pharmacopeia Specifications for all such formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopeia. Product Specifications of given sample is "Manufacturer's Specifications" and it is manufactured after the expiration timeline to apply such specifications despite the availability of "Albendazole Tablet" monograph in USP 2023, so the

manufacturer's claim regarding product specifications is in contradiction to DRAP circular and in violation to Drugs Act 1976.

Mis-Branded (Does not Comply)

UNIFORMITY OF DOSAGE UNIT (Weight Variation)

Max. AV=L1:15% (Complies)

IDENTIFICATION: Albendazole Identified.

Analytical Technique: By HPLC

ASSAY:

Albendazole: Stated: 200 mg/Tablet
Determined: 196.24 mg/ Tablet
Percentage: 98.12%
Limit: 90-110% (Complies)

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

Tolerance Limit: NLT 80%(Q) of the labeled amount of Albendazole is dissolved in 30 minutes.

LEVEL	UNITS	% RELEASE						AVERAGE	REMARKS
S1	6	No Unit is less than 85% (Q+5)						S1	Does not Comply
		U#1	U#2	U#3	U#4	U#5	U#6		
Determined	%	54.3%	45.3%	55.1%	68.4%	65.6%	59.0%		

* As the criteria of S3 i.e., NMT 2 units are < Q-15%, And no unit is <Q-25% is achieved. So, the results conform at S1 Stage. **The quantity Q, is specified amount of dissolved active substance, expressed as percentage on the label claim. (Does Not Comply)

RESULT: The above-mentioned sample is **Mis-Branded** as defined under section 3(s)(iv) of the Drugs Act, 1976, in compliance to DRAP Order No. F. 3-5/2020-I & V-II (M-297) dated 7th February 2022 & Sub-Standard on the basis of Dissolution Test.

- iii. Storekeeper, Main Medicine Store, O/o Chief Executive Officer, (DHA) Khanewal provided invoice/ warranty No. 2300039 dated 10-03-2023 issued by M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar, as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to 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, and they were asked to explain their position and provide the requisite information in this regard.
- vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.
- vii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the

sample was declared **Substandard** as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
BENDAZOL TABLET (ALBENDAZOLE 200mg)	K-296	M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar	0233-P/2023 dated: 30-10-2023	<p>Analysis with specifications applied: USP-43</p> <p>Labeling:</p> <p>Determined: Product specification of given sample is "Manufacturer Specification" and it is manufactured after the expiration timeline to apply such specification despite the availability of "Albendazole Tablet" monograph in USP, 50 the manufacturer's claim regarding product specification is in contradiction to DRAP circular and in violation to Drugs Act 1976.</p> <p>Limit: As per DRAP Order No. F. 3-5/2020-1 & V-II (M-297) dated 7th February 2022 states, "all registration holders shall follow official pharmacopoeia specification for all such formulation for which official monograph of the drug product is available in the most recent edition of such pharmacopoeia. Does not comply with labeling rules (Section 3 (s) (iv) of Drugs Act 1976) in compliance to DRAP Order No. F.3-5/2020-1 & V-II (M-297) dated 7th February 2022.</p> <p>Dissolution Test:</p> <p>Determined: All six tablets deviated from the limit.</p> <p>Limit: Not less than 80% (9Q) of the labeled amount of (C₁₂H₁₅N₃O₂ S) is dissolved in 30 minutes. (Does not comply with USP-43)</p> <p>Remarks:</p> <p>Percentage release of drug among all six units tested at first level is found less than 85% (Q+5%) of the stated amount of Albendazole. Moreover, drug release in all six units is found less than Q-25% at S1 level. Therefore, Dissolution test is stopped at first stage</p> <p>Result: The sample is of Substandard quality on the basis of tests performed and Misbranded, as defined under section 3(s)(iv) of the Drugs Act, 1976, in compliance to DRAP Order No. F. 3-5/2020-I &V-II (M-297) dated 7th February 2022</p>

viii. Copy of NIH report was sent to M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar.

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. **Manufacturing for sale /sale of Substandard and Misbranded drugs**
- b. **Issuance of false warranty**

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

Reply to Show Cause Notice:

Dear Sir,

We have received your Kind letter No: PQCB/R-444/2023 dated 11-06-2024 received on 27-06.2024.

M/S Stanley Pharma Peshawar hereby justify our position regarding the subject, that we have the capacity to manufacture Bendazol Tablets Batch No K-296 at once not in portion wise, there is no chance of unequal distribution of API(Albendazole) in Finished product with strong evidence that the Product Bendazol 200mg Tablets (Albendazole) of same Batch No. K-296 declared **STANDARD QUALITY** by DTL Lahore.

Moreover, DTL Multan declared results of Bendazol Tablets Batch no. K-296 dissolution on stage 1 S1 (average 57.95%) , while NIH does not mentioned detail dissolution report Bendazol Tablets Batch no. K-296, which is clearly justify our position in this regard.

We M/S Stanley Pharma Peshawar hereby also informed you that the same Product Tablet Bendazol 200mg (Albendazole 200mg) Batch No: K-296 declared Standard Quality by DTL Lahore from two different stations like Data Gunj Baksh Town & CEO Office Sheikhpura (reports attached).

The firm further verified the names of technical staff of the firm.

Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:03-2023**
- **Exp. Date: 03-2027**
- **Sampling date (Form 4): 27-03-2023**
- **Sent to DTL (Form 6): 27-03-2023**
- **Date of receipt in DTL: 29-03-2023**
- **DTL Report Date (Form 7): 26-05-2023 (on 59th day)**
- **Time Extension to DTL: Not Time barred**
- **DI 1st intimation to firm: 26-07-2023**
- **Retesting request if any: Yes, allowed in 26th -CM, dated: 11-10-2023**
- **Fate of Retesting Request: NIH Substandard and Misbranded (Reported on 14th Day)**
- **Investigation report Dated: 09-01-2024**
- **Permission of SCN: 275th meeting dated 31-01-2024**
- **SCN Issued: 11-06-2024**
- **Reply of the firm Yes**
- **History (3 years) Firm: 52 cases**
- **Product: 20 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:



Case No. 17

No. PQCB/ R-397/2023

Lyallpur Town Faisalabad

ATTENDANCE

Secretary DQCB Drug Inspector	<p>1. M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar through Chief Executive Officer (CEO), Abdullah Shah</p> <p>2. Abdullah Shah Chief Executive Officer (CEO)/Warrantor</p> <p>3. Imran Khan Production Incharge</p> <p>4. Umar Kamran Marwat Quality Control Incharge</p> <p>of M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar.</p>
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Lyallpur Town, District Faisalabad reported that: -

- i. He, on 20-03-2023 inspected the premises of Main Medicine Store Chief Executive Officer, District Health Authority, District Faisalabad, took different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 161056 dated 20-03-2023.
- ii. The subject drug sample, after test/ analysis was declared **Substandard & Misbranded** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report No. & Date	DTL Test Report Result
Uncoated Tablet. Bendazol [Each uncoated tablet contains: (Albendazole USP) 200mg) Mfg Date:	K-296	M/s Stanley Pharmaceuticals (Pvt) Ltd., 84-B Industrial Estate Hayatabad, Peshawar-Pakistan	01-68023254/ DTL dated 16-05-2023	<p>Results of test/analysis with specifications applied: USP 2023</p> <p>DESCRIPTION: White colored, round shaped, flat tablets engraved STANLEY on one side and plain from other side, contained in ALU-PVC packing of 02 units, packed in outer hard carton.</p> <p>NOTE: As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states “all registration holders shall follow official pharmacopeial specifications for all such formulations for which official monographs of the drug product is available in the most recent edition of such pharmacopoeia”. Product specifications of the given sample is “(Mfg. Stanley Specifications)” and it is manufactured after the expiration of timeline to apply such specifications despite the availability of Albendazole tablet’s monograph in USP 2022 and 2023, so the manufacturer’s claim</p>

March-2023

Exp. Date:
March-2027

Regn. No:
006095

regarding product specifications is in contradiction to DRAP circular and in violation to Drugs Act 1976. **(Does not Comply)**

UNIFORMITY OF DOSAGE UNIT (Weight Variation): Complies the acceptance criteria of Uniformity of dosage unit (weight variation) as per USP 2023.

(Average weight of Tablet= 487.54 mg)

Acceptance Criteria: Acceptance value \leq L1%=15%

Determined: Acceptance value= 7.528% (Complies)

IDENTIFICATION: Albendazole is identified.

ASSAY:

Stated	200mg / Tablet
Determined	206.706 mg / Tablet
Percentage	103.353 % (Complies)
Limit	90 – 110% (USP 2023)

DISSOLUTION TEST: Does not comply with USP's acceptance criteria of Dissolution Test as detailed below:

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

Level	Unit Tested	Acceptance Criteria						Remarks
S1	6	Each unit is not less than Q+5%						Does Not Comply
	Time	UNIT 1	UNIT 2	UNIT 3	UNIT 4	UNIT 5	UNIT 6	
	After 30 minutes	48.9%	45.5%	40.2%	51.5%	53.6%	44.3%	

NOTE: Amount of Albendazole dissolved among all six units tested at first level is found less than 85% (Q+5%) of the labeled amount. Furthermore, Amount of Albendazole dissolved among all six units is found less than Q-

25%. Therefore, Dissolution test is stopped at first stage. **(Does Not Comply)**

RESULT: Given sample is **Sub-Standard** with regards to Dissolution Test and **Misbranded** as per Section 3 (s) (iv) of The Drug Act 1976, in compliance to DRAP Order No. F.3-5/2020-I & V-II (M-297) dated 7th February, 2022.

- iii. Storekeeper Main Medicine Store Chief Executive Officer, District Health Authority, District Faisalabad provided Invoice/ warranty No. 2300035 dated 09-03-2023 issued by M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar as a proof of its purchase.
- iv. Warrantor portion of the subject drug sample was sent to 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 with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to the request of M/s Stanley Pharmaceuticals Pvt Ltd., 84-B Industrial Estate Hayatabad, Peshawar, the retesting request of the subject drug sample was considered in 25th Committee Meeting of the Board held on 13-09-2023 and the subject drug sample was sent to NIH, Islamabad, from where the sample was declared **Sub-standard & Misbranded** as detailed below:

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Bendazol Tablet 200mg	K-296	M/s Stanley Pharmaceuticals (Pvt) Ltd., 84-B Industrial Estate Hayatabad, Peshawar-Pakistan	0186-P/2023 dated 30-10-2023	<p><u>LABELING:</u></p> <p><u>Determined:</u> Product specification of given sample is “Manufacturer Specifications” and it is manufactured after the expiration timeline to apply such specification despite the availability of “Albendazole Tablet” monograph in USP, so the manufacturer’s claim regarding product specification is in contradiction to DRAP circular and in violation to Drugs Act 1976.</p> <p><u>Limit:</u> As per DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022 states “all registration holders shall follow official pharmacopeia specification for all such formulation for which official monograph of the drug product is available in the most recent edition of such pharmacopoeia”.</p> <p>Does not comply with labeling rules (Section 3 (s) (iv) of Drugs Act 1976) in compliance to DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022.</p> <p><u>DISSOLUTION TEST:</u></p> <p><u>Determined:</u> All the six tablet deviated from the limit.</p> <p><u>Limit:</u> Not less than 80% (Q) of the labeled amount of (C₁₂H</p>

				<p>N₃O₂S) is dissolved in 30 minutes.</p> <p>Does not comply with USP-43.</p> <p>REMARKS: Percentage release of drug among all six units tested at first level is found less than 85% (Q+5%) of the stated amount of albendazole. Moreover, drug release in all six units is found less than Q-25% at S1 level. Therefore, Dissolution test is stopped at first stage</p> <p>RESULT: The sample is of Sub-standard quality on the basis of test performed and Misbranded, as defined under Section 3 (s) (iv) of Drugs Act 1976) in compliance to DRAP order No. F.3-5/2020-I & V-II (M-297) dated 7th February 2022.</p>
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2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

- i. **Manufacturing for Sale / Sale of Sub-standard & Misbranded Drug.**
- ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated. 21-03-2024.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 29-03-2024 stating that:

084

Dear Sir,

We have received your Kind letter No: PQCB/R-397/2023 dated 21.03.2023 received on 29.03.2024. Please refer to the subject cited above, it is stated that we M/S Stanley Pharma Peshawar hereby justify our Position & drawn your attention on the following points.

1. NIH(Appellate Laboratory) declared substandard our Product namely Tablet Bendazol Batch # K-296 on the basis of Dissolution Test, in NIH report is self-explanatory i.e. deviates the DRAP Order No.F 3-5/2020-1 & V-II (M-297) dated 07.02.2022 by applying most recent edition of official Pharmacopeia.

NIH (Appellate Laboratory) applies the Method of Dissolution Test as mentioned in USP Monograph 2020 Instead of most recent edition of USP Monograph 2023.

NIH(Appellate Laboratory) applied the formula to calculate the quantity in mg of Albendazole dissolved by the formula $22.5C(Au/As)$ as mentioned in USP Monograph 2020 instead of most recent edition of USP Monograph 2023 formula i.e. to calculate the quantity in mg of Albendazole dissolved by the formula

Result: $(Au/As) \times (Cs/L) \times V \times D \times 100$

Where Au: Absorbance of Sample solution at about 308nm- Absorbance of Sample solution at about 350nm

As: Absorbance of Standard solution at about 308nm- Absorbance of Standard solution at about 350nm

Cs: Concentration of USP Albendazole RS in the standard solution(mg/ml)

L: Label claim(mg/Tablet)

V: Volume of medium 900ml

D: Dilution factor of sample solution, 25

The Formula mentioned in most recent edition of USP Monograph 2023 may have great impact on dissolution test result of Albendazole instead of applying formula of USP Monograph 2020.

Moreover for your kind information Albendazole is a low soluble drug & belong to BCS Class II/IV, on above said reason on the basis of solubility of Albendazole USP have revised their Dissolution test in most recent edition of USP Monograph 2023 & 2021-2022 and also mentioned Test 2 where RPM changed from 50RPM to 75RPM. So briefly NIH (Appellate Laboratory) did not follow the most recent edition of USP Monograph 2023.

2. We M/S Stanley Pharma Peshawar hereby also informed you that the same Product Tablet Bendazol 200mg (Albendazole 200mg) Batch No: K-296 declared Standard Quality by DTL Lahore from two differed stations like Data Gunj Baksh Town & CEO Office Sheikhpura (reports attached).

3. Moreover We M/S Stanley Pharma have the capacity to manufactured Bendazol Tablets Batch No K-29 Batch Size 300000Tablets at once not in portion wise, there is no chance of unequal distribution API (Albendazole) in Finished product.

PQCB Lahore already decided to issue Warning after rectification of both innermost packing of Unit carton Aluminium Foil of Bendazol Tablets Batch # K-296 where USP Specifications (Reports attached) mentioned.

Hope you will consider our justification and may warned us in this regard.

2. We M/S Stanley Pharma Peshawar hereby also informed you that the same Product Tablet Bendazol 200mg(Albendazole 200mg) Batch No: K-296 declared Standard Quality by DTL Lahore from two different stations like Data Gunj Baksh Town & CEO Office Sheikhpura(reports attached)

3. Moreover We M/S Stanley Pharma have the capacity to manufactured Bendazol Tablets Batch NO K-296 Batch Size 300000Tablets at once not in portion wise, there is no chance Of unequal distribution Of API (Albendazole) in Finished product.

PQCB Lahore already decided to issue Warning after rectification Of both innermost packing of Unit carton & Aluminium Foil of Bendazol Tablets Batch # K-296 where USP Specifications (Reports attached) mentioned.

Hope you will consider our justification and may warned us in this regard.

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	20-03-2023
2	Sample Sent to DTL (Form-6)	20-03-2023
3	Receipt Date in DTL	23-03-2023
4	Issuance of DTL Report	16-05-2023
5	Time Extension	N/A
6	DI First Communication with Firm	16-06-2023
7	Retesting Request	26-06-2023
8	Investigation Report by DI	25-11-2023
9	SCN Permission	275 th meeting dated
10	Show Cause Notice Issued	21-03-2024
12	History (3 years)	Firm's Reported: 79
		Product's Reported: 37

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 18

PQCB/R-121/2023

Aroop Town District Gujranwala

ATTENDENCE

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Stanley Pharmaceuticals (Pvt.) Ltd., 84-B Industrial Estate, Hayatabad, Peshawar, Pakistan through its CEO, Abdullah Shah, 2. Abdullah Shah CEO/ Warrantor 3. Imran Khan Production Incharge 4. Umar Kamran Marwat Quality Control Manager of M/S Stanley Pharmaceuticals (Pvt.) Ltd., 84-B Industrial Estate, Hayatabad, Peshawar, Pakistan.
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BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Aroop Town, District Gujranwala reported that: -

- i. His predecessor, on 25.03.2023, inspected the premises of Main Medicine Store, DHO Office Sialkot Road Gujranwala and took different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide memorandum no. 161695 dated 25.03.2023.
- ii. Following Drug samples after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Faisalabad, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tablet Kamic Forte (Mefenamic Acid: 500mg) Mfg Date: 02.2023 Expiry Date: 02.2027	K-222	M/s Stanley Pharmaceuticals (Pvt.) Ltd., 84-B Industrial Estate, Hayatabad, Peshawar, Pakistan.	01-68023372/ DTL dated: 11.05.2023	Specifications applied: BP 2023 Description: Light yellow colored oblong shaped uncoated tablets engraved with "STANLEY" on one side and plain on other side, contained in ALU-PVC packing of 10 units further packed in outer hard carton. NOTE: Manufacturer in its method of analysis specifies " White uncoated oblong shaped tablets ", but given sample is " Light yellow uncoated oblong shaped tablets " which does not comply with manufacturer's description (appearance) of Tablets. (Does not Comply) Uniformity Of Dosage Unit (Mass): Complies Identification: Mefenamic Acid is identified. ASSAY: Complies Disintegrations Test: Complies RESULT: Given sample is Sub-Standard with regards to description

Regn No.				(Physical Characteristics) of Tablets.
043343				

- iii. Store Keeper of Main Medicine Store, DHO Office Sialkot Road Gujranwala provided Invoice/warranty 2300037, Dated. 27.02.2023 issued by M/S Stanley Pharmaceuticals (Pvt.) Ltd., 84-B Industrial Estate, Hayatabad, Peshawar, Pakistan as a proof of its purchase.
 - iv. Warrantor portion of drug sample was sent to M/S Stanley Pharmaceuticals (Pvt.) Ltd., 84-B Industrial Estate, Hayatabad, Peshawar, Pakistan and they were asked to explain their position in this regard.
3. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of :-

- a. **Manufacturing/ Distribution/ Selling of Substandard drug**
- b. **Issuance of false warranty**

4. Show cause notice(s) issued to accused person(s) on 07-09-2023.

Reply of the firm to show cause notice vide letter dated 25-09-2023:

Dear Sir,

Reference your Kind Letter No. PQCB/R-121/2023 dated 07.09.2023 received on 25.09.2023. Please refer to the subject cited above, it is stated that Drug Testing Laboratory Faisalabad TRA No: 01-68023372/DTL dated 11.05.2023 Declared substandard our product namely Tablet Kamic Forte (Mefenamic Acid 500mg) Batch No K-222 Mfg Date 02-2023 Exp Date 02-2027 on the basis of Description(Physical Characteristics) of Tablets regarding

that manufacturer in its method of analysis specifies "White uncoated tablets oblong shaped tablets instead of Light Yellow colored oblong shaped uncoated tablets"

We M/S Stanley Pharma Peshawar hereby justified our position that is purely Typographical mistake is done in Manufacturer method of analysis specifies White uncoated tablets oblong shaped tablets instead of Light Yellow colored oblong shaped uncoated tablets"

Moreover We hereby notified your attention that in Analysis reports of Compressed Tablets and Finished product report clearly mentioned Light Yellow color oblong shaped uncoated tablets in kamic Forte Batch No K-222 Batch manufacturing Record(BMR), which is the strong evidence of Typographical mistake is done in Manufacturer method of analysis

Drug Testing Laboratory Faisalabad report shows that all chemical tests of kamic Forte batch No K-222 complies BP 2023 including Identification, Weight Variation, Assay & Disintegration Time which shows our product is chemically of Standard Quality and not harm to the patients on the basis of Typographical mistake done in manufacturer method of

analysis The same Product of same Batch No: K-222 declared STANDARD QUALITY by DTL Multan & Rawalpindi (Reports attached)

Kindly reconsider the case and it is humble requested to may warned us in this regard and declare our product Standard Quality on the basis of chemical tests not harm to the patients (including Identification, Weight Variation, Assay & Disintegration) complies BP 2023.

5. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 02-2023**
- **Exp. Date: 02-2027**
- **Sampling date (Form 4): 25-03-2023**
- **Sent to DTL (Form 6): 25-03-2023**
- **Date of receipt in DTL: 29-03-2023**
- **DTL Report Date (Form 7): 11-05-2023**
- **DI 1st intimation to firm: 09-06-2023**
- **Retesting request if any: Nil**
- **Fate of Retesting: NA**
- **Investigation report Dated: 20-06-2023**
- **Permission of SCN: 264th meeting dated 14-07-2023**
- **SCN Issued: 07-09-2023**
- **Reply of the firm: Yes**
- **History (3 years) Firm: 52 cases**
- **Product: 03 cases**

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 19

No. POCB/R-110/2023

Tehsil & District Jhang

Secretary DQCB Drug Inspector	<p>1. M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar through Chief Executive Officer (CEO), Abdullah Shah</p> <p>2. Abdullah Shah Chief Executive Officer (CEO)/Warrantor</p> <p>3. Imran Khan Production Incharge</p> <p>4. Umar Kamran Marwat Quality Control Incharge</p> <p>of M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar.</p>
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BRIEF FACTS OF THE CASE

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

- i. She, on 11-03-2023, inspected the premises of Medicine Store o/o Chief Executive Officer DHA Jhang, took sample of seven different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum No. 0000160216 dated 11-03-2023.
- ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:
- iii. Store Keeper, Medicine Store o/o Chief Executive Officer DHA Jhang submitted Invoice/warranty No. 2300033 dated 07-03-2023 issued by M/s Stanley Pharmaceuticals (Pvt.) Ltd 84-B, Industrial Estate, Hayatabad, Peshawar-Pakistan as a proof of its purchase of the said drug.
- iv. Warrantor Portion of the drug sample was sent to M/s Stanley Pharmaceuticals (Pvt.) Ltd 84-B, Industrial Estate, Hayatabad, Peshawar-Pakistan and they were asked to provide requisite information in this regard.
- v. A copy of test report was sent to M/s Stanley Pharmaceuticals (Pvt.) Ltd 84-B, Industrial Estate, Hayatabad, Peshawar-Pakistan and they were asked to provide requisite information in this regard.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Uncoated tablet Kamic Forte (Each uncoated tablet contains: Mefenamic acid	K-147	M/s Stanley Pharmaceuticals (Pvt.) Ltd 84-B, Industrial Estate,	TRA No. 01-68023056/DTL Dated:-11-05-2023	<u>Result of Test/ Analysis with specifications applied:</u> BP 2023 <u>Description:</u> Light yellow colored, oblong shaped uncoated tablets engraved with "STANLEY" on one side and plain on

(BP)...500mg)		Hayatabad, Peshawar- Pakistan		other side, contained in ALU-PVC packing of 10 units further packed in outer hard carton.								
Mfg.date:				NOTE: Manufacturer in its method of analysis specifies “White uncoated oblong shaped tablets”. But given sample is “Light yellow uncoated oblong shaped tablets” which does not comply with manufacturer’s description (appearance) of Tablets. (Does not Comply)								
Jan-2023				Identification: Mefenamic acid is identified.								
Exp. date:				Assay:								
Jan-2027												
Regn No.												
043343												
				<table border="1"> <thead> <tr> <th>Stated</th> <th>Determined</th> <th>Percentage</th> <th>Limit (USP 2023)</th> </tr> </thead> <tbody> <tr> <td>500mg/tablet</td> <td>497.770mg/tablet</td> <td>99.554%</td> <td>95-105%</td> </tr> </tbody> </table>	Stated	Determined	Percentage	Limit (USP 2023)	500mg/tablet	497.770mg/tablet	99.554%	95-105%
Stated	Determined	Percentage	Limit (USP 2023)									
500mg/tablet	497.770mg/tablet	99.554%	95-105%									
				(Complies)								
				Disintegration Test:								
				Stated: NMT 15 minutes (BP 2023)								
				Determined: All 6 units disintegrated within 15 minutes (Complies)								
				RESULT: Given sample is Sub-Standard with regards to description (Physical Characteristics) of Tablets.								

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

- i. Manufacturing for Sale / Sale of Sub-standard Drug.
- ii. Issuance of false warranty.

3. Showcause was issued to accused person(s) vide dated. 18-08-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. nil dated 30-08-2023 stating that:

Reference your Kind letter No: PQCB/R-110/2023 dated received on 30.08.2023.

Please refer to the subject cited above, it is stated that Drug Testing Laboratory Faisalabad TRA No: 01-68023056/DTL dated 11-05-2023 Declared substandard our product namely Tablet Kamik Forte (Mefenamic Acid 500mg) Batch No: K-147 Mfg. Date 01-2023 Exp. Date

01-2027 on the basis Of Description(Physical Characteristics) of Tablets regarding manufacturer in its method of analysis specifies "White uncoated tablets oblong shaped tablets instead of Light yellow oblong shaped uncoated tablets"

WS Stanley Pharma Peshawar hereby justified our position that is purely Typographical mistake is done in Manufacturer method of analysis specifies White uncoated tablets oblong shaped tablets instead of Light Yellow coloured oblong shaped uncoated tablets".

Moreover we hereby notified your attention that in Analysis reports of Compressed Tablets and Finished product report clearly mentioned Light Yellow colour oblong shaped uncoated tablets in kamic Forte Batch No K-147 Batch manufacturing is the strong evidence of Typographical mistake is done in Manufacturer method of analysis.

drug Testing Laboratory Faisalabad report shows that all chemical tests of kamic Forte batch No K- 147 complies BP 2023 including Identification, Weight Variation, Assay & Disintegration Time which shows our product is chemically of

So declared our Product namely kamic Forte batch No K- 147 Substandard on the basis of Typographical mistake is injustice. There is no risk for harmful.

It is requested to accept our justification/clarification and release the product for consumption as there is no patient risk involved in this case.

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	11-03-2023
2	Sample Sent to DTL (Form-6)	11-03-2023
3	Receipt Date in DTL	14-03-2023
4	Issuance of DTL Report	11-05-2023
5	Time Extension	N/A
6	DI First Communication with Firm	29-05-2023
7	Retesting Request	31-05-2023
8	Investigation Report by DI	03-06-2023
9	SCN Permission	262

		nd meeting
10	Show Cause Notice Issued	18-08-2023
11	History (3 years)	Firm's Reported: 79
		Product's Reported: 03

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 20

No. POCB/R-590/2022

Tehsil and District Attock

ATTENDANCE

Secretary DQCB Drug Inspector	<p>1. M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar through Chief Executive Officer (CEO), Abdullah Shah</p> <p>2. Abdullah Shah Chief Executive Officer (CEO)/Warrantor</p> <p>3. Imran Khan Production Incharge</p> <p>4. Umar Kamran Marwat Quality Control Incharge</p> <p>Of M/s Stanley Pharmaceuticals Pvt. Ltd., 84-B Industrial Estate Hayatabad, Peshawar.</p>
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BRIEF FACTS OF THE CASE

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

- i. He, on 13-07-2022 inspected the premises of M/S Bilal Pharmacy, Siddiqui Road, Attock and took sample of subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 0000133139 dated 13-07-2022.
- ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Suspension Furamid 60ml [Furazolidone 25mg/5ml, Metronidazole 75mg/5ml] Mfg. Date:05-2022 Exp. Date:05-2024 Reg# 00638	P-134	M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	01-74005084/ DTL dated: 12 Nov 2022	Result of test/ analysis with specifications applied MS <u>PHYSICAL DESCRIPTION:</u> Yellow-coloured suspension, filled in an ambered-coloured glass bottle with affixed label, sealed with silver aluminum screw cap imprinted with company name, further packed in labeled outer carton. ASSAY: FURAZOLIDONE: Stated: 25mg/5ml Determined: 28.044 mg/5ml Percentage 112.17%

				<p>LIMIT: 90-115%</p> <p>METRONIDAZOLE:</p> <p>Stated: 75mg/5ml</p> <p>Determined: 93.454 mg/5ml</p> <p>Percentage 124.61% (Does not comply)</p> <p>LIMIT: 90-115%</p> <p>RESULT:</p> <p><u>The sample is Substandard on the basis of Assay test performed for Metronidazole.</u></p>
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- iii. M/S Bilal Pharmacy, Siddiqui Road, Attock provided invoice/warranty No. 21448 dated 07-06-2022 issued by M/S Rabbani Traders, House No. CBA-1581, Opp Sports Complex, Attock Cantt.
- iv. Warrantor Portion was sent to M/S Rabbani Traders, House No. CBA-1581, Opp Sports Complex, Attock Cantt.
- v. M/S Rabbani Traders, House No. CBA-1581, Opp Sports Complex, Attock Cantt provided invoice/warranty No. 4280 dated 07-06-2022 issued by M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar .
- vi. A copy of Test/ Analysis report was sent to M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar and they were directed to provide requisite information in this regard. In response, the firm challenged the DTL report and requested for re-testing of the drug sample from Appellate Laboratory, National Institute of Health (NIH), Islamabad.
- vii. Pursuant to the retesting request of the firm, sample was sent to Appellate Laboratory, National Institute of Health (NIH), Islamabad from where the sample was declared substandard.

Name of Drug	Batch No.	Name of Manufacturer	Test Report No.	Details of Result of Test/analysis (With protocols of test applied)															
Suspension Furamid 60ml	P-134	M/S Stanley Pharmaceuticals (Pvt.) Ltd. 84-B Industrial Estate, Hayatabad, Peshawar	022-P/2023 dated: 24th Mar 2023	<p>Reference: MS</p> <table border="1"> <thead> <tr> <th>Assay</th> <th>Stated</th> <th>Found</th> <th>Limit</th> <th>%</th> </tr> </thead> <tbody> <tr> <td>Furazolidone</td> <td>25mg/5ml</td> <td>34.87mg/5ml</td> <td>90-120%</td> <td>139.49%</td> </tr> <tr> <td>Metronidazole Benzoate eq to Metronidazole</td> <td>75mg/5ml</td> <td>76.16mg/5ml</td> <td>90-115%</td> <td>101.55%</td> </tr> </tbody> </table> <p>CONCLUSION:</p> <p><u>The above sample is of SUB-STANDARD quality on the basis of test</u></p>	Assay	Stated	Found	Limit	%	Furazolidone	25mg/5ml	34.87mg/5ml	90-120%	139.49%	Metronidazole Benzoate eq to Metronidazole	75mg/5ml	76.16mg/5ml	90-115%	101.55%
Assay	Stated	Found	Limit	%															
Furazolidone	25mg/5ml	34.87mg/5ml	90-120%	139.49%															
Metronidazole Benzoate eq to Metronidazole	75mg/5ml	76.16mg/5ml	90-115%	101.55%															

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

- i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
- ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 31-08-2023

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	13-07-2022
2	Sample Sent to DTL (Form-6)	13-07-2022
3	Receipt Date in DTL	18-07-2022
4	Issuance of DTL Report	12-11-2022
5	Time Extension	251 meeting dated 20-10-2022
6	DI First Communication with Firm	29-11-2022
7	Retesting Request	02-12-2022
8	Investigation Report by DI	10-06-2023
9	SCN Permission	264 th meeting
10	Show Cause Notice Issued	31-08-2023
12	History (3 years)	Firm's Reported: 79
		Product's Reported: 01

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 21

PQCB/R-808/2019

Tehsil and District Jhang

ATTENDANCE

Secretary DQCB Drug Inspector	<ol style="list-style-type: none">1. M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi through its Managing Director Muhammad Muzammil Nazar2. Muhammad Muzammil Nazar Managing Director3. Ghulam Nabis Khoso Production Manager4. Naima Khanam Quality Control Manager/ Warrantor <p>Of M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi</p>
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BRIEF FACTS OF THE CASE

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

- i. The then Drug Inspector, on 01-08-2019, inspected the premises of Medicine Store office of Chief Executive Officer (DHA) Jhang, took sample of six different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum No. 0000046600 dated 02-08-2019.
- ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:
- iii. Store Keeper, Medicine Store office of Chief Executive Officer (DHA) Jhang submitted Invoice/warranty No. 001598 dated 18-06-2019 in favor of Medical Superintendent DHQ Hospital Jhang issued by M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi as a proof of its purchase of the said drug.
- iv. Warrantor Portion of the drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to provide requisite information in this regard.
- v. A copy of test report was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to provide requisite information in this regard.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Tablet Amarox (Each tablet contains: glimepiride USP...2mg)	062	M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi	TRA No. 01-56004539/DTL Dated:-29-11-2019	Result of Test/ Analysis with specifications applied: MS/USP 2019 Description: Blue colored, round shaped tablets scored from one side & plain from other side, contained in blister and packed in outer unit carton. Identification: Glimepiride identified.

						19	20	21	22	23	24	
						66.353 %	61.489 %	63.522 %	67.161 %	62.071 %	66.437 %	

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

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

- i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
- ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated.23-06-2023

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	01-08-2019
2	Sample Sent to DTL (Form-6)	02-08-2019
3	Receipt Date in DTL	07-08-2019
4	Issuance of DTL Report	29-11-2019
5	Time Extension	211 meeting dated 30-09-2019
6	DI First Communication with Firm	07-04-2020
7	SCN Permission	258 th meeting
8	Show Cause Notice Issued	23-06-2023
9	History (3 years)	Firm's Reported: 111
		Product's Reported:00

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 22

PQCB/R-610/2021

Tehsil & District Khushab

ATTENDANCE:

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <p>1. M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan through its Managing Director Muhammad Muzammil Nazar</p> <p>2. Muhammad Muzammil Nazar Managing Director</p> <p>3. Ghulam Nabi Khoso Production Manager</p> <p>4. Naima Khanam Quality Control Manager/ Warrantor</p> <p>Of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan.</p>
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BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil & District Khushab reported that:

- i. His Predecessor, on 16-06-2021, inspected the premises of Medicines Store of District Health Officer Khushab and took sample of four different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memorandum no. 0000098074 dated 17-06-2021.
- ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Syrup Zinkrol 120 ml (Each 5 ml contains Zinc Sulphate Monohydrate Eq. To Elemental Zinc 20mg) Mfg. date: Jan-2021 Exp. date: Jan-2023	172-21	M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan	TRA No. 01-75001691/DTL Dated: -21-08-2021	<u>Analysis with specifications applied:</u> IP 2019 <u>Physical Description:</u> Visibly clear, orange coloured solution with medicinal odour, filled in amber coloured plastic bottle with affixed label, sealed with white coloured plastic screw cap. <u>PH:</u> Observed: 4.79 at 25°C (DOES NOT COMPLY)

Reg. No.				Limit: 2.5-4.5								
086949				Assay:								
				<table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 15%;">Stated</th> <th style="width: 15%;">Determined</th> <th style="width: 15%;">Percentage</th> <th style="width: 15%;">Limit</th> </tr> </thead> <tbody> <tr> <td>20 mg/ 5ml</td> <td>21.476 mg/ 5 ml</td> <td>107.38 %</td> <td>90- 110%</td> </tr> </tbody> </table>	Stated	Determined	Percentage	Limit	20 mg/ 5ml	21.476 mg/ 5 ml	107.38 %	90- 110%
Stated	Determined	Percentage	Limit									
20 mg/ 5ml	21.476 mg/ 5 ml	107.38 %	90- 110%									
				RESULT:								
				<u>The above sample is ‘Substandard’ with respect to pH Test Performed.</u>								

- iii. Store Keeper of Medicines Store of District Health Officer Khushab submitted Invoice/warranty no. 000964 dated 25-05-2021 issued by M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan as a proof of its purchase of the said drug.
- iv. Warrantor portion of the drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan and they were asked to provide the requisite information in this regard.
- vi. The company challenged the report of DTL Rawalpindi in the appellate laboratory and the case was placed in 239th meeting of Provincial Quality Control Board held on 24-02-2022 where the Board after due deliberation unanimously decided to Turn Down the subject request for retesting of the sample and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

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 01-12-2022.

4. Personal Hearing notice(s) issued to accused person(s) dated 05-06-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 262nd meeting held on 13-06-2023

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **262nd meeting** held on **13-06-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Ahmad Khan, Secretary DQCB, District Khushab attended the meeting online via zoom link & Mr. Furqan Qureshi Drug Inspector Tehsil & District Khushab was present along with original case record. Among the nominated accused persons, Naima

Khanam, Quality Control Manager/ Warrantor of **M/s Lisko Pakistan (Pvt) Ltd. L-10-D, Block-21 F.B Industrial Area, Karachi, Pakistan** appeared before the Board and submitted that their product is complying all quality parameters except a minor deviation of pH from the limit that may have been exceeded because stabilising agent could not play its role resulting in alteration of pH value. She further added that they have taken corrective measures by upgrading working protocols & standards regarding pH and no such issue has been reported in current supplies provided to the institutions.

6. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample has been declared Substandard by Drug Testing Laboratory, Rawalpindi on the basis of pH that was found to be 4.79 25°C while the permissible limit was 2.5-4.5. All other parameters of the subject drug sample were well within the official limits. The Board further observed that firm has not provided replacement of substandard stock with fresh stock till date. The Board expressed concern over irresponsible behaviour of the firm and directed the firm to provide replacement of the stock to the institution within two weeks positively. The Board further directed the Secretary, District Quality Control Board concerned to ensure that firm provides replacement in time and intimate to Board regarding the status of stock replacement provided by the firm.
7. Keeping in view the foregoing facts of the case, the Board after due deliberation and discussion decided to **pend the case** until the issue of stock replacement gets resolved with the institution.

Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:01-2021**
- **Exp. Date: 01-2023**
- **Sampling date (Form 4): 16-06-2021**
- **Sent to DTL (Form 6): 17-06-2021**
- **Date of receipt in DTL: 24-06-2021**
- **DTL Report Date (Form 7): 21-08-2021 (0n 59th day)**
- **Time Extension to DTL: Report Not time barred**
- **DI 1st intimation to firm: 28-09-2021**
- **Retesting request if any: Yes**
- **Fate of Retesting Request: Turned down in 239th -M, dated: 24-02-2022**
- **Investigation report Dated: 23-09-2022**
- **Permission of SCN: 253rd meeting dated 29-11-2022**
- **SCN Issued: 01-12-2022**
- **Reply of the firm No**
- **History (3 years) Firm: 110 cases**
- **Product: 06 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

PQCB/R-611/2021

Tehsil & District Khushab

ATTENDANCE:

<p>Secretary DQCB</p> <p>Drug Inspector</p>	<p><u>Accused Persons involved in subject case</u></p> <p>1. M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan through its Managing Director Muhammad Muzammil Nazar</p> <p>2. Muhammad Muzammil Nazar Managing Director</p> <p>3. Ghulam Nabi Khoso Production Manager</p> <p>4. Naima Khanam Quality Control Manager/ Warrantor</p> <p>Of M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan.</p>
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BRIEF FACTS OF THE CASE

Provincial Inspector of drugs Tehsil & District Khushab reported that:

- i. His Predecessor, on 16-06-2021, inspected the premises of Medicines Store of District Health Officer Khushab and took sample of four different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memorandum no. 0000098075 dated 17-06-2021.
- ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
<p>Syrup Zinkrol 120 ml (Each 5 ml contains Zinc Sulphate Monohydrate Eq. To Elemental Zinc 20mg)</p> <p>Mfg. date: Jan-2021</p> <p>Exp. date: Jan-2023</p> <p>Reg. No. 086949</p>	171-21	M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan	<p>TRA No. 01-75001692/DTL</p> <p>Dated: -21-08-2021</p>	<p><u>Analysis with specifications applied:</u></p> <p>IP 2019</p> <p><u>Physical Description:</u></p> <p>Visibly clear, orange coloured solution with medicinal odour, filled in amber coloured plastic bottle with affixed label, sealed with white coloured plastic screw cap.</p> <p><u>PH:</u></p> <p>Observed: 4.76 at 25°C (DOES NOT COMPLY)</p> <p>Limit: 2.5-4.5</p> <p><u>Assay:</u></p>

Stated	Determined	Percentage	Limit
20 mg/ 5ml	21.345 mg/ 5 ml	106.73 %	90-110%

RESULT:

The above sample is "Substandard" with respect to pH Test Performed.

- iii. Store Keeper of Medicines Store of District Health Officer Khushab submitted Invoice/warranty no. 000964 dated 25-05-2021 issued by M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan as a proof of its purchase of the said drug.
 - iv. Warrantor portion of the drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan and they were asked to provide the requisite information in this regard.
 - v. A copy of test/analysis report was sent to M/s Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan and they were asked to provide the requisite information in this regard.
 - vi. The company challenged the report of DTL Rawalpindi in the appellate laboratory and the case was placed in 239th meeting of Provincial Quality Control Board held on 24-02-2022 where the Board after due deliberation unanimously decided to Turn Down the subject request for retesting of the sample and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.
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 01-12-2022.
 4. Personal Hearing notice(s) issued to accused person(s) dated 05-06-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 262nd meeting held on 13-06-2023

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **262nd meeting** held on **13-06-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Ahmad Khan, Secretary DQCB, District Khushab attended the meeting online via zoom link & Mr. Furqan Qureshi Drug Inspector Tehsil & District Khushab was present along with original case record. Among the nominated accused persons, Naima Khanam, Quality Control Manager/ Warrantor of **M/s Lisko Pakistan (Pvt) Ltd. L-10-D, Block-21 F.B Industrial Area, Karachi, Pakistan** appeared before the Board and submitted that their product is complying all quality parameters except a minor deviation of pH from the limit that may have been exceeded because stabilising agent could not play its role resulting in alteration of pH value. She further added that they have taken corrective measures by upgrading working protocols & standards

regarding pH and no such issue has been reported in current supplies provided to the institutions.

6. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample has been declared Substandard by Drug Testing Laboratory, Rawalpindi on the basis of pH that was found to be 4.76 25°C while the permissible limit was 2.5-4.5. All other parameters of the subject drug sample were well within the official limits. The Board further observed that firm has not provided replacement of substandard stock with fresh stock till date. The Board expressed concern over irresponsible behaviour of the firm and directed the firm to provide replacement of the stock to the institution within two weeks positively. The Board further directed the Secretary, District Quality Control Board concerned to ensure that firm provides replacement in time and intimate to Board regarding the status of stock replacement provided by the firm.
7. Keeping in view the foregoing facts of the case, the Board after due deliberation and discussion decided to **pend the case** until the issue of stock replacement gets resolved with the institution.

Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:01-2021**
- **Exp. Date: 01-2023**
- **Sampling date (Form 4): 16-06-2021**
- **Sent to DTL (Form 6): 17-06-2021**
- **Date of receipt in DTL: 24-06-2021**
- **DTL Report Date (Form 7): 21-08-2021 (On 59th day)**
- **Time Extension to DTL: Report Not time barred**
- **DI 1st intimation to firm: 28-09-2021**
- **Retesting request if any: Yes**
- **Fate of Retesting Request: Turned down in 239th -M, dated: 24-02-2022**
- **Investigation report Dated: 23-09-2022**
- **Permission of SCN: 253rd meeting dated 29-11-2022**
- **SCN Issued: 01-12-2022**
- **Reply of the firm No**
- **History (3 years) Firm: 110 cases**
- **Product: 06 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 23

PQCB/R-712/2021

Aroop Town District Gujranwala

ATTENDENCE

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Lisko Pkaistan Pvt. Ltd. , Block 21 FB Industrial Area, Karachi through its Managing Director Muzammil Nazar 2. Muzammil Nazar Managing Director 3. Ghulam Nabi Khoso Production In-charge 4. Naeema Khanum Quality Control In-charge/ Warrantor of M/S Lisko Pkaistan Pvt. Ltd. , Block 21 FB Industrial Area, Karachi.
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BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Aroop Town, Gujranwala reported that: -

- His Predecessor, on 19-06-2021, inspected the premises of Medicine Store DHO, DHA Gujranwala and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo. No. 98567, dated 21-06-2021.
- 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
Syp. Zinkrol, {each5 ml contains zins sulphate monohydrate equivalent to Elemental Zinc (USP)...20mg] Mfg Date: Jan-2021 Exp Date: Jan-2023	172-21	M/S Lisko Pakistan Pvt. Ltd., Block 21 FB Industrial Area, Karachi.	01- 68010466/DTL Dated. 13-08- 2021	<u>Analysis with specifications applied: IP 2020.</u> <u>Description:</u> Orange color syrup, contained in amber colored plastic bottle with sealed plastic screw cap. <u>Identification:</u> Zinc sulfate is identified. <u>Assay:</u> Stated: 20 mg/ 5ml Determined: 20.80 mg/ 5ml Percentage: 104.0% (Complies)

Registration No.				<p>Limit: 90-110% (IP 2020)</p> <p>pH:</p> <p>Stated: 2.5-4.5 (IP 2020)</p> <p>Determined: 4.81 (Does not Comply)</p> <p>Result:</p> <p>Given sample is Sub-standard with regards to pH Test.</p>
086949				

- iii. Drug Inspector directed the store keeper not to dispose of stock in his possession vide Form-3 dated 24-09-2021. Time extension was granted for a period of 90 days by PQCB in 238th meeting dated 09-02-2022.
- iv. Store keeper of Medicine Store DHO, DHA Gujranwala provided invoice/warranty No. 902 dated 19-05-2021 issued by M/S Lisko Pakistan Pvt. Ltd., Block 21 FB Industrial Area, Karachi.as a proof of its purchase.
- v. Warrantor portion of drug sample was sent to M/S Lisko Pakistan Pvt. Ltd., Block 21 FB Industrial Area, Karachi..
- vi. A copy of test/analysis report was sent to M/S Lisko Pakistan Pvt. Ltd., Block 21 FB Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard. In response, the firm requested for re-test/ analysis of the drug sample.
- vii. Pursuant to the request of manufacturer, the PQCB portion of the drug sample was sent to Appellate Laboratory. The drug was declared substandard from Appellate Laboratory, National Institute of Health Sciences, Islamabad as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Report No. & Date	NIH Test Report Result
Syrup Zinkrol 120 ml	172-21	M/S Lisko Pakistan Pvt. Ltd., Block 21 FB Industrial Area, Karachi.	0305-P/2022 dated 6 th January, 2023	<p>Analysis with specifications applied: Manufacturer's Specifications.</p> <p>pH Test:</p> <p>Determined:</p> <p>5.1±0.06</p> <p>Limit:</p> <p>2.5-4.5.</p> <p>Does not comply with manufacturer specification</p> <p>Result:</p> <p>The sample is of Sub-standard quality on the basis of tests performed.</p>

- viii. A copy of NIH Report was sent to M/S Lisko Pakistan Pvt. Ltd., Block 21 FB Industrial Area, Karachi with directions to explain their position and provide requisite information in this regard.

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

person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of :-

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

3. Show cause notice(s) issued to accused person(s) on 31-05-2023.

4. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 01-2021**
- **Exp. Date: 01-2023**
- **Sampling date (Form 4): 19-06-2021**
- **Sent to DTL (Form 6): 21-06-2021**
- **Date of receipt in DTL: 22-06-2021**
- **DTL Report Date (Form 7): 13-08-2021**
- **DI 1st intimation to firm: 08-10-2021**
- **Retesting request if any: 17-08-2021**
- **Fate of Retesting: Allowed in 253rd Meeting held on 29-11-2022.**
- **Investigation report Dated: 02-02-2023**
- **Permission of SCN: 258th meeting dated 05-04-2023**
- **SCN Issued: 31-05-2023**
- **Reply of the firm: No**
- **History (3 years) Firm: 110 cases**
- **Product: 06 cases**

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 24

PQCB/R-608/2021

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

ATTENDANCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <p>1. M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan through its Managing Director Muhammad Muzammil Nazar</p> <p>2. Muhammad Muzammil Nazar Managing Director</p> <p>3. Ghulam Nabi Khoso Production Manager</p> <p>4. Naima Khanam Quality Control Manager/ Warrantor</p> <p>Of M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan</p>
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BRIEF FACTS OF THE CASE:

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

- i. His Predecessor, on 05-05-2021, inspected the premises of Chief Executive Officer (District Health Authority) office, Dera Ghazi Khan and took sample of two different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum no. 0000091553 dated 05-05-2021.
- ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results				
Zinkrol (Elemental Zinc 20 mg / 5 ml) Syrup 120 ml. Mfg. date: Jan-2021 Exp. date: Jan-2023 Reg. No.	172- 21	M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan	TRA No. 01- 89003682/DTL Dated: 30-06- 2021	<u>Analysis with specifications applied:</u> IP 2019 <u>Physical Description:</u> Orange color liquid, in a labeled amber plastic bottle sealed with white screw cap. <u>Identification:</u> Elemental Zinc as Zinc Sulfate Monohydrate Identified. <u>Assay: Titration</u> <table border="1" style="width: 100%;"><thead><tr><th>Stated</th><th>Determined</th><th>Percentage</th><th>Limit</th></tr></thead></table>	Stated	Determined	Percentage	Limit
Stated	Determined	Percentage	Limit					

086949				20 mg/ 5ml	18.96 mg/ 5 ml	94.83 %	90- 110%
				<p>(Complies)</p> <p><u>PH Value:</u></p> <p>Range: 2.5-4.5</p> <p>Determined: 4.86 at 25°C</p> <p>(Does not Comply)</p> <p><u>RESULT:</u></p> <p>The above sample is <u>Sub-Standard</u> on the basis of pH Test.</p>			

- iii. Store Keeper, Chief Executive Officer (District Health Authority) office, Dera Ghazi Khan submitted Invoice/warranty no. 000808 dated 25-04-2021 issued by M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan as a proof of its purchase of the said drug.
 - iv. Warrantor portion of the drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan and they were asked to provide the requisite information in this regard.
 - v. A copy of test/analysis report was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan and they were asked to provide the requisite information in this regard.
 - vi. The company challenged the report of DTL Multan in the appellate laboratory and the case was placed in **239th meeting** of Provincial Quality Control Board held on 24-02-2022 where the Board after due deliberation unanimously decided to **Turn Down** the subject request for retesting of the sample and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.
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**
 - c. **Disobeying the lawful authority of drug inspector by non-provision of requisite information**
 3. Show cause Notice (s) issued to the accused person(s) Dated 01-12-2022.
 4. Personal Hearing notice(s) issued to accused person(s) dated 05-06-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 262nd meeting held on 13-06-2023

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **262nd meeting** held on **13-06-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. M. Asif Abbas, Secretary DQCB, Dera Ghazi Khan attended the meeting online via zoom link & Mr. Faisal Mahmood Khan Drug Inspector Tehsil Dera Ghazi Khan (Urban) District Dera Ghazi Khan was present along with original case record. Among the nominated accused persons, Naima Khanam, Quality Control Manager/ Warrantor of **M/s Lisko Pakistan (Pvt) Ltd. L-10-D, Block-21 F.B Industrial Area, Karachi, Pakistan** appeared before the Board and submitted that their product is complying all quality parameters except a minor deviation of pH from the limit that may have been exceeded because stabilizing agent could not play its role resulting in alteration of pH value. She further added that they have taken corrective measures by upgrading working protocols & standards regarding pH and no such issue has been reported in current supplies provided to the institutions. Drug Inspector Dera Ghazi Khan (Urban) apprised the Board that firm has not provided replacement of the stock till date and the firm remained reluctant to respond during the investigation process which resulted in delayed in completion of investigation.
6. The Board after careful perusal of the case record and scrutiny of DTL report observed that the subject drug sample has been declared Substandard by Drug Testing Laboratory, Multan on the basis of pH that was found to be 4.86 at 25°C while the permissible limit was 2.5-4.5. All other parameters of the subject drug sample were well within the official limits. The Board expressed concern over irresponsible behaviour of the firm and directed the firm to provide replacement of the substandard stock with the fresh stock to the institution within two weeks positively. The Board further directed the Secretary, District Quality Control Board concerned to ensure that firm provides replacement in time and intimate to Board regarding the status of stock replacement provided by the firm.
7. Keeping in view the foregoing facts of the case, the Board after due deliberation and discussion decided to **pend the case** until the issue of stock replacement gets resolved with the institution.

Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

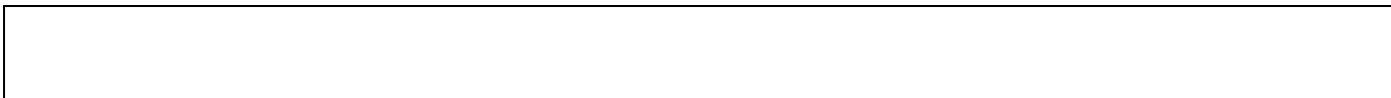
Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:01-2021**
- **Exp. Date: 01-2023**
- **Sampling date (Form 4): 05-05-2021**
- **Sent to DTL (Form 6): 05-05-2021**
- **Date of receipt in DTL: 06-05-2021**
- **DTL Report Date (Form 7): 30-06-2021 (0n 56th day)**
- **Time Extension to DTL: Report Not time barred**
- **DI 1st intimation to firm: 26-10-2021**
- **Retesting request if any: Yes**
- **Fate of Retesting Request: Turned down in 239th -M, dated: 24-02-2022**
- **Investigation report Dated: 24-10-2022**
- **Permission of SCN: 253rd meeting dated 29-11-2022**
- **SCN Issued: 01-12-2022**
- **Reply of the firm No**
- **History (3 years) Firm: 110 cases**
- **Product: 06 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 25

PQCB/R-615/2021

Tehsil and District Bahawalnagar

PQCB/R-615/2021

Tehsil and District Bahawalnagar

ATTENDANCE:

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

BRIEF FACTS OF THE CASE:

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

- His Predecessor, on 02-07-2021 inspected the premises of Main Medicine Store CEO-(DHA), Bahawalnagar, took below mentioned drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 0000099947 dated 02-07-2021.
- 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
Capsule Libracin [Doxycycline Hyclate eq to Doxycycline:100mg] Mfg Date: Expiry Date: Regn No. June-2021 June-2023 004597	476-21	M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan	01-77004814/ DTL dated: 24-08-2021
DTL Test Report Result			
Result of test/ analysis with specifications applied: USP 2020			
Description: Yellow color powder filled in green Hard Gelatin Capsule packed in blister packing enclosed in outer carton.			

Uniformity of Dosage Unit (Weight Variation): Does not comply the acceptance criteria of uniformity of dosage unit (weight variation) as per USP 2020 (Average Weight of contents of capsule:274.37mg)

Acceptance Criteria:

1. Acceptance value of first 10 dosage units is less than or equal to L1 (i.e. 15)
2. Final acceptance value of 30 dosage units is, L1 and no individual content of any dosage unit is less than $[1-(0.01) (L2)] M$ not more than $[1+(0.01) (L2)] M$.

Determined:

1. Acceptance value of 10 dosage units= 36.5 (Does not comply)
2. Acceptance value of 30 dosage units=27.1 (Does not comply)

Unit No.	1	2	3	4	5	6	7	8	9	10	Average X
Net content Weight (w) mg	260.5	281.6	203.1	273.1	312.3	266.5	285.7	229.7	234.1	316.9	91.85%
Estimated contents (x) %	87.21	94.27	67.99	91.42	104.55	89.21	95.64	76.89	78.37	106.08	
Unit No.	11	12	13	14	15	16	17	18	19	20	
Net content Weight (w) mg	293.1	297.2	287.2	306.9	278.3	296.9	292.7	288	277.9	294.4	
Estimated contents (x) %	98.12	99.49	96.14	102.74	93.16	99.39	97.98	96.41	93.03	98.55	
Unit No.	21	22	23	24	25	26	27	28	29	30	
Net content Weight (w) mg	287.9	263.1	245.2	295.5	225.1	331.5	263	229	279.6	235.2	
Estimated	96.38	88.07	82.08	98.92	75.35	110.97	88.04	76.65	93.60	78.74	

contents (x) %										
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Dissolution Test (USP): Comply with the specifications as described below:

Tolerance Limit: NLT 85% (Q) of the labelled amount of Doxycycline is dissolved in 60 minutes.

Level	Units	Acceptance Criteria							Remarks
		Each unit is not less than Q+5% (90%) and not more than 2 units are less than Q-15% (70%) and no unit is less than Q-25% (60%)							
S1	6	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Average	Comply with the specifications
Determined		94.13%	106.15%	103.39%	100.14%	94.72%	105.66%	100.70%	

Identification (USP): Doxycycline is identified.

Assay (USP):

Doxycycline:

Stated	100mg/cap
Determined	91.85mg/cap
Percentage	91.85%
Assay	90.0-120.0%

RESULT: The sample is declared **Sub-Standard** on the basis of **weight variation test [Uniformity of dosage unit test]**.

- iii. Store Keeper of Main Medicine Store CEO-(DHA), Bahawalnagar provided invoice/warranty number 001195 dated 23-06-2021 issued by M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan as a proof of its purchase.
- iv. Warrantor portion of the drug sample was sent to M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-2 1, F.B. Industrial Area, Karachi-Pakistan with directions to explain their position in this regard.
- v. A copy of Test/ Analysis report was sent to M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan with the directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 240th meeting of

Provincial Quality Control Board held on 31-05-2022 **allowed** to send the drug sample to NIH, Islamabad for retesting.

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result
Capsule Libracin [Doxycycline Hyclate eq to Doxycycline:100mg]	476-21	M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan	F.61- 80/073- P/2022- DC&TMD Dated. 03- 08-2022 F.61- 80/073- P/2022- DC&TMD Dated. 04- 10-2022	Reference letter no. PQCB/P-794-08/2021, Regarding test/analysis of drug sample Capsule Libracin 100mg, Batch No. 476-21. 2. It Is to inform you that mentioned sample could not be tested due to non-availability of facilities. Reference letter no. PQCB/P-794-08/2021, Regarding test/analysis of drug sample Capsule Libracin 100mg, Batch No. 476-21. 2. It Is to inform you that mentioned sample could not be tested due to non-availability of HPLC Column (L21).

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

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

3. Personal hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 02-07-2021

Date of DTL: 02-07-2021

Date of receipt in DTL: 03-07-2021

Issuance date of DTL Report: 24-08-2021

Time Extension: Not Time Barred

1st DI Communication with firm on dated: 27-09-2021

Retesting Request of Firm: Firm requested for Retesting Request dated 27-08-2021

Fate of Retesting Request: Sample sent to NIH in 240 meeting dated 15-03-2022

Investigation Report Dated: 29-12-2022

Permission of Show cause notice: 253-M

Show Cause Notice Date: 11-10-2023

Reply of the firm: Not Received till date

History of the firm of last 3 years:

Firm: 109 cases of the subject firm

Product: 04 cases of the subject product including subject product

Manufacturing Date: 06-2021

Expiry Date: 06-2023

PROCEEDINGS & DECISION BY THE BOARD:

Acceptance Criteria:

1. Acceptance value of first 10 dosage units is less than or equal to L1 (i.e. 15)
2. Final acceptance value of 30 dosage units is, L1 and no individual content of any dosage unit is less than $[1-(0.01) (L2)] M$ not more than $[1+(0.01) (L2)] M$.

Determined:

1. Acceptance value of 10 dosage units= 23.5 (Does not comply)
2. Acceptance value of 30 dosage units=20.1 (Does not comply)

Unit No.	1	2	3	4	5	6	7	8	9	10	Average X
Net content Weight (w) mg	268.2	240.3	281.6	282.9	283.5	250	307.8	269.4	305.8	257.6	95.38%
Estimated contents (x) %	91.44	81.93	96.01	96.46	96.66	85.24	104.95	91.85	104.26	87.83	
Unit No.	11	12	13	14	15	16	17	18	19	20	
Net content Weight (w) mg	271.7	280.6	255.6	270.1	327.7	256.4	251.1	283.6	254.6	261.1	
Estimated contents (x) %	92.64	95.67	87.15	92.09	111.73	87.42	85.61	96.70	86.81	89.02	
Unit No.	21	22	23	24	25	26	27	28	29	30	
Net content Weight (w) mg	280.4	313.3	329.3	290.3	279.2	331.2	255.9	257.4	304.2	291.4	
Estimated contents (x) %	95.60	106.82	112.28	98.98	95.19	112.92	87.25	87.76	103.72	99.35	

Dissolution Test (USP): Comply with the specifications as described below:

Tolerance Limit: NLT 85% (Q) of the labelled amount of Doxycycline is dissolved in 60 minutes.

Level	Units	Acceptance Criteria							Remarks
		NLT 85% (Q) in 60 minutes							
S1	6	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Average	Comply with the specifications
Determined		97.70%	95.18%	98.52%	85.40%	88.50%	90.41%	92.62%	

Identification (USP): Doxycycline is identified.

Assay (USP):

Doxycycline:

Stated	100mg/cap
Determined	95.38mg/cap
Percentage	95.38%
Assay	90.0-120.0%

RESULT: The sample is declared **Sub-Standard** on the basis of **weight variation test [Uniformity of dosage unit test]**.

- iii. Store Keeper of Main Medicine Store CEO-(DHA), Bahawalnagar provided invoice/warranty number 000088 & 000089, dated. 29-07-2021 issued by M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan as a proof of its purchase.
 - iv. Warrantor portion of the drug sample was sent to M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-2 1, F.B. Industrial Area, Karachi-Pakistan with directions to explain their position in this regard.
 - v. A copy of Test/ Analysis report was sent to M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan with the directions to explain their position and provide requisite information in this regard.
2. Drug Inspector requested for grant of permission for prosecution against the above- mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -
 - a. **Manufacture for Sale /Sale of Substandard Drug**
 - b. **Issuance of false warranty**
 3. Personal hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 28-08-2021

Date of DTL: 28-08-2021

Date of receipt in DTL: 30-08-2021

Issuance date of DTL Report: 25-10-2021

Time Extension: Not Time Barred

1st DI Communication with firm on dated: 18-11-2021

Retesting Request of Firm: N/A

Investigation Report Dated: 20-10-2022

Permission of Show cause notice: 262-M

Show Cause Notice Date: 11-10-2023

Reply of the firm: Not Received till date

History of the firm of last 3 years:

Firm: 110 cases of the subject firm

Product: 04 cases of the subject product including subject product

Manufacturing Date: 06-2021

Expiry Date: 06-2023

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 27

PQCB/R-812/2021

(DHQ Hospital Kasur)

ATTENDENCE

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

Provincial Inspector of Drugs, District Head Quarter Hospital, District Kasur reported that: -

- i. The then drug inspector, on 22-06-2021 inspected the premises of Main Medicine Store of District Head Quarter Hospital, District Kasur, took three different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Lahore vide memorandum no. 98888 dated 23-06-2021.
- ii. The subject drug samples, after test/analyses were declared as **Substandard** by Government Analyst, Drug Testing Laboratory Lahore as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Tablet. ARTILIS (ARTEMETHER 20mg, LUMEFANTRINE 120mg) Mfg Date: May-2021 Expiry Date: May-2023	420-21	M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan.	01-156001491/DTL dated 21-08-2021	Results of test/analysis with specifications applied: International Pharmacopoeia <u>PHYSICAL DESCRIPTION:</u> YELLOW COLOURED, ROUND SHAPED TABLET WITH TWO SCORED LINES PASSING EACH OTHER ON ONE SIDE AND PLAIN FROM THE OTHER SIDE PACKED IN BLISTER PACK OF SIXTEEN UNITS. <u>UNIFORMITY OF MASS:</u> Fails to comply the "Ph. Int." as detailed below: - <u>Tolerance Limit:</u> Not more than 2 out of 20 tablets should deviate from $\pm 5\%$ and none deviates from $\pm 10\%$ of average weight. <u>Determined:</u> Average weight of 20 tablets: 303.24mg. 3 units were found out of the limit of $303.24\text{mg} \pm 5\%$

<p>Regn No.</p> <p>082142</p>			<p>(Min: 288.08 mg – Max: 318.4 mg)</p> <p>(DOES NOT COMPLY)</p> <p><u>DISINTEGRATION TEST:</u> All six units disintegrated within specified time.</p> <p><u>IDENTIFICATION:</u> The retention time of the major peaks in the sample chromatogram correspond to the retention time of the major peaks in standard chromatogram (ARTEMETHER AND LUMEFANTRINE IDENTIFIED).</p> <p><u>ASSAY OF ARTEMETHER:</u></p> <p>Stated: 20 mg / Tab</p> <p>Determined: 19.34 mg / Tab</p> <p>Percentage: 96.72%</p> <p>Limit: 90.0 – 110.0% of the Label Claim</p> <p><u>ASSAY OF LUMEFANTRINE:</u></p> <p>Stated: 120 mg / Tab</p> <p>Determined: 113.92 mg / Tab</p> <p>Percentage: 94.93%</p> <p>Limit: 90.0 – 110.0% of the Label Claim</p> <p><u>RESULT:</u> The above sample is SUB-STANDARD, on the basis of UNIFORMITY OF MASS performed as per International Pharmacopoeia.</p>
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- iii. Storekeeper of Main Medicine Store of District Head Quarter Hospital, District Kasur, provided invoice/warranty bearing No. 001132 dated 17-06-2021 issued by M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan as a proof of its purchase of the subject drug sample.
- iv. Warrantor portion of the drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan.
- v. A copy of Test/ Analysis report was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health,

Islamabad.

vi. Pursuant to the request of M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan the retesting request of the subject drug sample was considered by the Board in its 239th meeting held on 24-02-2022 wherein the retesting request of the subject drug sample was turned down by the Board.

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

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

3. The Show-Cause Notice was issued to the accused person (s).

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

PROCEEDINGS & DECISION BY THE BOARD:

6. Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **283rd meeting** held on **08.08.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice-Chairperson PQCB. Marium Sharif, Secretary DQCB District Kasur attended the meeting online via zoom link along with original case record. No among nominated accused appeared before the Board on the behalf of M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan.

7. The Board decided to adjourn the case and also decided to provide another opportunity of personal hearing in best interest of justice.

Summary:

Manufacturing Date: 05.2021

Expiry Date: 05.2023

Sampling Date (Form 4): 22.06.2021

Sent to DTL (Form 6): 23.06.2021

Date of receipt in DTL: 24.06.2021

DTL Report Date (Form 7): 21.08.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 09.09.2021

Date of Retesting Request of Firm: 23.09.2021

Fate of Retesting: Turn Down in 239-M dated 24.02.2022

Investigation Report Dated: 06.07.2023

Permission of SCN: 265-M

SCN issued: 29.08.2023

Reply of firm: No Reply

History (Last 03 Years): Product: 01 case reported, Firm: 110 cases reported.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 28

PQCB/R-146/2022

Tehsil and District Bahawalnagar

ATTENDANCE:

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

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

- His Predecessor, on 30-11-2021 inspected the premises of Main Medicine Store CEO-(DHA), Bahawalnagar, took below mentioned drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 0000111861 dated 30-11-2021.
- The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory **Bahawalpur** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Suspension. Artilis [Artemether:15mg, Lumefantrine: 90mg/5ml, 60ml] Mfg Date: Oct-2021 Expiry Date: Oct-2023 Regn No.	G001- 22	M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	01- 86000401/ DTL dated: 31- 01-2022	Result of test/ analysis with specifications applied: IP 2020 <u>Composition:</u> Each Reconstituted 5ml Contains: Artemether IP.....15mg Lumefantrine IP.....90mg <u>Description:</u> Yellow colored liquid upon reconstitution of pale colored powder in sealed amber glass bottle, enclosed in outer carton. Identification (IP): Artemether is identified. Lumefantrine is identified.

082151

Assay (IP):

Assay	Stated	Determined	Percentage	Limit
Artemether	15mg/5ml	15.63mg/5ml	104.22%	90.0-110.0%
Lumefantrine	90mg/5ml	59.49mg/5ml	66.10%	90.0-110.0%

Does not comply with specifications.

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

- iii. Main Medicine Store CEO-(DHA), Bahawalnagar provided invoice/warranty number 000288 & 000289 dated 27-10-2021 issued by M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi as a proof of its purchase.
- iv. Warrantor portion of the drug sample was sent to M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi with directions to explain their position in this regard.
- v. A copy of Test/ Analysis report was sent to M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi with the directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 244th meeting of Provincial Quality Control Board held on 31-05-2022 **allowed** to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result															
Powder for Oral Suspension Atilis 60ml	G001-22	M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	0158-P/2022 dated 07-09-2022	<p>Analysis with specifications applied: MS</p> <p>Assay:</p> <table border="1"> <thead> <tr> <th>Assay</th> <th>Stated</th> <th>Found</th> <th>Limit</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Artemether</td> <td>15mg/5ml</td> <td>15.46mg/5ml</td> <td>90-110%</td> <td>103.06%</td> </tr> <tr> <td>Lumefantrine</td> <td>90mg/5ml</td> <td>14.73mg/5ml</td> <td>90-110%</td> <td>16.36%</td> </tr> </tbody> </table> <p>Does not comply with manufacturer's specifications.</p> <p>CONCLUSION: The sample is of Substandard quality on the basis of test performed.</p>	Assay	Stated	Found	Limit	Percentage	Artemether	15mg/5ml	15.46mg/5ml	90-110%	103.06%	Lumefantrine	90mg/5ml	14.73mg/5ml	90-110%	16.36%
Assay	Stated	Found	Limit	Percentage															
Artemether	15mg/5ml	15.46mg/5ml	90-110%	103.06%															
Lumefantrine	90mg/5ml	14.73mg/5ml	90-110%	16.36%															

vii. A copy of test report was sent to M/S Lisko Pakistan (Pvt) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

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

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

b. **Issuance of false warranty**

3. Personal hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 30-11-2021

Date of DTL: 30-11-2021

Date of receipt in DTL: 03-12-2021

Issuance date of DTL Report: 31-01-2022

Time Extension: Not Time Barred

1st DI Communication with firm on dated: 16-02-2022

Retesting Request of Firm: Firm requested for Retesting Request dated 22-08-2022

Fate of Retesting Request: Sample sent to NIH in 244 meeting dated 31-05-2022

Investigation Report Dated: 20-10-2022

Permission of Show cause notice: 253-M

Show Cause Notice Date: 15-06-2023

Reply of the firm: Not Received till date

History of the firm of last 3 years:

Firm: 110 cases of the subject firm

Product: 03 cases of the subject product including subject product

Manufacturing Date: 10-2021

Expiry Date: 10-2023

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 29

PQCB/R-367/2022

Tehsil and District Lodhran

ATTENDENCE

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan through its Director M. Muzammil Nazar 2. M. Muzammil Nazar Director 3. Naima Khanam Quality Control Manager/ Warrantor 4. Ghulam Nabi Khoso Production Manager Of M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan
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BRIEF FACTS OF THE CASE:

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

- i. His Predecessor, on 11-11-2021, inspected the premises of Main Medicine Store, office of CEO (DHA) Lodhran, took sample of four different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum no. 0000110765 dated 11-11-2021.
- ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Artilis (Artemether 15mg/5ml + Lumefantrine 90 mg/5ml) Powder for Oral Suspension.	G001-22	M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan	TRA No. 01-94000581/DTL Dated: 28-01-2022	<u>Result of test/ analysis with specifications applied:</u> IP 2020 <u>Description:</u> Yellow color dry powder, which upon reconstitution gives yellow to lemon color suspension in a labeled amber glass bottle, sealed with aluminum cap packed in a labeled outer hard carton. <u>Identification:</u> Artemether & Lumefantrine Identified. <u>Assay:</u> Artemether
Mfg. date: Oct-2021				
Exp. date: Oct-2023				

Reg. No. 082151				<table border="1"> <thead> <tr> <th>Stated</th> <th>Determined</th> <th>Percentage</th> <th>Limit</th> </tr> </thead> <tbody> <tr> <td>15mg/5ml</td> <td>14.13mg/5ml</td> <td>94.22 %</td> <td>90-110%</td> </tr> </tbody> </table>	Stated	Determined	Percentage	Limit	15mg/5ml	14.13mg/5ml	94.22 %	90-110%
				Stated	Determined	Percentage	Limit					
15mg/5ml	14.13mg/5ml	94.22 %	90-110%									
<p>(COMPLIES)</p> <p>Lumefantrine</p> <table border="1"> <thead> <tr> <th>Stated</th> <th>Determined</th> <th>Percentage</th> <th>Limit</th> </tr> </thead> <tbody> <tr> <td>90mg/5ml</td> <td>64.11mg/5ml</td> <td>71.23 %</td> <td>90-110%</td> </tr> </tbody> </table> <p>(DOES NOT COMPLY)</p> <p>RESULT:</p> <p>The above sample is Sub-Standard on the basis of the Assay of Lumefantrine.</p>	Stated	Determined	Percentage	Limit	90mg/5ml	64.11mg/5ml	71.23 %	90-110%				
Stated	Determined	Percentage	Limit									
90mg/5ml	64.11mg/5ml	71.23 %	90-110%									

- iii. Store Keeper, Main Medicine Store, office of CEO (DHA) Lodhran submitted Invoice/warranty no. 000267 dated 14-10-2021 issued by M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan as a proof of its purchase of the said drug.
- iv. Warrantor portion of the drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-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.
- vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 248th meeting held on 04-08-2022 **allowed** to send the drug sample to NIH, Islamabad for retesting from where the sample was declared **Substandard** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result								
Powder for oral Suspension Artilis 60 ml.	G001-22	M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan	0216-P/2022 dated 07-09-2022	<p>ASSAY:</p> <p>Lumefantrine</p> <table border="1"> <thead> <tr> <th>Stated</th> <th>Found</th> <th>Limit</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Stated	Found	Limit	Percentage				
Stated	Found	Limit	Percentage									

				90mg/5ml	11.9668mg/5ml	90-110%	13.29%
<p>Does not comply with manufacturer specification.</p> <p>CONCLUSION: The sample is of Sub-Standard quality on the basis of tests performed.</p>							

vii. The Copy of NIH report was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi-Pakistan

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: -

- i. **Manufacture for sale/sale of the Substandard drug**
- ii. **Issuance of false warranty**
- iii. **Disobeying the lawful authority of drug inspector by non-provision of requisite information**

3. Show cause Notice (s) issued to the accused person(s) Dated 20-04-2023.

4. Personal Hearing notice(s) issued to accused person(s) dated 18-05-2023.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 261st meeting held on 25-05-2023

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **261st meeting** held on **25-05-2023** under the chairpersonship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice Chairperson, PQCB). Mr. Misbah-ud-Din Qamar, Secretary DQCB, District Lodhran attended the meeting online via zoom link & Dr. Naveed Aslam, Drug Inspector, Tehsil & District Lodhran were present along with the original case record. No one among the nominated accused persons of **M/s Lisko Pakistan (Pvt) Ltd. L-10-D, Block-21 F.B Industrial Area, Karachi, Pakistan** appeared before the Board. However, representative of the firm, Masood Alam, Data supervisor/Sales officer appeared before the Board on behalf of the firm and submitted that Naima Khanam (Quality Control Manager/Warrantor) could not appear before the Board due to sudden illness. However, he presented her ticket as an evidence before the Board.

6. The Board accepted the arguments presented by the firm's representative and after due deliberation and discussion unanimously decided to **adjourn** the case in best interest of justice. The Board further decided to provide another opportunity of personal hearing to the accused persons.

7. Personal Hearing notice(s) issued to accused person(s) dated 05-06-2023.

PQCB's 262nd meeting held on 13-06-2023

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **262nd meeting** held on **13-06-2023** under the Chairmanship of Secretary, Primary and Secondary Healthcare Department, Punjab. Mr. Misbah-ud-Din Qamar, Secretary DQCB, Lodhran attended the meeting online via zoom link & Dr. Naveed Aslam, Drug Inspector Tehsil & District Lodhran was present along with original case record. Among the nominated accused persons, Naima Khanam, Quality Control Manager/ Warrantor of **M/s Lisko Pakistan (Pvt) Ltd. L-10-D, Block-21 F.B Industrial Area, Karachi, Pakistan** appeared before the Board and acknowledged that the product might have been deteriorated due to poor storage conditions. She further requested to take

lenient view from the Board.

9. The Board after careful perusal of the case record observed that the subject drug sample has been declared substandard on the basis of assay of Lumefantrine. The Board further observed that the Government Analyst, Drug Testing Laboratory Multan has applied International Pharmacopoeia specifications in test/ analysis of the subject drug sample as the Specifications mentioned on the label of the product are IP Specifications, whereas, Appellate Laboratory of National Institute of Health has applied Manufacturer specifications in the test/ analysis of the product. Keeping in view the facts of the case, the Board after due deliberation and discussion unanimously decided to **Pend the case with directions to seek clarification from National Institute of Health Sciences, Islamabad** regarding the manufacturers specification's applied for the purpose of test/ analysis and reported NIH Test report No. 0216-P/2022 dated 07-09-2022.

Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:10-2021**
- **Exp. Date: 10-2023**
- **Sampling date (Form 4): 11-11-2021**
- **Sent to DTL (Form 6): 11-11-2021**
- **Date of receipt in DTL: 16-11-2021**
- **DTL Report Date (Form 7): 28-01-2022 (0n74th day)**
- **Time Extension to DTL: 238th meeting, dated: 09-02-2022**
- **DI 1st intimation to firm: 19-07-2022**
- **Retesting request if any: Yes**
- **Fate of Retesting Request: NIH Substandard**
- **Investigation report Dated: 01-02-2023**
- **Permission of SCN: 258th meeting dated 05-04-2023**
- **SCN Issued: 20-04-2023**
- **Reply of the firm No**
- **History (3 years) Firm: 110 cases**
- **Product: 03 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 30

PQCB/R-726/2022

Tehsil Phalia District Mandi Bahauddin

ATTENDENCE

<p>Secretary DQCB</p> <p>Drug Inspector</p>	<p><u>Accused Persons involved in subject case</u></p> <p>1. M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan through its Managing Director, Muzammil Nazar</p> <p>2. Muzammil Nazar Managing Director</p> <p>3. Ghulam Nabi Khoso Production Incharge</p> <p>4. Naima Khanam Quality Control Incharge/ Warrantor</p> <p>of M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan.</p>
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BRIEF FACTS OF THE CASE:

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

- i. He, on 01-09-2022, inspected the premises of Main Medicine Store THQ Hospital Phalia District Mandi Bahauddin, took three different types of drug samples on Form No. 04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory Faisalabad vide memorandum no. 138867 dated 01-09-2022.
- ii. The following drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Faisalabad**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result
Syrup. Full Iron [Each 5ml contains: Iron III Hydroxide Polymaltose Complex eq. to Elemental Iron 50 mg)	005-23	M/S LISKO PAKISTAN (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan.	01-68018305/DTL dated 14-Oct-2022	<p>Analysis with specifications applied: MS</p> <p><u>DESCRIPTION:</u> <u>Brown colored liquid having unpleasant odor and dark reddish-brown precipitates sedimented at bottom of the bottle</u> contained in amber colored glass bottle sealed with white colored metallic screw cap, packed in outer hard carton.</p> <p><u>NOTE:</u> Manufacturer specifies appearance of syrup as, “Reddish brown syrup” in its method of analysis but given sample contains “Brown colored liquid having unpleasant odor and dark reddish-brown precipitates sedimented at bottom of the bottle” that does not comply with description (physical characteristics) of syrup. (Does not Comply)</p> <p><u>IDENTIFICATION:</u> Iron is identified.</p> <p><u>ASSAY:</u></p>
Mfg Date				

July 2022				Stated:	50 mg / 5ml
Expiry Date:				Determined:	52.852 mg / 5ml
July 2024				Percentage:	105.704% (Complies)
Regn No.				Limit:	80 – 120% (Manufacturer's Specifications)
086915				RESULT: <u>Given sample is Substandard with regards to physical characteristics of syrup.</u>	

- iii. Storekeeper of Main Medicine Store THQ Hospital Phalia District Mandi Bahauddin provided invoice/warranty bearing No. 000078 dated 10-08-2022 issued by M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan.
- v. A copy of test/analysis report was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area Karachi-Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

3. Show cause notice(s) issued to accused person(s) on 31-01-2024.

4. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 07-2022**
- **Exp. Date: 07-2024**
- **Sampling date (Form 4): 01-09-2022**
- **Sent to DTL (Form 6): 01-09-2022**
- **Date of receipt in DTL: 06-09-2022**
- **DTL Report Date (Form 7): 14-10-2022**
- **DI 1st intimation to firm: 07-11-2022**
- **Retesting request if any: Nil**
- **Fate of Retesting: NA**
- **Investigation report Dated: 08-11-2023**
- **Permission of SCN: 272nd meeting dated 22-11-2024**
- **SCN Issued: 23-01-2024**
- **Reply of the firm: No**
- **History (3 years) Firm: 52 cases**
- **Product: 04 cases**

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 31

[PQCB/R-778/2022](#)

THQ Hospital Sarai Alamgir

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">1. M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi through its Managing Director M. Muzammil Nazar2. M. Muzammil Nazar Managing Director3. Ghulam Nabi Khoso Production Manager4. Naima Khanam Quality Control Manager/ Warrantor <p>of M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi.</p>
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BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, THQ Hospital Sarai Alamgir reported that: -

- The then Drug Inspector, on 08-10-2022, inspected the premises of Main Medicine Store 1st Floor THQ Hospital Sarai Alamgir District Gujrat and took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo no. 00001437721 dated 10-10-2022.
- 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 No. & Date	DTL Test Report Result
Syrup Full Iron (Each 5 ml contains: Iron III Hydroxide POlymaltose Complex eq. to Elemental Iron...50mg) Mfg Date: Jul-2022 Expiry Date: Jul-2024 Regn No. 086915	005-23	M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi	01-68019398/ DTL Dated 16-11-2022	<p>Result of Test/ Analysis with specifications applied: MS</p> <p>DESCRIPTION: Brown colored liquid having unpleasant odor and dark reddish-brown precipitates sedimented at bottom of the bottle contained in amber colored glass bottle sealed with white colored metallic screw cap, packed in outer hard carton.</p> <p>NOTE: Manufacturer specifies appearance of syrup as, "Reddish brown syrup" in its method of analysis but given sample contains "Brown colored liquid having unpleasant odor and dark reddish-brown precipitates sedimented at bottom of the bottle" that does not comply with description (physical characteristics) of syrup. (Does not comply)</p> <p>IDENTIFICATION: Iron is identified.</p> <p>ASSAY:</p>

Stated	Determined	Percentage	Limit
50mg/5ml	47.329mg/5ml	94.658% (Complies)	80-120% (Manufacturer's specifications)

RESULT: Given sample is **Sub-Standard** with regards to physical characteristics of syrup.

- iii. Store Keeper Main Medicine Store 1st Floor THQ Hospital Sarai Alamgir District Gujrat provided Invoice/warranty No. 000164 dated 03-09-2022 issued by M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi.
 - iv. Warrantor portion was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to provide the requisite information in this regard.
 - v. A copy of test/analysis report was sent to M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to provide the requisite information in this regard.
2. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of :-
 - a. **Manufacture for sale /sale of Substandard drug**
 - b. **Issuance of false warranty**
 3. Show cause notice(s) issued to accused person(s) on 20-05-2024.
 4. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 07-2022**
- **Exp. Date: 07-2024**
- **Sampling date (Form 4): 08-10-2022**
- **Sent to DTL (Form 6): 10-10-2022**
- **Date of receipt in DTL: 14-10-2022**
- **DTL Report Date (Form 7): 16-11-2022**
- **DI 1st intimation to firm: 01-12-2022**
- **Retesting request if any: Nil**
- **Fate of Retesting: NA**
- **Investigation report Dated: 20-12-2023**
- **Permission of SCN: 275th (S) meeting dated 31-01-2024**
- **SCN Issued: 20-05-2024**
- **Reply of the firm: No**
- **History (3 years) Firm: 52 cases**
- **Product: 04 cases**

PROCEEDINGS & DECISION BY THE BOARD:



Assay

Paracetamol	Stated:	120 mg/5 mL	
	Determined:	129.78 mg/5 mL	
	Percentage:	108.15%	
	Limit:	90-110%	(Complies)
pH:	Stated:	4.0 – 6.9	
	Determined:	6.02	(Complies)

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

- iii. Store Keeper, Main Medicine Store, THQ Level Hospital, Chowk Azam, Layyah, provided invoice/warranty No. 000642 dated 13-03-2021 issued by M/s Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi, as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/s Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.
- v. A copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi and they were asked to explain their position and provide the requisite information in this regard.
- vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.
- vii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Parapol (Paracetamol 120mg/5ml) Paediatric Suspension 120ml	296-21	M/s Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi	0286-P/2022 dated: 07- 12-2022	Analysis with specifications applied: MS <u>Description:</u> Pinkish red colored liquid contained in an amber colored labeled glass bottle having undissolved solid crystalline masses visible to naked eye which did not disperse even on shaking further packed in an outer carton. (Does Not Comply with Manufacturer Specifications which states that "Pinkish red to reddish pink syrup"). <u>Result:</u> The sample is of <u>Substandard</u> quality on the basis of tests performed.

- viii. Copy of NIH report was sent to M/S Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi.

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)/ Personal Hearing notice issued to the accused on 28-02-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB's 277th meeting held on 07-03-2024

4. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **277th meeting** held on **07-03-2024** under the Chairmanship of Special Secretary (Operations)/ Vice-Chairperson PQCB, Primary & Secondary Healthcare Department Punjab. Mr. Amir Shakeel, Secretary DQCB, District Layyah attended the meeting online via zoom link and Mr. Shahid Zafar, Drug Inspector, Tehsil and District Layyah was present along with original case record. No one among the nominated accused persons was present. However, Zahoor Alam was present on behalf of M/s Lisko Pakistan (Pvt.) Ltd, L-10-D, Block-21, F.B. Industrial Area, Karachi. Secretary PQCB has apprised the Board that the firm has submitted written request for adjournment vide letter dated 06-03-2024. The Board after due deliberation and discussion unanimously decided to **adjourn the case** on request of the firm. The Board further decided to provide another/ final opportunity of personal hearing to the accused.

Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Case is placed before the board for decision

Summary of the case:

- **Mfg. date:03-2021**
- **Exp. Date: 03-2023**
- **Sampling date (Form 4): 20-04-2022**
- **Sent to DTL (Form 6): 21-04-2022**
- **Date of receipt in DTL: 27-04-2022**
- **DTL Report Date (Form 7): 25-06-2022 (Reported on 60th Day)**
- **DI 1st intimation to firm: 27-12-2023**
- **Retesting request if any: Yes, allowed in 252nd meeting, dated: 01-11-2022**
- **Fate of Retesting Request: NIH Substandard (Reported on 24th Day)**
- **Investigation report Dated: 04-01-2024**
- **Permission of SCN: 275th meeting dated 31-01-2024**
- **SCN Issued: 28-02-2024**
- **Reply of the firm** **No**
- **History (3 years)** **Firm: 110 cases**
- **Product: 87 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:



Case No. 33

PQCB/ MSS-176662/2023

THQ Hospital Sillanwali, District Sargodha

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi through its Chief Executive Officer/ Managing Director, M. Muzammil Nazar. 2. M. Muzammil Nazar Chief Executive Officer/ Managing Director 3. Ghulam Nabi Khoso Production Manager 4. Naima Khanam Quality Control Manager/ Warrantor of M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, THQ Hospital Sillanwali reported that: -

- i. She, on 28.09.2023, inspected the premises of Main Medicine Store, THQH Sillanwali situated at Kachahri Road, Sillanwali, District Sargodha and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No. 176662, dated 20.09.2023.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Rawalpindi, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Suspension Parapol 120mL (Paracetamol: 120mg/5ml) Mfg Date: Exp Date: Registration No. 07.2023 07.2025 002772	052-24	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-75007737/DTL Dated. 12.12.2023

DTL Test Report Result

Specification applied: USP 2023

Physical Description: Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton.

As per USP<1151> Pharmaceuticals Dosage Forms; “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase” while in actual the sample is clear viscous solution. (Does not comply)

pH: Complies

Identification: Paracetamol identified

Assay: Complies

RESULT: The above sample is **SUB-STANDARD** on the basis of **Physical Description as per USP.**

- iii. Store Keeper, Main Medicine Store, THQH Sillanwali situated at Kachahri Road, Sillanwali, District Sargodha provided delivery challan/ Invoice/warranty No. 000172, dated 09.09.2023 issued by M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi as a proof of its purchase.
- v. A copy of test/analysis report was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard. In response the firm submitted request for retesting. In 32nd meeting of Committee of PQCB the firm submitted request to withdraw its request for retesting which was accepted by the Committee.

Previous Proceedings & Decision by the Board: (Regarding Retesting Request)

32nd Committee Meeting held on 25-01-2024

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **32nd meeting** held on 25-01-2024 under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. Haji Javed, Quality Control Manager of M/S Lisko Pakistan (Pvt.) appeared before the committee to plead the case.

3. The Secretary PQCB apprised the Committee that the Manufacturer requested for retesting vide letter Reference No. Nil dated 19-12-2023. The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. MSS-177699, 176662, 178849, 178850, 177698/23 dated 16-01-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard).

4. The representative of the firm appeared before the committee and submitted withdrawal request vide letter no Nil dated 24-01-2024. The committee after due deliberation and discussion unanimously **decided to accept the firm's request for withdrawal of the retesting request** of the drug samples and the Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board

5. 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**

6. Show cause Notice (s) issued to the accused person(s) Dated 20-06-2024.

Note: Firm AGAIN requested for retesting of the subject drug samples vide letter addressed to Drug Inspector dated 06-06-2024, as follows:

Subject: PROVISION OF DETAILS OF TECHNICAL STAFF & VERIFICATION OF INVOICES AGAINST SUPPLIED BATCH NO 052-24 OF PARAPOL SUSPENSION 120MG/5ML

With reference to your letter no# 137/DI/SLW in which you have informed us that DTL Rawalpindi has declared batch no# 052-24 of Parapol susp 120mg/5ml as sub-standard on the basis of **physical description**, we would like to bring in your kind knowledge that we have already **contested and challenged all reports by DTL Rawalpindi in PQCB and we have requested PQCB to send our samples to NIH, Islamabad for conclusive report** as DTL Rawalpindi has declared our batches sub-standard on the basis of non-pharmacopeia test whereas product complies 100% against all USP test.

As requisite, we are submitting documents and verify all invoices against supplied stock (batch no 052-24) to THQ Hospital Silanwali:

1. DML and renewal challan attached

2. Following persons were responsible for manufacturing, QC analysis and distribution:

Details of Managing Director

M. Muzammil Nazar

Add: House No 693, DOHS, Phase 1, Malir Cantt., Karachi

CNIC No# 42101-9965280-7

Details of Production Manager

Mr. Ghulam Nabi Khoso

Add: House No: 47-A, Sindhi Para, Shanti Nagar, Dalmia, Karachi

CNIC No# 42201-7504385-7

Details of QC Manager+ Warrantor

Mrs. Naima Khanam

Add: House No. 407-A, Block 1, U.C-5, Gulshan-e-Iqbal Karachi

CNIC No# 42201-1930079-6

We request you to kindly submit complete investigation report to honorable PQCB so that **PQCB send samples of said batches for retesting by appellate lab i.e NIH, Islamabad.**

7. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024

SUMMARY OF THE CASE		
1	Sampling Date: (Form 4)	28.09.2023
2	Sent to DTL (Form 6):	28.09.2023 (20-10-2023 as per DTL Report)
3	Date of receipt in DTL	23-10-2023 (After approx. 22 days from Form-4)

4	DTL Report date	12-12-2023
5	Time extension granted	Not Time Barred
6	1ST DI Communication with firm	12-03-2024
7	Retesting Request of Firm	Yes (19-12-2023)
8	Fate of Retesting Request	Withdrawal request of firm accepted in 32 nd CM dated 25-01-2024
11	Investigation Report of DI	13-05-2024
12	SCN permission	281-M dated 06-06-2024
13	Show cause issued	20-06-2024
14	Reply of the firm	Not Yet
15	Firm History: (3 years)	Firm: 110 Product: 87

8. Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 34

PQCB/MSS-178849,178850/2023

Tehsil & District Sargodha

ATTENDANCE:

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

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

- i. He, on 17.10.2023, inspected the premises of Main Medicine Store, situated at CEO (DHA) Office Sargodha and took below mentioned drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide Memo. No. 178849 and 178850, dated 17.10.2023.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Rawalpindi, as detailed below:

Sr.	Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
01	Suspension Parapol 120mL (Paracetamol: 120mg/5ml) Mfg Date: Exp Date: Registration No. 07.2023 07.2025 002772	054- 24	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-75007807/DTL Dated. 12.12.2023
DTL Test Report Result Specification applied: USP 2023 Physical Description: Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton. As per USP<1151> Pharmaceuticals Dosage Forms; “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase” while in actual the sample is clear viscous solution. (Does not comply)				

	<p>pH: Complies</p> <p>Identification: Paracetamol identified</p> <p>Assay: Complies</p> <p>RESULT: The above sample is <u>SUB-STANDARD</u> on the basis of Physical Description as per USP.</p>			
02	Suspension Parapol 120mL (Paracetamol: 120mg/5ml) Mfg Date: Exp Date: Registration No. 07.2023 07.2025 002772	058-24	M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi	01-75007808/DTL Dated. 12.12.2023
<p>DTL Test Report Result</p> <p>Specification applied: USP 2023</p> <p>Physical Description: Pinkish Red coloured liquid, filled in amber coloured plastic bottle, having affixed label, sealed with white coloured plastic screw cap, further packed in outer labelled carton.</p> <p>As per USP<1151> Pharmaceuticals Dosage Forms; “A suspension is a biphasic preparation consisting of solid particles dispersed throughout a liquid phase” while in actual the sample is clear viscous solution. (Does not comply)</p> <p>pH: Complies</p> <p>Identification: Paracetamol identified</p> <p>Assay: Complies</p> <p>RESULT: The above sample is <u>SUB-STANDARD</u> on the basis of Physical Description as per USP.</p>				

- iii. Store Keeper, Main Medicine Store, situated at CEO (DHA) Office Sargodha provided delivery challan/ Invoice/warranty No. 000163, dated 09.09.2023 issued by M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal “B” Industrial Area, Karachi as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, F.B. Industrial Area, Karachi as a proof of its purchase.
- v. A copy of test/analysis report was send to M/S Lisko Pakistan (Pvt.) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road, Federal “B” Industrial Area, Karachi and they were directed to explain their position and to provide the requisite information in this regard. In response the firm submitted request for retesting. In 32nd meeting of Committee of PQCB the firm submitted request to withdraw its request for retesting which was accepted by the Committee.

Previous Proceedings & Decision by the Board: (Regarding Retesting Request) (For both batches)

32nd Committee Meeting held on 25-01-2024

2. The subject request for retesting of the drug sample was placed before the Committee of Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its **32nd meeting** held on 25-01-2024 under the chairmanship of Director General, Drugs Control, Convener of Committee, Provincial Quality Control Board, Punjab. Haji Javed, Quality Control Manager of M/S Lisko Pakistan (Pvt.) appeared before the committee to

plead the case.

3. The Secretary PQCB apprised the Committee that the Manufacturer requested for retesting vide letter Reference No. Nil dated 19-12-2023. The office of the Provincial Quality Control Board asked to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. MSS-177699, 176662, 178849, 178850, 177698/23 dated 16-01-2024 and to provide all relevant raw data, observations and calculations regarding QC analysis of batch release (Legible copy of complete BMR of the above-mentioned batch and procurement proof of Primary Standard/Secondary Standard).

4. The representative of the firm appeared before the committee and submitted withdrawal request vide letter no Nil dated 24-01-2024. The committee after due deliberation and discussion unanimously decided to accept the firm's request for **withdrawal** of the retesting request of the drug samples and the Committee further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

5. 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 drugs**
- b. **Issuance of false warranty**

6. Show cause Notice (s) issued to the accused person(s) Dated 20-06-2024.

Note: Firm AGAIN requested for retesting of the subject drug samples vide letter addressed to Drug Inspector dated 06-06-2024, as follows:

Subject: PROVISION OF DETAILS OF TECHNICAL STAFF & VERIFICATION OF INVOICES AGAINST SUPPLIED BATCH NO 054-24 & 058-24 OF PARAPOL SUSPENSION 120MG/5ML

With reference to your letter no# 137/DI/SLW in which you have informed us that DTL Rawalpindi has declared batch no# 054-24 & 058-24 of Parapol susp 120mg/5ml as sub-standard on the basis of **physical description**, we would like to bring in your kind knowledge that we have already **contested and challenged all reports by DTL Rawalpindi in PQCB and we have requested PQCB to send our samples to NIH, Islamabad for conclusive report** as DTL Rawalpindi has declared our batches sub-standard on the basis of non-pharmacopeia test whereas product complies 100% against all USP test.

As requisite, we are submitting documents and verify all invoices against supplied stock (batch no 054-24 & 058-24) to DHA Sargodha:

1. DML and renewal challan attached

2. Following persons were responsible for manufacturing, QC analysis and distribution:

Details of Managing Director

M. Muzammil Nazar

Add: House No 693, DOHS, Phase 1, Malir Cantt., Karachi

CNIC No# 42101-9965280-7

Details of Production Manager

Mr. Ghulam Nabi Khoso

Add: House No: 47-A, Sindhi Para, Shanti Nagar, Dalmia, Karachi

CNIC No# 42201-7504385-7

Details of QC Manager+ Warrantor

Mrs. Naima Khanam

Add: House No. 407-A, Block 1, U.C-5, Gulshan-e-Iqbal Karachi

CNIC No# 42201-1930079-6

We request you to kindly submit complete investigation report to honorable PQCB so that **PQCB send samples of said batches for retesting by appellate lab i.e NIH, Islamabad.**

7. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024

SUMMARY OF THE CASE		
1	Sampling Date: (Form 4)	17.10.2023
2	Sent to DTL (Form 6):	17.10.2023
3	Date of receipt in DTL	25-10-2023 (on 8 th day)
4	DTL Report date	12-12-2023
5	Time extension granted	Not Time Barred
6	1ST DI Communication with firm	15-12-2023
7	Retesting Request of Firm	Yes (19-12-2023)
8	Fate of Retesting Request	Withdrawal request of firm accepted in 32 nd CM dated 25-01-2024 But firm again requested for retesting addressing Drug Inspector
11	Investigation Report of DI	13-05-2024
12	SCN permission	281-M dated 06-06-2024
13	Show cause issued	20-06-2024

14	Reply of the firm	Not Yet
15	Firm History: (3 years)	Firm: 110 Product: 87

8. Case is placed before the Board for Decision

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 35

PQCB/R-885/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaquat 2. Kashif Liaquat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaquat Warrantor
	Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan

BRIEF FACTS OF THE CASE:

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

- i. He, on 29-04-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000035229, dated. 29-04-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 03-2019 Exp Date: 03-2022 Registration No. 062671	WI-350	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001534/DTL Dated. 16-06-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 05 ampoules out of 21 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5.3 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 11.34 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 25-04-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 29-04-2019

Date of DTL: 29-04-2019

Date of receipt in DTL: 30-04-2019

Issuance date of DTL Report: 16-06-2019

Time Extension: Not Time Barred (47 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 03-2019

Expiry Date: 03-2022

Flaw observed in case File: Gazette notification is beyond sampling date

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 36

PQCB/R-886/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaquat 2. Kashif Liaquat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaquat Warrantor
	Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan

BRIEF FACTS OF THE CASE:

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

- i. He, on 29-04-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000035235, dated. 29-04-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 03-2019 Exp Date: 03-2022 Registration No. 062671	WI-350	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001536/DTL Dated. 16-06-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 02 ampoules out of 21 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5.23 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 5.934 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 25-04-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 29-04-2019

Date of DTL: 29-04-2019

Date of receipt in DTL: 30-04-2019

Issuance date of DTL Report: 16-06-2019

Time Extension: Not Time Barred (47 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 03-2019

Expiry Date: 03-2022

Flaw observed in case File: Gazette notification is beyond sampling date

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 37

PQCB/R-887/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaqat 2. Kashif Liaqat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaqat Warrantor
	Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan

BRIEF FACTS OF THE CASE:

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

- i. He, on 29-04-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000035249, dated. 29-04-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 12-2018 Exp Date: 12-2021 Registration No. 062671	WI-334	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001538/DTL Dated. 16-06-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 08 ampoules out of 21 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5.23 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 6.622 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 18-04-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 29-04-2019

Date of DTL: 29-04-2019

Date of receipt in DTL: 30-04-2019

Issuance date of DTL Report: 16-06-2019

Time Extension: Not Time Barred (47 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 12-2018

Expiry Date: 12-2021

Flaw observed in case File: Gazette notification is beyond sampling date

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 38

PQCB/R-888/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaqat 2. Kashif Liaqat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaqat Warrantor Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan
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BRIEF FACTS OF THE CASE:

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

- i. He, on 29-04-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000035230, dated. 29-04-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 03-2019 Exp Date: 03-2022 Registration No. 062671	WI-352	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001535/DTL Dated. 16-06-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 02 ampoules out of 21 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5.36 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 14.51 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 25-04-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 29-04-2019

Date of DTL: 29-04-2019

Date of receipt in DTL: 30-04-2019

Issuance date of DTL Report: 16-06-2019

Time Extension: Not Time Barred (47 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 03-2019

Expiry Date: 03-2022

Flaw observed in case File: Gazette notification is beyond sampling date

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 39

PQCB/R-889/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaquat 2. Kashif Liaquat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaquat Warrantor
	Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan

BRIEF FACTS OF THE CASE:

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

- i. He, on 28-05-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 40111, dated. 28-05-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 04-2019 Exp Date: 04-2022 Registration No. 062671	WI-362	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001871/DTL Dated. 04-07-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 03 ampoules out of 20 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5.13 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 14.35 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 24-05-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 28-05-2019

Date of DTL: 28-05-2019

Date of receipt in DTL: 30-05-2019

Issuance date of DTL Report: 04-07-2019

Time Extension: Not Time Barred (35 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278-M

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 04-2019

Expiry Date: 04-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 40

PQCB/R-890/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaquat 2. Kashif Liaquat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaquat Warrantor
	Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan

BRIEF FACTS OF THE CASE:

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

- i. He, on 28-05-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 40134, dated. 28-05-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 04-2019 Exp Date: 04-2022 Registration No. 062671	WI-363	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001872/DTL Dated. 15-07-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 03 ampoules out of 15 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 15.45 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 24-05-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 28-05-2019

Date of DTL: 28-05-2019

Date of receipt in DTL: 30-05-2019

Issuance date of DTL Report: 15-07-2019

Time Extension: Not Time Barred (46 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278-M

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 04-2019

Expiry Date: 04-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 41

PQCB/R-891/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaquat 2. Kashif Liaquat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaquat Warrantor Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan
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BRIEF FACTS OF THE CASE:

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

- i. He, on 28-05-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000040127, dated. 28-05-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 04-2019 Exp Date: 04-2022 Registration No. 062671	WI-365	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001870/DTL Dated. 15-07-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 04 ampoules out of 20 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5.06 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 15.51 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 24-05-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 28-05-2019

Date of DTL: 28-05-2019

Date of receipt in DTL: 30-05-2019

Issuance date of DTL Report: 15-07-2019

Time Extension: Not Time Barred (46 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278-M

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 04-2019

Expiry Date: 04-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 42

PQCB/R-892/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaqat2. Kashif Liaqat Managing Partner3. Khalid Shafique Production Incharge4. Muhammad Fazil Quality Control Manager5. Yasir Liaqat Warrantor <p>Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan</p>
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BRIEF FACTS OF THE CASE:

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

- He, on 28-05-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000040177, dated. 28-05-2019.
- 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
Water for Injection Fynk [5ml] Mfg Date: 03-2019 Exp Date: 03-2022 Registration No. 062671	WI-361	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001873/DTL Dated. 15-07-2019	<p><u>Analysis with specifications applied:</u> USP 2018</p> <p><u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 03 ampoules out of 20 ampoules with naked eye. (Does not comply with the parenteral specifications).</p> <p><u>Volume:</u> Stated: 5ml Determined: 5.27 ml</p> <p><u>Conductivity:</u> Limit: NMT 25μ/cm Determined: 14.23 μ/cm</p>

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 24-05-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 28-05-2019

Date of DTL: 28-05-2019

Date of receipt in DTL: 30-05-2019

Issuance date of DTL Report: 15-07-2019

Time Extension: Not Time Barred (46 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278-M

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 03-2019

Expiry Date: 03-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 43

PQCB/R-893/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaqat 2. Kashif Liaqat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaqat Warrantor Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan
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BRIEF FACTS OF THE CASE:

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

- i. He, on 28-05-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000040178, dated. 28-05-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 04-2019 Exp Date: 04-2022 Registration No. 062671	WI-367	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001874/DTL Dated. 15-07-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 04 ampoules out of 20 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 11.49 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 24-05-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 28-05-2019

Date of DTL: 28-05-2019

Date of receipt in DTL: 30-05-2019

Issuance date of DTL Report: 15-07-2019

Time Extension: Not Time Barred (46 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 04-2019

Expiry Date: 04-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 44

PQCB/R-894/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaquat 2. Kashif Liaquat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaquat Warrantor
	Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan

BRIEF FACTS OF THE CASE:

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

- i. He, on 28-05-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000040123, dated. 28-05-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 04-2019 Exp Date: 04-2022 Registration No. 062671	WI-365	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65001875/DTL Dated. 15-07-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 06 ampoules out of 20 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5.1 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 13.10 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 24-05-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 28-05-2019

Date of DTL: 28-05-2019

Date of receipt in DTL: 30-05-2019

Issuance date of DTL Report: 15-07-2019

Time Extension: Not Time Barred (46 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278-M

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 04-2019

Expiry Date: 04-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 45

PQCB/R-895/2019

Tehsil and District CEO (DHA) Bahawalnagar

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	1. M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan through its Managing Partner Kashif Liaquat 2. Kashif Liaquat Managing Partner 3. Khalid Shafique Production Incharge 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaquat Warrantor
	Of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan

BRIEF FACTS OF THE CASE:

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

- i. He, on 25-06-2019, inspected the business premises of Main Medicine Store CEO (DHA) Bahawalnagar and took one drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo no. 0000043812, dated. 25-06-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Water for Injection Fynk [5ml] Mfg Date: 04-2019 Exp Date: 04-2022 Registration No. 062671	WI-369	M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan	01-65002213/DTL Dated. 21-08-2019	<u>Analysis with specifications applied:</u> USP 2018 <u>Description:</u> Colorless liquid in sealed transparent glass ampoule. Visible particulate matter is seen in 05 ampoules out of 20 ampoules with naked eye. (Does not comply with the parenteral specifications). <u>Volume:</u> Stated: 5ml Determined: 5.1 ml <u>Conductivity:</u> Limit: NMT 25 μ /cm Determined: 6.963 μ /cm

				<p><u>Sterility:</u> The product is sterile</p> <p><u>Result:</u></p> <p>The above sample is Substandard, on the basis of Physical Test.</p>
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- iii. Store Keeper of Main Medicine Store CEO (DHA) Bahawalnagar provided Delivery Challan/Invoice/Warranty No. DC/19/2018-19 dated 21-06-2019 issued by M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan as a proof of its purchase.
- iv. Warrantor Portion was send to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan and they were asked to provide the requisite information in this regard. In reply firm challenged the DTL test report and Provincial Quality Control Board in its 16th Committee meeting held on 16-06-2021 turn down the retesting request of the firm.

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

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

3. Show cause cum personal hearing notice(s) issued to accused person(s) dated 15-04-2024.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. Case were considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **279th meeting** held on **24-04-2024** under the Chairmanship of Special Secretary (Operations), Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Ms. Tayyaba Aslam Secretary DQCB, Bahawalnagar attended the meeting via zoom link and Mr. Yahya Drug Inspector Tehsil and District Bahawalnagar was present along with original case record. No one among nominated accused persons of M/S Fynk Pharmaceuticals 19-Km, G.T. Road, Kalashah Kaku, Lahore Pakistan however, the firm submitted written request for adjournment.

5. The Board after discussion decided to **adjourn** the cases and to provide another opportunity to appear before the Board in the best interest of justice.

6. Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Summary:

Date of sampling: 25-06-2019

Date of DTL: 25-06-2019

Date of receipt in DTL: 27-06-2019

Issuance date of DTL Report: 21-08-2019

Time Extension: Not Time Barred (55 Days)

1st DI Communication with firm on dated: 12-10-2019

Retesting Request of Firm: Firm requested for Retesting Request dated 18-10-2019

Fate of Retesting Request: Retesting Request was turn down in 16th Committee Meeting dated 16-06-2021

Investigation Report Dated: 27-02-2024

Permission of Show cause notice: 278

Show Cause Notice Date: 15-04-2024

Reply of the firm: Reply not received till date

History of the firm of last 3 years:

Firm: 16 cases of the subject firm

Product: 5 cases of the subject product

Manufacturing Date: 04-2019

Expiry Date: 04-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 46

PQCB/R-109/2022
Teaching Hospital Dera Ghazi Khan

ATTENDENCE:

Secretary DQCB	Accused Persons involved in subject case: 1. M/s Fynk Pharmaceuticals 19-K.M, G.T. Road Kalashah Kaku Lahore through its Managing Partner Kashif Liaqat 2. Kashif Liaqat Managing Partner 3. Khalid Farroq Production Manager 4. Muhammad Fazil Quality Control Manager 5. Yasir Liaqat Warrantor Of M/s Fynk Pharmaceuticals 19-K.M, G.T. Road Kalashah Kaku Lahore.
Drug Inspector	

BRIEF FACTS OF THE CASE

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

- i. He, on 10-02-2022, inspected premises of Main Store Teaching Hospital, Dera Ghazi Khan and took sample of drug on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Multan vide memorandum no. 0000118157 dated 10-02-2022.
- ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:
- iii. Store Keeper, Main Store Teaching Hospital, Dera Ghazi Khan submitted Invoice/warranty no. T-20210 dated 03-02-2022 issued by M/s Fynk Pharmaceuticals 19-K.M, G.T. Road Kalashah Kaku Lahore as a proof of its purchase of the said drug.
- iv. Warrantor portion and a copy of test/analysis report was sent to M/s Fynk Pharmaceuticals 19-K.M, G.T. Road Kalashah Kaku Lahore and they were asked to provide the requisite information in this regard.
- v. The company challenged the report of DTL Multan in the appellate laboratory vide letter No. Nil dated 15-04-2022 and the case was placed in 247th meeting of Provincial Quality Control Board held on 21-07-2022 where the Board after due deliberation and discussion unanimously decided to Turndown firm's request of the re-testing request of the subject drug sample and further directed the Drug Inspector of the concerned area to expedite investigation of the subject case and submit final report for consideration by the Board.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Drospa (Drotaverine HCl 40mg/ 2 ml) Injection. Mfg.date:	DR-292	M/s Fynk Pharmaceuticals 19-K.M, G.T. Road Kalashah Kaku Lahore	TRA No. 01-94002172/DTL Dated:-25-03-2022	<u>Analysis with specifications applied:</u> MS <u>Description:</u> Yellow color solution filled in amber colored glass ampoule with white printed label in labeled outer hard carton. 100 ampoules holding in beehives are placed in a unit outer hard carton (100* 2 ml Ampoules)

Jan-2022				<p><u>Particulate Contamination:</u></p> <p><u>Stated:</u> “Inspected unit must be free from visible particulates when examined without magnification against a black and white background approximately for 05 seconds”.</p> <p><u>Determined:</u> When examined against white and black background, 04 out of 20 ampoules contain visible particulates.</p> <p>(DOES NOT COMPLY)</p> <p><u>Extractable Volume:</u> Limit: NLT stated</p> <p style="text-align: center;">Determined: 2.08 ml (Complies)</p> <p><u>PH:</u> Range: 3.30-4.50</p> <p style="text-align: center;">Determined: 3.98 (Complies)</p> <p><u>Identification</u> Drotaverine HCL Identified.</p> <p><u>Assay</u></p> <p><u>Drotaverine HCL:</u></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Stated</th> <th style="text-align: center;">Determined</th> <th style="text-align: center;">Percentage</th> <th style="text-align: center;">Limit</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">40mg/ 2ml</td> <td style="text-align: center;">40.64 mg/ ml</td> <td style="text-align: center;">101.60%</td> <td style="text-align: center;">90-110%</td> </tr> </tbody> </table> <p>(Complies)</p> <p><u>Sterility:</u> It conforms to sterility test (Complies)</p> <p>RESULT:</p> <p>The above sample is <u>Substandard</u>, on the basis of visible particulate matter.</p>	Stated	Determined	Percentage	Limit	40mg/ 2ml	40.64 mg/ ml	101.60%	90-110%
Stated	Determined	Percentage	Limit									
40mg/ 2ml	40.64 mg/ ml	101.60%	90-110%									

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

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

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

Firm filed writ petition no. 77305/2022 titled as M/s Fynk Pharmaceuticals Vs province of Punjab etc in which Lahore High Court Lahore in order dated 09-12-2022... *the operation of impugned order to the extent of initiating criminal prosecution against the petitioners shall remain suspended*

IN THE LAHORE HIGH COURT LAHORE

JUDICIAL DEPARTMENT

W.P No. 77305 of 2022

M/s Fynk Pharmaceuticals Vs Province of Punjab etc

Date of Order: 16-11-2023

This order shall decide the present writ petition as well as connected writ petitions mentioned in Schedule A' as identical issue of law is involved in all the writ petition.

2. For the purposes of this order only the facts of the present case shall be stated.

3. This writ petition calls into question order dated 21.07.2022 passed by Provincial Quality Control Board/respondent No.2 (the Board) in rejecting the request of the petitioner for retesting of its drug. Petitioner No.1 (the petitioner) is a pharmaceutical company which manufactures Drospa (Drotaverine Hcl 40mg/2ml) injection (drug in question). The Drug Inspector took a sample of the drug in question from the main store, Teaching Hospital, Dera Ghazi Khan on Form No.4 and sent the sample of the drug in question to the Drug Testing Laboratory, Multan. The drug in question was declared to be sub-standard by the Government Analyst whereafter the petitioner requested through letter dated 05.04.2022 for retesting the sample under section 22 of the Drug Act, 1976 (the Act). The Board through the impugned order rejected the request and directed the Drug Inspector "...to expedite investigation of the subject case and submit final report for consideration by the Board." Pursuant to the said order, the Board has issued a show cause notice to the petitioner on 15.11,2022.

5. In impugning the report of the Government Analyst declaring the drug in question to be substandard, it was argued that the report failed to specify the size and number of particles in the drug in question. It was added that the drug in question complied with all the physical and chemical specifications and thus it could not be termed as substandard. In this regard, reliance was placed on section 32(2) of the Act and judgment reported as Provincial Quality Control Board and others v. Irza Pharma and others 1992 MLD 418. It is also the case of the petitioner that the impugned drug testing report failed to meet the mandatory requirements of Rule 11(1) of Punjab Drug Rules, 2007 and clause 7 of the Form 7 in as much as it failed to provide the details of the result of test/analysis.

6. Report and Parawise comments have been filed on behalf of respondents in which stance of the petitioner has been controverted. Learned Assistant Advocate General placed reliance on the judgment reported as Province of Punjab through Secretary Primary and Secondary Healthcare v. Ms Bloom Pharmaceuticals (Pvt.) Limited etc 2021 SCMR 590 to submit that the matter for retesting the drug in question rests in the absolute discretion of the Board and that the petitioner had no right to have the drug retested at its desire particularly when the report of the Government Analyst duly complied with all the requirements of law.

7. This Court has minutely examined the reports of the Durg Testing Laboratory in all the petitions. It is apparent that the reports duly provided the test/analysis and the details thereof. As such prima facie the requirements of clause 6 and 7 of Form-7 have been met with.

8. Section 32(2) of the Act reads as under:.

(2) A drug shall not be deemed to be misbranded or adulterated or sub-standard only by reason of the fact that there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug fit for carriage or consumption and not to increase the bulk, weight or measure of the drug or to conceal its inferior quality or other defect or there is a decomposed substance which is the result of a natural process of decomposition:

Provided that such decomposition is not due to any negligence on the part of the manufacturer

of the drug or the dealer thereof and that it does not render the drug injurious to health or does not make it substandard.

9. The report of the Drug Testing Laboratory in regard to the standard for Particulate Contamination stated that Inspected unit must be free from visible particulates when examined without magnification against a black and white background approximately for 05 seconds." As far as the physical verification of the drug in question, the report of Drug Testing Laboratory stated "When examined against white and black background, 04 out of 20 ampoules contain. visible particulates. " The Drug Testing Laboratory under the heading "Result" stated that The above Sample is Sub-standard, on the basis of visible particulate matter. "

10. The Board in its impugned decision referred to British Pharmacopoeia (BP-2018) which under the heading Parenteral Preparations" noted that "Solutions for infusion, examined under the suitable conditions of visibility, are clear and practically free from particles. " Similarly, the labelling instructions of the Drug in question were also mentioned in the impugned decision which stated that "These should not be used if visible particles are present.

11. The Board in the impugned order expressed its opinion on the report of the Drug Testing Laboratory by observing that The visible undissolved particles were observed in samples by the naked eye. The visible particulate matter is greater enough in size to pass through small arteries and veins which circulate the blood throughout the body including vital organs like heart and may cause a fatal disease i.e. myocardial infarction (M) or it may block some arteries supplying blood to the brain which may cause another life-threatening disease i.e. CVA and hemiplegia (paralysis). According to the guidelines of American Society of Parenteral and Enteral Nutrition, particles of 5 to 20 um and larger are capable of obstructing blood flow through the pulmonary capillaries, which may lead to complications such as pulmonary embolism and death of the patient.

12. It is thus clear that the Board has taken a well thought and conscious decision in rejecting the plea of the petitioner for retesting the drug in question. The judgment by the Supreme Court in the case of Messrs Bloom Pharmaceuticals held that the Board had the discretion to allow or disallow the request for retesting of the drug in question. This Court in the exercise of its Constitutional jurisdiction cannot substitute its opinion for that of the Board which has concluded that the petitioner has not been able to make out any case for retesting of the samples of the drug in question.

13. After going through the record, this Court is satisfied that the Board lawfully exercised the jurisdiction vested in it in refusing the request of the petitioner for retesting of the drug in question.

14. It is evident that through the impugned order, the Board directed the Drug Inspector to expedite the investigation of the case and to submit the final report to it for its consideration. After the impugned decision, the Board issued a show cause notice to the petitioner. The Board has thus not yet made a final order in the case of the petitioner. The Courts have always deprecated the practice of piecemeal challenge made to the decision-making process. The only exception is where the issue relates to the inherent jurisdiction of the decision-making authority or the issue goes to the root of the case. The Board has made its decision over the retesting of the sample of the drug in question and therefore the proceedings before it shall necessarily continue and after it has rendered its final decision and in case the matter is directed to be sent to the Drug Court for initiation of a criminal trial the petitioners shall have all the opportunity to avail the remedies provided under the Code of Criminal Procedure. The fact in this case and in connected petitions remains that the rights of the petitioners have not been finally decided and as such the challenge to the impugned order by recourse to Constitutional jurisdiction of this Court cannot be allowed.

15. The Court has gone through the judgment cited by the learned counsel for the petitioner which is not relevant to the controversy in issue in this writ petition.

16. for what has been stated above, this writ petition and the connected writ petitions having no merit are **dismissed**.

4. Personal hearing notice(s) issued to the accused persons(s) dated 26-08-2024

	Summary of the case	
1	Sampling Date: (Form 4)	10-02-2022
2	Sent to DTL (Form 6):	10-02-2022
3	Date of receipt in DTL	15-02-2022
4	DTL Report date	25-03-2022
5	Time extension granted	N/A
6	1 ST DI Communication	30-03-2022
7	Retesting Request of Firm	05-04-2022
8	Fate of Retesting Request	Turn down in 247-M dated 21-07-2022 Writ petition 77305/2022 dismissed vide LHC Order 16-11-2023
9	Investigation Report of DI	20-4-2022 and 28-09-2022
10	SCN permission	251-M dated 20-10-2022
11	Show cause notice issued	15-11-2022
12	Personal Hearing notice	26-08-2024
13	Firm History: (3 years)	Firm: 16

		Product: 2
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Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 47

PQCB/SM-30-12/2022, R-267/2023

(Tehsil Ferozewala, District Sheikhpura)

ATTENDENCE

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Fynk Pharmaceuticals, 19-Km G.T Road, Kalashah Kaku, Ferozewala through its Chief Executive Officer, Liaqat Ali. 2. Liaqat Ali Chief Executive Officer 3. Kashif Liaqat Director 4. Junaid Zafar Quality Control Manager / Warrantor 5. Abdul Rauf Production Manager of M/S Fynk Pharmaceuticals, 19-Km G.T Road, Kalashah Kaku, Ferozewala.
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BRIEF FACTS OF THE CASE

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

- i. He, on 17.12.2022, along-with other team members inspected the manufacturing premises of M/S Fynk Pharmaceuticals situated at 19-Km G.T Road, Kalashah Kaku, Lahore. During inspection, he recovered and seized following different types of drugs/ API/ material on Form 5:

Sr.	Name of Drug	Batch No.	Expiry Date	Name of Manufacturer	Quantity	Reason of Seizure & Sealing
1	API Betamethasone in blue plastic container	HBD-00922	04.2026	Haleyon Labs. (Pvt.) Ltd., India.	2.5kg Approx.	Stocking of API/ Raw material without documentation and record maintenance, violation of GMP
2	API Tramadol HCl in blue plastic container	LD/TM/0840721	06.2026		2Kg Approx.	Stocking of API/ Raw material without documentation and record maintenance, violation of GMP
3	BMR and other documents of API purchase and consumption not available.					

- ii. He **locked and sealed the raw material stock** of M/S Fynk Pharmaceuticals under section 18 (1) (h) of Drugs Act 1976 (amended) and rules framed under.
- iii. He also took sample 03 different types of drugs on Form 4 for the purpose of test/ analysis and send to Drug Testing Laboratory Lahore vide memo number 152232, 152233 and 152234 dated

22.12.2022.

iv. Following Drug sample after test/analysis was declared as **Misbranded** as detailed below and other 02 samples were declared of Standard Quality by Government Analyst Drug Testing Laboratory Lahore:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Syrup Cold-EEZE 60ml (Mepyramine Maleate: 6.25mg, Pheniramine Maleate: 6.25mg, Pseudoephedrine HCl: 15mg) Mfg Date: Exp Date: Registration No. 09.2022 09.2024 065897	037	M/S Fynk Pharmaceuticals, 19-Km G.T Road, Kalashah Kaku, Lahore	01-177003935/DTL Dated. 24.02.2023
DTL Test Report Result Specification applied: MS Physical Characteristics: Orange colored liquid claimed to be syrup in amber colored glass bottle with sealed aluminium screw cap with label pasted on it. Claimed volume: 60ml. IDENTIFICATION: Mepyramine Maleate, Pheniramine Maleate, Pseudoephedrine HCl identified. ASSAY: Complies Labelling: The product does not bear dosage and instructions in urdu on the label of innermost container, as well on outer carton. Hence, Misbranded as per the Drugs (Labeling and Packing) Rules 1986 [3{h(ii)(iii)}] RESULT: The above sample is Misbranded as per the Drugs (Labeling and Packing) Rules 1986 [3{h(ii)(iii)}].			

v. A copy of test/analysis report was sent to M/S Fynk Pharmaceuticals, 19-Km G.T Road, Kalashah Kaku, Lahore and they were directed to explain their position and to provide the requisite information in this regard

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

- a. Stocking of APIs and Raw Materials without proper documentation
- b. Without maintenance of Sale/ Purchase Record
- c. Violation of GMP
- d. Manufacturing of Misbranded Drug

3. The Show-Cause Notice was issued to the accused person (s).

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

Summary:

Inspection Date: 17.12.2022 (The Board in its 255th meeting dated 29.12.2022 granted permission to keep the custody of seized drugs articles on Form-5 and also granted the extension in the sealing period for 60days beyond the initial sealing period of two weeks.

Manufacturing Date: 09.2022

Expiry Date: 09.2024

Sampling Date (Form 4): 17.12.2022

Sent to DTL (Form 6): 22.12.2022

Date of receipt in DTL: 23.12.2022

DTL Report Date (Form 7): 24.02.2023

Time Extension: Granted in 259-Meeting dated 18.04.2023

1ST DI Communication with firm on dated: 16.03.2023

Date of Retesting Request of Firm: N/A

Fate of Retesting: N/A

Investigation Report Dated: 12.07.2023

Permission of SCN: 265-M

SCN issued: 09.05.2024

Reply of firm: No Reply

History (Last 03 Years):

(Misbranded) Product: 01 subject case reported, Firm: 04 cases reported.

(Substandard) Product: 00 case reported, Firm: 16 cases reported.

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 48

PQCB/R-750/2020

(Tehsil & District Bhakkar)

ATTENDENCE

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Cotton Craft (Pvt) Ltd, Plot No. 407, 408 Sundar Industrial Estate, Raiwind Road, Lahore through its Managing Director Mr. Salman Shahid. 2. Mr. Salman Shahid Managing Director 3. Hafiz Tariq Mahmood Production Manager/ Warrantor 4. Ms. Nuzhat Kausar Mumtaz Quality Control Manager of M/S Cotton Craft (Pvt) Ltd, Plot No. 407, 408 Sundar Industrial Estate, Raiwind Road, Lahore.
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BRIEF FACTS OF THE CASE

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

- i. His Predecessor, on 08.06.2020 inspected the premises of Medicine Store, O/o CEO-(DHA), Bhakkar, took below mentioned drug sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory Rawalpindi vide memorandum no. 0000067953 dated 08.06.2020.
- ii. The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory **Bahawalpur** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Surgical Bandage (open Wove Bandage size 15cm x 6m) Mfg Date: 02-2020 Expiry Date: 01-2023 Regn No.	33B20	M/S Cotton Craft (Pvt) Ltd, Plot No. 407, 408 Sundar Industrial Estate, Raiwind Road, Lahore	01-71000846/DTL dated: 09-07-2020	Specifications applied: BPC 1973 <u>Physical Description:</u> Cloth of plain weave, bleached to a good white, clean and reasonably free from weaving defects, leaf and shell, edges are evenly cut parallel with warp threads and reasonably free from loose threads. As per BPC, the bandage should be in one continuous length containing no joins. But the bandage is not in one continuous length and contains joins. Out of 08 units tested, 06 units were found to have joins. (Does not comply) <u>Warps:</u> Observed: 17.20/cm Limit: 17.1/cm ; SD 0.55 <u>Wefts:</u> Observed: 10.45/cm Limit: 10.7/cm ; SD 0.25 <u>Length:</u> Observed: 5.95m Limit: 6m <u>Width:</u> Observed: 15.4cm Limit: 15cm

006272				<p>Weight per unit area: Observed: 77.936g/m² Limit: 71g/m²; SD 2.5</p> <p>RESULT: The above sample is Substandard, on the basis of the Physical Characteristics observed.</p>
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- iii. Store Keeper of Main Medicine Store O/o CEO-(DHA), Bhakkar provided invoice/warranty number 0917 dated 17.06.2020 issued by M/S Cotton Craft (Pvt.) Ltd, Plot No. 407, 408 Sundar Industrial Estate, Raiwind Road, Lahore as a proof of its purchase wherein batch no. of said sample as written as 39B20 instead of 33B20. In your letter Ref:786/1087/2020 dated 15.09.2020 you have admitted the manufacturing of drug in question which was supplied to CEO (DHA) Bhakkar and also admitted that during routine checking it was found that there was some over/ misprinting / writing error in the batch number 39B20 of Surgical Bandage BPC, as to read “33B20” or “39B20” and all the printed labels were rechecked and out of 2030 labels 100 labels were found not easily readable.
- iv. Warrantor portion of the drug sample was sent to M/S Cotton Craft (Pvt.) Ltd, Plot No. 407, 408 Sundar Industrial Estate, Raiwind Road, Lahore with directions to explain their position in this regard.
- v. A copy of Test/ Analysis report was sent to M/S Cotton Craft (Pvt.) Ltd, Plot No. 407, 408 Sundar Industrial Estate, Raiwind Road, Lahore with the directions to explain their position and provide requisite information in this regard.
2. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way –

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

3. The Show-Cause Notice was issued to the accused person (s).

Reply of SCN by Frim:

This is with reference to the Show Cause Notice No. PQCB/R-750/2020 dated 03.07.2023, served to this firm, concerning the Surgical Bandages (Open Wove Bandage) BPC 15cm x 6m, Batch No. 33B20, Mfg. Feb. 2020 and Exp. Jan. 2023, sample taken on 08.06.2020 from Medicine Store, O/O CEO (DHA) Bhakkar and declared sub-standard by the by Government Analyst, Punjab DTL Rawalpindi vide report No. TRA-01-71000846/DTL dated 09.07.2020 on the basis of Physical Characteristics.

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

The details of DTL report No. No. TRA-01-71000846/DTL dated 09.07.2020 along-with our explanations/comments are given here under for evaluation and kind consideration at your end please.

Test performed	Stated Values	Determined/ Observed	Comments
Warps	Limit average 17.1/cm+S.D 0.5	17.20/cm	Complies
Wefts	Limit average 10.7/cm+S.D 0.25	10.45/cm	Complies

Length	6 meter	5.95 meter	Complies
Width	15cm	15.4cm	Complies
Weight/Area (g/m ²)	Average 71 g/m ² + S.D 2.5	77.936g/m ²	Complies
Description	Cotton cloth of plain weave, bleached to a good white, in one continuous length containing no joins, clean, and reasonably free from weaving defects, leaf and shell, the edges are evenly cut, parallel with the warp threads, and are reasonable free from loose threads.	As per BPC, the bandage should be in one continuous length containing no joints. But the bandage is not in one continuous length and containing joints. Out of 08 units tested, 06 units were found to have joints.	Does Complies Not

Please observe from the above analysis Report No. TRA-01-71000846/DTL dated 09.07.2020 the Drug/Medical Device under reference complies all necessary parameters (Warp, Weft, Length, Width and Weight per unit area etc.) required under BPC specifications but the Analyst declared it sub-standard only in Physical Description on the basis of "joints."

In this way our submission are as under.

- i. Joints: It is stated that usually we use big beams/Rolls of (1000-1200 Mtrs. length) joint together for washing and processing purposes. These rolls of continues length put over machines for production of bandages. We always take care to sort out the bandages having joints, even though some bandages with joint goes to the finished stock and supplies by human mistake. We are fully confident that it might be seen in one or two piece not in entire pack stock, but it happens very rare, which we understand is ignorable issue as the bandages are manufactured only for external use.

It is relevant to mention here that we tested the retained sample of the said No. 33B20 Surgical Bandages (Open Wove Bandage BPC 15cm x 6m, at our Quality Control Lab and observe it is of "Standard Quality" and there is no such shortfall in the sample as reported by the Analyst in his report. Copy of Lab Test Report dated 18.07.2020 is attached herewith for your ready reference. It is categorically declared that we have not received any warrantor portion from the concerned Provincial Inspector of Drugs, Tehsil & District Bhakkar.

It is stated that product under reference has been declared substandard on the grounds of physical description and has no chemical affect. The Surgical Bandages (Open Wove Bandage) is meant for external use only. It is stated that this item has many commercial usage other than medical purposes like Cleaning of Machinery, HVAC System & Pipe Fittings, Generator cleaning, Polishing, Sanitary and Rexene are major industries for use of Gauze Cloth, Bandage cloths called as Mulmul). Further it is mentioning here that the stock under reference seized in the consignee's store has already be.

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 find by the Analyst for declaring sub-standard are unfortunate, ignorable. Even though if the authority feel it necessary we are ready to replace the seized / expired 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/Sale of Substandard drug (b) Issuance of false warranty.

Particulars of Managing Director	
Name	Mr. Salman Shahid
CNIC	35202-7897961-3
Address	C/O Cotton Craft (Pvt.) Ltd.
Particulars of Production Incharge	
Name	Hafiz Tariq Mahmood
CNIC	36502-5621789-5
Address	C/O Cotton Craft (Pvt.) Ltd.
Particulars of QC Incharge	
Name	Ms. Nuzhat Kausar Mumtaz
CNIC	35202-3730500-6
Address	C/O Cotton Craft (Pvt.) Ltd.
Particulars of Warrantor	
Name	Hafiz Tariq Mahmood
CNIC	36502-5621789-5
Address	C/O Cotton Craft (Pvt.) Ltd.
Attested Copy of valid Manufacturing License	Attached
Attested Copy of Valid Drug Registration Certificate	Attached
Copies of CNICs of MD and Technical Staff	Attached
Copies of Job Certificates and Appointment letters of Technical Staff	Attached
Email Id for Correspondence	info@cottoncraftpvt.com
WhatsApp Number	0321-8482839

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, set aside the case at your end and allow to return seized expired stock to this firm with the conditions of replacement with fresh stock of standard quality to settle this issue at your level.

Thanking you and assuring you our best cooperation for all the time we remain.

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

Summary:

Manufacturing Date: 02.2020

Expiry Date: 01.2023

Sampling Date (Form 4): 08.06.2020

Sent to DTL (Form 6): 08.06.2020

Date of receipt in DTL: 17.06.2020

DTL Report Date (Form 7): 09.07.2020

Time Extension: N/A

1ST DI Communication with firm on dated: 04.08.2020

Date of Retesting Request of Firm: N/A

Fate of Retesting: N/A

Investigation Report Dated: 05.05.2021

Permission of SCN: 262-M

SCN issued: 03.07.2023

Reply of firm: 13.07.2023

History (Last 03 Years): Product: 02 case reported, Firm: 16 cases reported.

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 49

PQCB/R-617/2021

Tehsil and District Bahawalnagar

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/S Cotton Craft (Pvt) Limited, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan 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) Limited, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan
Drug Inspector	

BRIEF FACTS OF THE CASE:

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

- He, on 28-08-2021, inspected the premises of Main Medicine Store CEO-(DHA) Bahawalnagar and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo. No.0000104961, dated. 28-08-2021.
- 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				
Guaze Pro-Med Roll Absorbent Guaze [Absorbent Gauze: 4Ply Folded Gauze 1m x 30m]	52E21	M/S Cotton Craft (Pvt) Limited, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan	01-77005223/DTL Dated. 27-10-2021	<u>Analysis with specifications applied: BPC 1973.</u> <u>Description:</u> Cotton Cloth of plain weave, bleached to a white, clean and reasonably free from weaving defects, cotton leaf and shell. <u>Warp (BPC 1973):</u> <table border="1"><tr><td>Limit</td><td>Avg 73/10cm (SD:1.33)</td></tr><tr><td>Determined</td><td>73/10cm</td></tr></table> <u>Weft (BPC 1973):</u>	Limit	Avg 73/10cm (SD:1.33)	Determined	73/10cm
Limit	Avg 73/10cm (SD:1.33)							
Determined	73/10cm							
Mfg Date: May-2021								
Exp Date:								

April-2024				<table border="1"> <tr> <td>Limit</td> <td>Avg 57/10cm (SD: 1.33)</td> </tr> <tr> <td>Determined</td> <td>54/10cm</td> </tr> </table>	Limit	Avg 57/10cm (SD: 1.33)	Determined	54/10cm								
Limit	Avg 57/10cm (SD: 1.33)															
Determined	54/10cm															
Registration No.				<p><u>Weight/Unit Area (BPC 1973):</u></p> <table border="1"> <tr> <td>Limit</td> <td>Avg 15gm/m² (SD: 0.33)</td> </tr> <tr> <td>Determined</td> <td>18.58gm/m²</td> </tr> </table> <p>Does not comply with the specifications.</p> <p><u>Sinking Time (BPC 1973):</u></p> <table border="1"> <tr> <td>Limit</td> <td>Not more than 10 seconds</td> </tr> <tr> <td>Determined</td> <td>4.11 seconds</td> </tr> </table> <p><u>Acidity/Alkalinity (BPC 1973):</u></p> <table border="1"> <tr> <td>Limit</td> <td>Phenolphthalein=No pink color Methyl Orange=Yellow Color</td> </tr> <tr> <td>Determined</td> <td>No pink color with Phenolphthalein and yellow color with Methyl Orange.</td> </tr> </table> <p><u>Result:</u></p> <p>The sample is declared Substandard on the basis of Wight/m² Test.</p>	Limit	Avg 15gm/m² (SD: 0.33)	Determined	18.58gm/m²	Limit	Not more than 10 seconds	Determined	4.11 seconds	Limit	Phenolphthalein=No pink color Methyl Orange=Yellow Color	Determined	No pink color with Phenolphthalein and yellow color with Methyl Orange.
Limit	Avg 15gm/m² (SD: 0.33)															
Determined	18.58gm/m²															
Limit	Not more than 10 seconds															
Determined	4.11 seconds															
Limit	Phenolphthalein=No pink color Methyl Orange=Yellow Color															
Determined	No pink color with Phenolphthalein and yellow color with Methyl Orange.															
006269																

- iii. Main Medicine Store CEO-(DHA) Bahawalnagar provided Invoice/warranty No 0933, dated 17-06-2021 and 1129 dated 11-08-2021 issued by M/S Cotton Craft (Pvt) Limited, Plot No. 407-408, Sundar 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 (Pvt) Limited, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan and they were asked to explain their position in this regard.
- v. A copy of test/analysis report was sent to M/S Cotton Craft (Pvt) Limited, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan and they were asked to provide the requisite information in this regard. In response the firm challenged the Drug Testing Laboratory Report in the office of Provincial Quality Control Board, Provincial Quality Control Board placed the said retesting request in its 248^h meeting dated 04-08-2022 in which the Board allowed the firm to withdraw its retesting request.

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

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

3. Personal hearing notice(s) issued to accused person(s) dated 26-08-2024.

Reply of the firm to show cause notice

This is with reference to the Show Cause Notice No. PQCB/R-617/2021 dated 01.12.2022, served to this firm, concerning the Pro-Med Absorbent Gauze BPC IM X 30M, Batch No.52E21, Mfg. MAY-2021 and APR-2024, sample taken on 28.08.2021 from the Main Medicine Store CEO (DHA) Bahawalnagar and declared substandard by the by Government Analyst, Punjab DTL Bahawalpur vide report No.TRA-01-77005223/DTL dated 27.10.2021 on the basis of **weight per unit area, which is excessive than the standard limit**. In this regard we would like to submit here as under.

We would like to bring to your kind notice that the sample of the same Batch No. 52E21 of the same item has also been taken from the Khan Pur and tested by the same DTL Punjab Bahawalpur, which declared as "Pass of Standard Quality". Copies of Form 7 issued by the DTL Punjab Bahawalpur is attached herewith for your ready reference.

In the light of above DTL report we are unable to understand that how the analyst DTL Punjab Bahawalpur declared the same batch 52E21 as "Sub-standard", against their own test report, where they declare the same Batch as **"Pass of Standard Quality"**. It is stated that the same batch was supplied at the same time to the both consignees.

Here we would like to share the details of DTL report no. TRA-01-77005223/DTL dated 27.10.2021 along-with our explanations/comments for your kind consideration please.

Test performed	Stated Values	Determined/Observed	Comments
Description	Cotton Cloth of plain weave, bleached to a white, clean and reasonable free from waving defects, cotton leaf and shell.	Cotton Cloth of plain weave, bleached to a white, clean and reasonable free from waving defects, cotton leaf and shell.	Complies
Warps/10cm	Avg. 73/10cm (SD:1.33)	73/10cm	Complies
Weft/10cm	Avg. 57/10cm (SD: 1.33)	54/10cm	Complies
Sinking Tike	Not more than 10 second	4.11 second	Complies
Acidity / Alkalinity	Phenolphthalein = No Pink color Methyl orange = Yellow color	No Pink color with Phenolphthalein and yellow color with Methyl orange. Methyl orange = Yellow color	Complies
Weight/Unit area	Avg. 15gm/ m ² (SD: 0.33)	18.58 gm/ m ²	Does not comply with the spec.

Please observe from the above analysis the product/Drug under reference complies all necessary parameters required under BPC specification and confirms it is up-to the standards but the Analyst declared it sub-standard in Weight per unit area which is on excessive side.

Hence our submissions are as under:-

As per Test Report No. TRA-01-77005223/DTL dated 27.10.2021 the Government Analyst declared the item sub-standard on the basis of Weight per unit, determined as 18.58 gm/ m² against the stated limit of 15gm/ m² (SD:0.33). Please note the weight per unit area is on the higher side, which is a good sign and shows the improvement of the 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 (b) Issuance of false warranty.

As directed the desired information/documentations are given here under:-

1	Particulars of Managing Director	Name CNIC Address	Mr. Salman Shahid Copy Attached C/O Cotton Craft (Pvt.) Ltd.
2	Particulars of Production Incharge	Name CNIC Address	Hafiq Tariq Mahmood Copy Attached C/O Cotton Craft (Pvt.) Ltd.
3	Particulars of QC Incharge	Name CNIC Address	Ns. Nuzhat Kausar Mumtaz Copy Attached C/O Cotton Craft (Pvt.) Ltd.
4	Particulars of Warrantor	Name CNIC Address	Hafiq Tariq Mahmood Copy Attached as above C/O Cotton Craft (Pvt.) Ltd.

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 not justified. Hence your kind authority is requested to look into the issue on merit and the stock under reference may kindly be accepted or otherwise allow to return "out of specification" seized stocks to us with the conditions of replacement by fresh stock of standard quality for which we shall be highly obliged.

Thanking you and assuring you our best services / cooperation at all the time, we remain.

Summary:

Date of sampling: 28-08-2021

Date of DTL: 28-08-2021

Date of receipt in DTL: 30-08-2021

Issuance date of DTL Report: 27-10-2021

Time Extension: Not Time Barred

1st DI Communication with firm on dated: 28-12-2021

Retesting Request of Firm: Firm requested for Retesting Request dated 01-02-2022

Fate of Retesting Request: Firm withdraw Retesting Request in 248 meeting dated 04-08-2022

Investigation Report Dated: 05-09-2022

Permission of Show cause notice: 253-M

Show Cause Notice Date: 01-12-2022

Reply of the firm: Received

History of the firm of last 3 years:

Firm: 15 cases of the subject firm

Product: 02 cases of the subject product including subject product

Manufacturing Date: 05-2021

Expiry Date: 04-2024

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 50

PQCB/R-411/2022

Tehsil and District Rahim Yar Khan

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/S Cotton Craft (Pvt) Limited, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan 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) Limited, Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan
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BRIEF FACTS OF THE CASE:

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

- i. He, on 30-03-2022 inspected the medicine Store of District Manager PHFMC District office Rahim Yar Khan, took following sample on Form No. 4 for the purpose of test/analysis and sent to Drug Testing Laboratory, Bahawalpur vide memorandum no. 122557 dated 31-03-2022.
- ii. Following sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, Bahawalpur as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Cotton Absorbent Cotton wool BPC 500g Cotton craft [Cotton roll] Mfg date: 02-2022 Exp. Date: 01-2025 Regn No. 006271	27B22	M/s Cotton Craft (Pvt) Ltd., Plot No. 407-408 Sunder Industrial Estate, Raiwind Road, Lahore	01-86001614/DTL dated: 30-04-2022	Result of test/ analysis with specifications applied BPC 1973 <u>DESCRIPTION:</u> Well carded odorless cotton fibres, bleached to good white almost white. Free from loose threads, leaf and shell of foreign matter. It offers appreciable resistance when pulled and does not shred appreciable quantity of dust when gently shaken. <u>ABSORBENCY:</u> <u>SINKING TIME:</u> Limit: NMT 10 seconds at 20-25°C (BPC 1973) NMT 15 seconds at 20-25°C (F.6-6/2005-Reg-II (South)) Determined: Average 28.30 seconds

				<p>(Does not comply)</p> <p><u>WATER HOLDING CAPACITY:</u></p> <p>Limit: NLT 23gm per gm of sample (BPC 1973)</p> <p>NLT 20gm per gm (F.6-6/2005-Reg-II (South))</p> <p>Determined: Average 23.85gm per gm</p> <p><u>ACIDITY/ ALKALINITY (BPC 1973):</u></p> <p>Limit: No pink color with Phenolphthalein</p> <p>And yellow color with Methyl orange</p> <p>Determined: No pink color appeared on addition of Phenolphthalein. Yellow color appeared upon addition of Methyl orange</p> <p><u>RESULT:</u> The sample is <u>SUB-STANDARD</u> on the basis of <u>SINKING TIME</u>.</p>
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- iii. District Manager PHFMC District office Rahim Yar Khan, provided invoice/ warranty No. 1912 dated 21-02-2022 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 for prosecution against the above- mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

- a. **Manufacture for sale/Sale of Sub-standard Drug.**
- b. **Issuance of false warranty.**

3. Personal hearing notice(s) issued to accused person(s) dated 26-08-2024.

Reply of the firm to show cause notice

This is with reference to your Show Cause Notice No. PQCB/R-411/2022 dated 12.05.2023, served to this firm concerning the sample of Absorbent Cotton Wool BPC, 500gm Batch 27B22, sample taken from Medicine Store of the District Office, PHFMC, Rahim Yar Khan on 30.03.2022 and declared sub-standard by the Provincial Drug Testing Laboratory Bahawalpur vide test Analysis report No. 01-86001614/DTL dated 30.04.2022 on the basis of Sinking time.

In this regards the details of DTL report No.TRA-01-86001614/DTL dated 30.04.2022 along-with our explanations comments are given here under for evaluation and kind consideration at your end please.

Test performed	Stated Values	Determined/Observed	Remarks
Physical Description	Well-carded cotton fibers bleached to good white, free from pieces of threads and reasonably free from leaf, shell and foreign matter. It does not shed any appreciable quantity of dust when gently shaken	Well-carded cotton fibers bleached to good white, free from pieces of threads and reasonably free from leaf, shell and foreign matter. It does not shed any appreciable quantity of dust when gently shaken	Comply
Water Holding Capacity	NLT 20g/g	23.85gm/gm	Comply
Acidity / Alkalinity	No Pink color with phenolphthalein and Yellow color with Methyl Orange	No pink color appeared on addition of Phenolphthalein. Yellow color appeared upon addition of Methyl Orange.	Comply
Absorbency/Sinking time	Not more than 15 Second at 20-25°C.	Average 28.30 Second	Does not comply

Please observe from the above analysis that according to the Test Analysis Report No. TRA-01-86001614/DTL dated 30.04.2022 the Medical Device under reference complies all necessary parameters (Description, Water Holding capacity Acidity/Alkalinity etc.) required under the BPC specifications but the Analyst declared it sub-standard in Sinking time, which is a physical test.

Hence our submissions are as under:-

Sinking time: Sinking time is a physical test, normally differ due to temperature of water and if it done with the water having temperature of required limit, it must be compiles. In this case we understand it may be happen due to temperature of water otherwise all the test done by the Analyst has been complies and we have no doubt above the quality of our product.

It is relevant to mention here that we tested the warrantor portions as well as the retained sample of the said Batch No.27B22 of Absorbent Cotton Wool BPC 500gm at our Quality Control Lab and observe it is of "Standard Quality" and there is no such shortfalls in the sample as reported by the Analyst in his report. A copy of Test Report performed at our QC Lab dated 27.05.2022 is attached herewith for your ready reference. Annexure-A.

It is worthwhile to mention here that product under reference has been declared out of specification on the grounds of Sinking time otherwise all necessary parameters has been complies. It is stated that this item has many commercial usage other than medical purposes like Cleaning of Machinery, HVAC System & Pipe Fittings, Generator cleaning, Polishing and filling of pillows etc.

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 find by the Analyst for declaring out of specification 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.**

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 (b) Issuance of false warranty.

1	Particulars of Managing Director	Name CNIC Address	Mr. Salman Shahid Copy Attached C/O Cotton Craft (Pvt.) Ltd.
2	Particulars of Production Incharge	Name CNIC Address	Hafiq Tariq Mahmood Copy Attached C/O Cotton Craft (Pvt.) Ltd.
3	Particulars of QC Incharge	Name CNIC Address	Ns. Nuzhat Kausar Mumtaz Copy Attached C/O Cotton Craft (Pvt.) Ltd.
4	Particulars of Warrantor	Name CNIC Address	Hafiq Tariq Mahmood Copy Attached as above C/O Cotton Craft (Pvt.) Ltd.

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. Hence your kind authority is requested to look into the issue on merit and the stock under reference may kindly be accepted and set aside the case at your end or otherwise allow to return "out of specification" seized stocks to us with the conditions of replacement by fresh stock of standard quality for which we shall be highly obliged.

Thanking you and assuring you our best cooperation for all the time we remain.

Summary:

Date of sampling: 30-03-2022

Date of DTL: 31-03-2022

Date of receipt in DTL: 02-04-2022

Issuance date of DTL Report: 30-04-2022

Time Extension: Not Time Barred

1st DI Communication with firm on dated: 19-05-2022

Retesting Request of Firm: Firm requested for Retesting Request dated 30-05-2022

Fate of Retesting Request: Firm withdraw Retesting Request in 249 meeting dated 23-08-2022

Investigation Report Dated: 08-03-2023

Permission of Show cause notice: 258-M

Show Cause Notice Date: 12-05-2023

Reply of the firm: Received

History of the firm of last 3 years:

Firm: 15 cases of the subject firm

Product: 06 cases of the subject product including subject product

Manufacturing Date: 02-2022

Expiry Date: 01-2025

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 51

No. POCB/R-497/2022

Lyallpur Town District Faisalabad

ATTENDANCE

<p>Secretary DQCB</p> <p>Drug Inspector</p>	<p>1. M/s Cotton Craft PVT Ltd. Plot no. 407, 408 Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan through its Managing Director, Salman Shahid</p> <p>2. Salman Shahid Managing Director</p> <p>3. Hafiz Tariq Mahmood Production Incharge/Warrantor</p> <p>4. Nuzhat Kausar Mumtaz Quality Control Incharge</p> <p>of M/s Cotton Craft PVT Ltd. Plot no. 407,408 Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan.</p>
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BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Lyallpur Town District Faisalabad reported that: -

- i. The then drug inspector, on 22-02-2022, inspected the premises of Main Medicine Store of Punjab Health Facilities Management Committee, District Faisalabad, took eight different types of drug samples on Form No. 04 for the purpose of test/ analysis and sent the subject drug sample to Government Analyst Drug Testing Laboratory, Faisalabad vide memorandum 119273 dated 22-02-2022.
- ii. The subject drug sample 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 No. & Date	DTL Test Report Result
Absorbent Cotton Wool (Absorbent Cotton Wool, BPC Wt. 500gms)	39A22	M/s Cotton Craft PVT Ltd. Plot no. 407,408 Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan.	01-68014076/ DTL Dated 09-04-2022	<p><u>Analysis with specifications applied:</u> BPC 1973</p> <p><u>DESCRIPTION:</u> Well carded cotton fibers, bleached to a good white, free from foreign pieces of thread and reasonably free from leaf shell, and foreign matter. It offers appreciable resistance when pulled and does not shed appreciable quantity of dust when gently shaken and it was almost odorless.</p> <p><u>SOLUBILITY:</u></p> <p>Stated: Soluble at 20°, in 66% v/v sulphuric acid (BPC 1973 and F.6-6/2005-Reg-II (South))</p> <p>Determined: Dissolve in 66% v/v sulphuric acid (Complies)</p> <p>Stated: Soluble in ammoniacal copper oxide solution</p>
Mfg Date				
Jan 2022				
Expiry Date				
Dec 2024				

<p>Regn No.</p> <p>006271</p>			<p>(BPC 1973 and F.6-6/2005-Reg-II (South))</p> <p>Determined: Dissolve in ammoniacal copper oxide solution (Complies)</p> <p>Stated: Insoluble in dilute (1.25M) Sodium hydroxide solution (BPC 1973 and F.6-6/2005-Reg-II (South))</p> <p>Determined: Insoluble in dilute (1.25M) Sodium hydroxide solution (Complies)</p> <p><u>ABSORBENCY:</u></p> <p><u>Sinking Time:</u></p> <p>Stated: NMT 10 seconds at 20-25 °C (BPC 1973)</p> <p>NMT 15 seconds at 20-25 °C (F.6-6/2005-Reg-II (South))</p> <p>Determined: Average of 3 Tests= 46.67 seconds (Does Not Comply)</p> <p><u>Water Holding Capacity:</u></p> <p>Stated: NLT 23 gm per gm of sample (BPC 1973)</p> <p>NLT 20 gm per gm (F.6-6/2005-Reg-II (South))</p> <p>Determined: Average of 3 tests= 24.18 gm per gm (Complies)</p> <p><u>ACIDITY/ALKALINITY:</u></p> <p>Stated: Should be Neutral in reaction with phenolphthalein solution and methyl orange solution.</p> <p>Determined: Neutral (Complies)</p> <p><u>FLUORESCENCE TEST:</u></p> <p>Stated: No intense blue fluorescence except that which may be shown by a few isolated fibers. (BPC 1973).</p> <p>Determined: No intense blue fluorescence was observed in the given sample at 365nm(Complies)</p> <p><u>RESULT:</u> Given sample is Sub-Standard with regards to Absorbency Test (Sinking time) of Absorbent Cotton Wool.</p>
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- iii. The District Manager of Punjab Health Facilities Management Committee, District Faisalabad provided Invoice/Warranty no. 1784 dated 14-02-2022 issued by M/s Cotton Craft PVT Ltd. Plot no. 407,408 Sundar 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 PVT Ltd. Plot no. 407,408 Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan.

v. A copy of test/analysis report was sent to M/S Cotton Craft PVT Ltd. Plot no. 407,408 Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan with directions to explain their position and provide requisite information in this regard.

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

- i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
- ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated.09-05-2023.

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no.786/0659/2023 dated21-06-2023 stating that:

This is with reference to the Show Cause Notice No. PQCB/R-4 7/2 2 ed 09.05.2023 served to this firm, concerning Absorbent Cotton Wool BPC 500g, Batch No.39A22, sample taken from Medicine Store of the District Office, PHFMC, Faisalabad on 22.02.2022 and declared sub-standard by the Provincial Drug Testing Laboratory Faisalabad vide test Analysis report No. TRA-01-68014076/DTL dated 09.04.2022 on the basis of sinking time.

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

The details of DTL report No. TRA-OI -68014076/DTL dated 09.04.2022 along-with our explanations / comments are given here under for evaluation and kind consideration at your end please.

Please observe from the above analysis that according to the Test Analysis Report No. TRA no. OI-68014076 dated 09-04-2022 the Medical Device under reference Complies all necessary parameters (Description, Solubility, Water Holding capacity Acidity/Alkalinity. Fluorescence etc.) Required under the BPC specifications but the Analyst declared it sub-standard in Sinking time, which is a physical test.

Hence our submissions are as under:-

Sinking time: Sinking time is a physical test, normally differ due to temperature of water and if it done with the water having temperature of required limit it must be compiles. In this case we understand it may be happen due to temperature of water otherwise all the test done by the Analyst has been complies and we have no doubt about the quality of our product.

It is relevant to mention here that we tested the retained sample of the said Batch No.39A22 of Absorbent Cotton Wool BPC 500gm at our Quality Control Lab and observe it is of "Standard Quality" and there is no such shortfalls in the sample as reported by the Analyst in his report. A copy of Test Report performed at our QC Lab dated 16.02.2023 is attached herewith for your ready reference.

It is worthwhile to mention here that product under reference has been declared out of specification on the grounds of Sinking time otherwise all necessary parameters has been complies. It is stated that this item has many commercial usage other than medical purposes like Cleaning of Machinery, HVAC System & Pipe Fittings, Generator cleaning, Polishing and filling of pillows etc.

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

As directed the desired information / documentations are given here under:-

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. Hence your kind authority is requested to look into the issue on merit and the stock under reference may kindly be accepted or otherwise allow to return "out of specification" seized stocks to us with the conditions of replacement by fresh stock of standard quality for which we shall be highly obliged.

Thanking you and assuring you our best services / cooperation at all the time, we remain.

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	22-02-2022
2	Sample Sent to DTL (Form-6)	22-02-2022
3	Receipt Date in DTL	26-02-2022
4	Issuance of DTL Report	09-04-2022
5	Time Extension	N/A
6	DI First Communication with Firm	02-09-2022
7	Investigation Report by DI	27-03-2023
8	SCN Permission	259 th meeting dated 18-04-2023
9	Show Cause Notice Issued	09-05-2023
10	History (3 years)	Firm's Reported: 15
		Product's Reported: 06

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 52

PQCB-R-449/2022

Punjab Health Facilities Management Company

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/S Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind Road Lahore, Pakistan through its Managing Director, Salman Shahid 2. Salman Shahid Managing Director 3. Hafiz Tariq Mahmood Production Incharge/ Warrantor 4. Nuzhat Kausar Mumtaz Quality Control Incharge of M/S Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind Road Lahore, Pakistan.
Drug Inspector	

BREIF FACTS OF THE CASE:

Provincial Inspector of Drugs, Punjab Health Facilities Management Company, Lahore reported that:

- i. He, on 05-08-2022 inspected the premises of PHFMC Medicine Store (Store inside Chief Executive Office (DHA) District, Vehari and took following sample on Form No. 4 for the purpose of test/analysis and sent to Drug testing Laboratory, Multan vide memorandum no. 136119 dated 05-08-2022.
- ii. Following 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	DTL Test Report Result
Bandages Surgical Bandages (Open Wove Bandage, 6.5cm X 6m) (B.P.C)	43F22	M/S Cotton Craft (Pvt) Limited Plot No. 407,408 Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan	01-94005202/DTL Dated: 16-09-2022	Specification applied: BPC 1973 <u>DESCRIPTION:</u> <u>Stated:</u> Cotton cloth of plain weave, bleached to good white, in one continuous length containing no joints, clean and reasonably free from weaving defects, leaf, and shell; the edges are evenly cut, parallel with the warp threads, and are reasonably free from loose threads. <u>Determined:</u> Cotton cloth of plain weave, bleached to a good white, in one continuous length containing no joints, clean & have weaving defects, free from leaf and shell, the edges are unevenly cut, not parallel to the warp threads and have loose threads. (Does Not Comply) <u>Warps:</u> Stated: NLT 17.1/cm
Mfg date: 06-2022				
Exp. Date: 05-2025				
Reg. No: 006272				

				<p>Determined: 17.22/cm (Complies)</p> <p>Wefts: Stated: NLT 10.7/cm (SD 0.75 & MOH 5%)</p> <p>Determined: 8.02/cm</p> <p>(Does Not Comply)</p>
				<p>Weigh g/m²: Stated: NLT 71g/m² (SD 7.5 & MOH 5%)</p> <p>Determined: 68.40g/m² (Complies)</p> <p>RESULT: The above sample is Sub-standard on the basis Result : The above sample is Substandard on the basis of tests performed.</p>

- iii. Storekeeper, PHFMC Medicine Vehari provided Invoice/Warranty bearing No. 786/0069/2022 dated 27-07-2022 issued by M/s Cotton Craft, Plot No. 407, 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, Pakistan with direction to explain their position and provide requisite information in this regard.

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

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

b. **Issuance of false warranty**

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

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/s Cotton Craft, Plot No. 407, 408 Sunder Industrial Estate Raiwind Road Lahore, Pakistan submitted written reply in response to showcause notice vide reference number 786/0598/2023 dated 26-05-2023

Dear Sir,

This is with reference to the Show Cause Notice No. PQCB/R-449/2022 dated 05.05.2023 served to this firm, concerning the Cotton Bandage (Open Wove Bandage) BPC 6.5cm x 6 meter Batch 43F22, sample taken from PHFMC Medicine Store CEO (DHA) District Vehari on 05.08.202 and declared substandard by the by Government Analyst, Drug Testing Laboratory Multan vide test Analysis report No. 01-94005202/DTL dated 16.09.2022 on the basis of Description and Weft threads. In this regard we would like to submit here as under.

The details of DTL report No. TRA-01-94005202/DTL dated 16.09.2022 along-with our explanations / comments are given here under for evaluation and kind consideration at your end please.

Test performed	Stated Values	Determined/Observed	Comments
Warps Wefts	Limit average 17.1/cm ±5% Limit average 10.7/cm ±5% Total:-27.8/cm ±5%	17.22/cm 08.02/cm 25.44/cm +5% 26.50 (Total count almost complies)	Complies
Weight/Area (g/m ²)	Average 71 g/m ² ±5%	68.40g/m ²	Complies
Length	6 meter	6 meter	Complies
Width	6.5cm	6.5cm	Complies
Description	Cotton cloth of plain weave, bleached to a good white, in one continuous length containing no joins, clean, and reasonably free from weaving defects, leaf and shell, the edges are evenly cut, parallel with the warp threads, and are reasonable free from loose threads.	Cotton cloth of plain weave, bleached to almost white, in one continues length consisting no joints, clean & have weaving defects, free from leaf and shell, the edges are unevenly cut, not parallel to the warp threads and have loose threads.	Does Not Complies

Please observe from the above the drug / Medical Device under reference complies test (Thread Per unit area, weight per unit area, width and length).

It is mentioning that the difference in warp and weft thread and weight up-to 5% is allowed as per Revised Specifications Notification issued by the Government of Pakistan, Ministry of Health, Islamabad vide No.F.6-6/2005-Reg-11 (South) dated 13 September, 2006. Copy of notification is attached herewith for your ready reference.

Please observe from the above analysis Report TRA. 01-94005202/DTL dated 16.09.2022 the Medical Device under reference complies all necessary parameters (Warp, Weft, Weight per unit area, Width, Length etc.) required under BPC specification but the Analyst declared it sub-standard only in Physical Description on the basis of "uneven cutting and loose threads."

In this way our submission are as under.

Unevenly Cut Edges with Loose Threads.:- We may mention here that Bandages cloth is very thin, and it is very difficult to manage but we do

it, and sometime minor dissimilarity seen after opening of bandage, which actually is not un-even cutting but it is because of thin cloth. Also it is confirmed that we cut the bandage edges very sharply over the automatic machines and do not left the chance of loose threads but again we clarify that due to very thin cloth it can be arise on opening of the bandage but very rare. So it is purely the Analyst's own discretion that how he/she judge uneven cutting and loose threads.

Further stated that it is cut edge bandage (Open Wove Bandage) made from very thin fabric and always takes care about loose threads and maintain it maximum level but some-time during opening of the packet and single bandage also threads comes out because of rough handling. If we judge loose threads when the roll is un-opened it will definitely be seen without loose thread. However we understand it is Analyst's own discretion that how to check it and judge it.

Furthermore it is cut edge bandage (Open Wove Bandage) and not a weave edge bandage, so it is natural to give the loose threads when opening of the packet and single bandage also threads comes out because of rough handling.

It is relevant to mention here that we tested the warrantor portion as well as the retained sample of the said Batch No.43F22 Cotton Bandages (Open Wove Bandage) BPC 6.5cm x 6m, at our Quality Control Lab and observe it is of "Standard Quality" and there is no shortfall in the sample as reported by the Analyst in his report.

It is stated that product under reference has been declared substandard on the grounds of description and has no chemical affect. The Surgical Bandages (Open Wove Bandage) is meant for external use only. It is stated that this item has many commercial usage other than medical purposes like Cleaning of Machinery, HVAC System & Pipe Fittings, Generator cleaning, Polishing, Sanitary and Rexene are major industries for use of Gauze Cloth, Bandage cloths called as Mulmul).

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 not correct, hence we request you to accept the quantity /stock under reference. Even though if the authority feel it necessary we are ready to replace the seized stock with the 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 (b) 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. Hence your kind authority is requested to look into the issue on merit and the stock under reference may kindly be accepted or otherwise allow to return "out of specification" seized stocks to us with the conditions of replacement by fresh stock of standard quality for which we shall be highly obliged.

Thanking you and assuring you our best services / cooperation at all the time, we remain.

Personal Hearing notice issued to accused person(s).

Sr.	Summary of the case	
1.	Date of sampling	05-08-2022
2.	Sent to DTL	05-08-2022
3.	Date of receipt in DTL	13-08-2022
4.	Issuance of DTL Report	16-09-2022
5.	Time Extension	N/A

6.	DI 1st communication with firm	13-10-2022
7.	Retesting Request	20-10-2022
8.	Fate of retesting request	Withdrawn- PQCB 256 th meeting dated 19-01-2023
9.	Investigation Report of DI	10-03-2023
10.	Permission of SCN	258 th meeting dated 28-02-2023
11.	SC Notice Issued	05-05-2023
12.	Reply of the firm	26-05-2023
13	History (3 years)	16 cases of the firm 03 cases of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 53

PQCB/R-905/2021

Sheikh Zayed Hospital, Rahim Yar Khan

ATTENDANCE:

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case:</u></p> <ol style="list-style-type: none">1. M/s Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan through its Chief Executive Officer Kashif Hussain.2. Kashif Hussain Chief Executive Officer3. Muhammad Irfan Murtaza Production Incharge4. Muhammad Naeem Quality Control Incharge5. Shakeel Bashir Warrantor <p>of M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan</p>
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BRIEF FACTS OF THE CASE:

Provincial Inspector of Drugs, Sheikh Zayed Hospital, Rahim Yar Khan reported that: -

- i. He, on 29-04-2021 inspected the premises of Central Pharmacy (Main Medicine Store) Sheikh Zayed Hospital Rahim Yar Khan and took sample of 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, **Bahawalpur** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Injection. Olam [Midazolam 1mg/ml] Mfg Date: March-2021, Exp Date: March-2023 Registration No. 093476	OL 11	M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan	01-77003922/DTL Dated. 26-06-2021
Specifications: USP 2020 Composition: Each ml contains: Midazolam.....1mg Description: Colorless liquid in sealed transparent glass ampoule. (Stated volume: 5ml). <i>04 ampoules out of 20 contain visible particulate matter. (Does not comply with the parenteral specifications).</i> Volume:			

Limit	NLT Nominal volume
Determined	5.1ml

pH:

Limit	2.5-3.7
Determined	3.0

Sterility: The product is sterile.

Identification: Midazolam is identified.

Assay: Midazolam

Stated	1mg/ml
Determined	0.977mg/ml
Percentage	97.70%
Limit	90.0-110.0%

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

- iii. Storekeeper, Sheikh Zayed Hospital Rahim Yar Khan provided Invoice/Warranty No. 551, 552, dated 17-04-2021 issued by M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan and they were asked to explain their position in this regard.
- v. A copy of test/analysis report was sent to M/S Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan and they were asked to provide the requisite information in this regard.

Previous Proceeding regarding retesting request

243rd meeting dated 12-05-2022

The subject request for retesting of the drug sample was placed before the Provincial Quality Control Board (PQCB) Punjab under section 22 of the Drugs Act 1976 in its 243rd meeting held on 12-05-2022. The Board after due deliberation and discussion unanimously decided to turn down the said retesting request.

Firm filed review petition dated 22-03-2023 received in office of PQCB dated 03-04-2023

PQCB vide letter dated 20-07-2023 that the review petition against retesting order of PQCB of given sample cannot be entertained as sample has expired.

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

- a. **Manufacture for sale/ sale of Sub-standard drug.**
- b. **Issuance of false warranty**

3 Show cause/personal hearing notice(s) issued to the accused

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

4. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **280th** meeting held on **16-05-2024** under the chairmanship of Special Secretary (operations) vice chairperson PQCB Primary and Secondary Health Care Department. Mr. Rafaqat Ali Secretary DQCB Rahim Yar Khan attended meeting via zoom link and Mr. Ilyas Drug Inspector Sheikh Zayed Hospital, Rahim Yar Khan was present along with original case record. No one among the nominated accused person of M/s Liven Pharmaceuticals, 49-km Lahore Multan Road, Pakistan was present. Firm submitted written request for adjournment vide letter ref #LVN/PQCB/QA/1 dated 15-05-2024.

5. The Board after due deliberation and discussion, unanimously decided to **adjourn** the case on request of the firm in the best interest of justice and provide another chance of hearing to the accused. 6. Moreover, the drug inspector is directed to retain an appropriate portion for Court purposes and dispose-off the remaining stock having Expiry date of 03-2023 from Expired Drug Disposal Committee (EDDC) of health facilities already constituted vide PSHD notification No. SO (HP) 2-9(2)/ 2021 dated 14-February, 2022 and PQCB order dated 06-05-2023 on guidelines regarding fate of case property and report to the office of Secretary PQCB within 7 days.

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

Summary of the cases		
1	Sampling Date: (Form 4)	29-04-2021
2	Sent to DTL (Form 6):	29-04-2021
3	Date of receipt in DTL	29-04-2021
4	DTL Report date	26-06-2021
5	Time extension granted	N/A
6	1 ST DI Communication with firm	28-07-2021
7	Retesting Request of Firm	31-07-2021

8	Fate of Retesting Request:	Turn down 243 rd meeting dated 12-05-2022. Firm file RP dated 22-03-2023 against retesting order on received in office of PQCB dated 03-04-2023 (after expiry of Drug 03-2023)
9	Investigation Report of DI	05-03-2024
10	SCN permission	278-M dated 28-3-2024
11	Show cause/PH notice issued	06-05-2024
12	Firm History: (3 years)	Firm: 10 Product: 2

Case is placed before the Board for Decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

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Case No. 54

PQCB-R-414,415,416/2023

Allama Iqbal Memorial Teaching Hospital, Sialkot

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<ol style="list-style-type: none">1. M/S Liven Pharmaceuticals (Pvt.) Ltd, 49km Lahore Multan Road, Pakistan through its Managing Director Kashif Hussain.2. Kashif Hussain Managing Director3. Syed Naveed Abbas Production Manager4. Muhammad Iqbal Quality Control Manager5. Shakeel Bashir Warrantor <p>of M/S Liven Pharmaceuticals (Pvt.) Ltd, 49km Lahore Multan Road, Pakistan.</p>

BREIF FACTS OF THE CASE:

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

- i. He, on 31-12-2022, inspected the premises of M/S Main Medicine Store Allama Iqbal Memorial Hospital, Sialkot and took three different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo. No.0000152933, 0000152935 and 0000152934 dated. 31-12-2022 respectively.
- ii. Following Drug samples after test/analysis were declared as **Substandard** by Government Analyst Drug Testing Laboratory **Faisalabad**, as detailed below:

Sr. No.	Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
1	Infusion Livocetamol 100ml [Each ml contains: Paracetamol.....10mg] Mfg Date: Nov-2022 Exp Date: Nov-2024 Registration No. 091544	LC98	M/S Liven Pharmaceuticals (Pvt) Ltd, 49km Lahore Multan Road, Pakistan	01-68021725/DTL Dated. 08-02-2023	<u>Analysis with specifications applied: Manufacturer's Specifications.</u> <u>Description:</u> Colorless liquid having particles visible to naked eye contained in 100ml glass vial with rubber stopper, aluminium seal and dark blue flip off cap packed in outer hard carton. <u>NOTE: Manufacturer specify description of solution as "Clear and colorless solution filled in 100ml glass vial but in case of given sample "Colorless solution having particles visible to the naked eye were observed in 02 out of 05 inspected vials" that does not comply with the manufacturer's description of appearance of solution filled in sealed vials (Does not comply).</u>

Identification:

Paracetamol is identified.

Assay:

Stated	10mg/ml
Determined	9.633mg/ml
Percentage	96.33% (Complies)
Limit	90-110% (Manufacturer Specifications)

pH

Stated	4.0-7.0 (Manufacturer's specifications)
Determined	5.69 (Complies)

Bacterial Endotoxin Test:

Stated	Not more than 0.35 EU/mg (Manufacturer's specifications)
Determined	Less than 0.35 EU/mg as no gel formation observed (Complies)

Sterility:

Stated	Must be sterile (Manufacturer's specifications)
Determined	Sterile (Complies)

Result:

Given sample is **Substandard** with regards to description: presence of visible particles in sealed vials.

2	Infusion Livocetamol 100ml [Each ml contains: Paracetamol.....10mg] Mfg Date: Nov-2022 Exp Date: Nov-2024 Registration No. 091544	LC99	M/S Liven Pharmaceuticals (Pvt) Ltd, 49km Lahore Multan Road, Pakistan	01-68021726/DTL Dated. 08-02-2023	<p><u>Analysis with specifications applied: Manufacturer's Specifications.</u></p> <p><u>Description:</u></p> <p>Colorless liquid having particles visible to naked eye contained in 100ml glass vial with rubber stopper, aluminium seal and dark blue flip off cap packed in outer hard carton.</p> <p><u>NOTE: Manufacturer specify description of solution as "Clear and colorless solution filled in 100ml glass vial but in case of given sample "Colorless solution having particles visible to the naked eye were observed in 03 out of 05 inspected vials" that does not comply with the manufacturer's description of appearance of solution filled in sealed vials (Does not comply).</u></p> <p><u>Identification:</u></p> <p>Paracetamol is identified.</p> <p><u>Assay:</u></p> <table border="1" data-bbox="992 976 1513 1424"> <tr> <td>Stated</td> <td>10mg/ml</td> </tr> <tr> <td>Determined</td> <td>9.749mg/ml</td> </tr> <tr> <td>Percentage</td> <td>97.49% (Complies)</td> </tr> <tr> <td>Limit</td> <td>90-110% (Manufacturer Specifications)</td> </tr> </table> <p><u>pH</u></p> <table border="1" data-bbox="992 1518 1513 1749"> <tr> <td>Stated</td> <td>4.0-7.0 (Manufacturer's specifications)</td> </tr> <tr> <td>Determined</td> <td>4.58 (Complies)</td> </tr> </table> <p><u>Bacterial Endotoxin Test:</u></p> <table border="1" data-bbox="992 1843 1513 2145"> <tr> <td>Stated</td> <td>Not more than 0.35 EU/mg (Manufacturer's specifications)</td> </tr> <tr> <td>Determined</td> <td>Less than 0.35 EU/mg as no gel formation observed</td> </tr> </table>	Stated	10mg/ml	Determined	9.749mg/ml	Percentage	97.49% (Complies)	Limit	90-110% (Manufacturer Specifications)	Stated	4.0-7.0 (Manufacturer's specifications)	Determined	4.58 (Complies)	Stated	Not more than 0.35 EU/mg (Manufacturer's specifications)	Determined	Less than 0.35 EU/mg as no gel formation observed
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3	<p>Infusion Livocetamol 100ml [Each ml contains: Paracetamol.....10mg]</p> <p>Mfg Date: Nov-2022</p> <p>Exp Date: Nov-2024</p> <p>Registration No. 091544</p>	LC100	M/S Liven Pharmaceuticals (Pvt) Ltd, 49km Lahore Multan Road, Pakistan	<p>01-68021727/DTL Dated. 08-02-2023</p>	<p>Analysis with specifications applied: Manufacturer's Specifications.</p> <p>Description:</p> <p>Colorless liquid having particles visible to naked eye contained in 100ml glass vial with rubber stopper, aluminium seal and dark blue flip off cap packed in outer hard carton.</p> <p>NOTE: Manufacturer specify description of solution as "Clear and colorless solution filled in 100ml glass vial but in case of given sample "Colorless solution having particles visible to the naked eye were observed in 02 out of 05 inspected vials" that does not comply with the manufacturer's description of appearance of solution filled in sealed vials (Does not comply).</p> <p>Identification:</p> <p>Paracetamol is identified.</p> <p>Assay:</p> <table border="1"> <tr> <td>Stated</td> <td>10mg/ml</td> </tr> <tr> <td>Determined</td> <td>9.805mg/ml</td> </tr> <tr> <td>Percentage</td> <td>98.05% (Complies)</td> </tr> <tr> <td>Limit</td> <td>90-110% (Manufacturer Specifications)</td> </tr> </table>	Stated	10mg/ml	Determined	9.805mg/ml	Percentage	98.05% (Complies)	Limit	90-110% (Manufacturer Specifications)
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Percentage	98.05% (Complies)												
Limit	90-110% (Manufacturer Specifications)												

					<p>pH</p> <table border="1"> <tr> <td>Stated</td> <td>4.0-7.0 (Manufacturer's specifications)</td> </tr> <tr> <td>Determined</td> <td>5.53 (Complies)</td> </tr> </table> <p>Bacterial Endotoxin Test:</p> <table border="1"> <tr> <td>Stated</td> <td>Not more than 0.35 EU/mg (Manufacturer's specifications)</td> </tr> <tr> <td>Determined</td> <td>Less than 0.35 EU/mg as no gel formation observed (Complies)</td> </tr> </table> <p>Sterility:</p> <table border="1"> <tr> <td>Stated</td> <td>Must be sterile (Manufacturer's specifications)</td> </tr> <tr> <td>Determined</td> <td>Sterile (Complies)</td> </tr> </table> <p>Result:</p> <p>Given sample is Substandard with regards to description: presence of visible particles in sealed vials.</p>	Stated	4.0-7.0 (Manufacturer's specifications)	Determined	5.53 (Complies)	Stated	Not more than 0.35 EU/mg (Manufacturer's specifications)	Determined	Less than 0.35 EU/mg as no gel formation observed (Complies)	Stated	Must be sterile (Manufacturer's specifications)	Determined	Sterile (Complies)
Stated	4.0-7.0 (Manufacturer's specifications)																
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Stated	Not more than 0.35 EU/mg (Manufacturer's specifications)																
Determined	Less than 0.35 EU/mg as no gel formation observed (Complies)																
Stated	Must be sterile (Manufacturer's specifications)																
Determined	Sterile (Complies)																

- iii. Drug Inspector also directed Store Keeper not to dispose off stock vide Form No. 3, dated 01-03-2023 for the drugs mentioned at serial No. 1 and 2 and vide Form No. 3, dated. 02-03-2023 for the drug mentioned at Serial No. 3
- iv. Store Keeper of M/S Main Medicine Store Allama Iqbal Memorial Hospital, Sialkot provided Invoice/warranty No 663, dated 26-12-2022 issued by M/S Liven Pharmaceuticals (Pvt) Ltd, 49km Lahore Multan Road, Pakistan as a proof of its purchase.
- v. Warrantor Portion was sent to M/S Liven Pharmaceuticals (Pvt) Ltd, 49km Lahore Multan Road, Pakistan and they were asked to provide the requisite information in this regard.
- vi. A copy of test/analysis report was sent to M/S Liven Pharmaceuticals (Pvt) Ltd, 49km Lahore Multan Road, Pakistan and they were asked to provide the requisite information in this regard. In response company challenged the report of Drug Testing Laboratory Report, Faisalabad and the said retesting request was placed in in 24th Committee meeting held on 10-08-2023 and the Committee unanimously decided to turn down the said retesting request, the company file the review petition against the orders dated. 10-08-2023 and the said review on retesting was placed in 272nd meeting held on 22-11-2023 in which the Board unanimously decided to upheld the said review.

2. Drug Inspector requested for grant of permission for prosecution against the above- accused

persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

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

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

Sr.	Summary of the case	
1.	Date of sampling	31-12-2022
2.	Sent to DTL	31-12-2022
3.	Date of receipt in DTL	06-01-2023
4.	Issuance of DTL Report	08-02-2023
5.	Time Extension	N/A
6.	DI 1st communication with firm	24-03-2023
7.	Retesting Request	10-05-2023
8.	Fate of retesting request	Turn-Down 24 th committee meeting dated 10-08-2023, Retesting review of the firm was turn down in 272 meeting dated 22-11-2023.
9.	Investigation Report of DI	16-02-2024
10.	Permission of SCN	276 th meeting dated 29-02-2024
11.	SC Notice Issued	29-05-2024
12.	Reply of the firm	Not received
13	History (3 years)	10 cases of the firm 03 cases of the product (Subject cases)

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:



Case No. 55

PQCB/R-772/2019

(Tehsil & District Sahiwal)

ATTENDENCE:

Secretary DQCB	<p>Accused Persons involved in subject case</p> <p>1. M/S Caraway Pharmaceuticals, Plot No. 12, street No. 3, National Industrial Zone, RCCI, Rawat, Islamabad through its Managing Director</p> <p>2. Umar Farooq.</p> <p>3. Umar Farooq Managing Director</p> <p>4. Arifullah Production Incharge/Warrantor</p> <p>5. Noor Faraz Quality Control Incharge</p>
Drug Inspector	<p>of M/S Caraway Pharmaceuticals, Plot No. 12, street No. 3, National Industrial Zone, RCCI, Rawat, Islamabad.</p>

BRIEF FACTS OF THE CASE

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

- i. His Predecessor, on 08-10-2019, inspected the business premises of M/S Sadar Muhammad Agencies Medical Store, 13-Huma Colony Fateh Sher Road Tehsil and District Sahiwal and took different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide Memo. No.0000050139, dated. 09-10-2019.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result						
Tablet Carafenac-P [Diclofenac Potassium 75mg]	9G408	M/S Caraway Pharmaceuticals, Plot No. 12, street No. 3, National Industrial Zone, RCCI, Rawat, Islamabad	01-25004571/DTL Dated. 28-11-2019	<p>Analysis with specifications applied: USP 2018</p> <p>Composition: Each Tablet contains: Diclofenac Potassium USP.....75mg</p> <p>Description (MS): Light Blue Color, round, biconvex tablet which is plain on both s Alu-Alu Pack of 10 tablets.</p> <p>Identification (USP): Diclofenac Potassium is identified.</p> <p>Assay (USP): Diclofenac Potassium:</p> <table border="1" style="width: 100%;"> <tr> <td>Stated</td> <td>75mg/tablet</td> </tr> <tr> <td>Determined</td> <td>80.16mg/tablet</td> </tr> <tr> <td>Percentage</td> <td>106.88%</td> </tr> </table>	Stated	75mg/tablet	Determined	80.16mg/tablet	Percentage	106.88%
Stated	75mg/tablet									
Determined	80.16mg/tablet									
Percentage	106.88%									

Registration No. 050019				Limit		90-110%			
				Dissolution Test (USP): Does not Complies with the specifications of USP as deta					
				Tolerance Limit: NLT 75% (Q) of the labelled amount of Diclofenac Potassium.					
				Stage	Number Tested	Acceptance Criteria			
S1	6	Each unit is not less than Q+5% and not more than 2 units are less than Q-15% and no unit is less than Q-25%							
Stage	Diclofenac Potassium	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6		
1		70.32%	39.67%	33.66%	44.05%	41.74%	39.11%		
Note: five out of six units (I.e., Unit no. 2,3,4,5 & 6) are less than Q-25%									
Result: The sample is declared Substandard on the basis of Dissolution Test..									

- iii. M/S Sadar Muhammad Agencies Medical Store, 13-Huma Colony Fateh Sher Road Tehsil and M/S Sadar Muhammad Agencies Medical Store, 13-Huma Colony Fateh Sher Road Tehsil and District Sahiwal provided Invoice/warranty No Inv-32808, dated 18-09-2019 issued by M/S Caraway Pharmaceuticals, Plot No. 12, Street No. 3, National Industrial Zone, RCCI, Rawat, Islamabad as a proof of its purchase.
 - iv. Warrantor portion of drug sample was sent to M/S Caraway Pharmaceuticals, Plot No. 12, street No. 3, National Industrial Zone, RCCI, Rawat, Islamabad and they were asked to explain their position in this regard.
 - v. A copy of test/analysis report was sent to M/S Caraway Pharmaceuticals, Plot No. 12, street No. 3, National Industrial Zone, RCCI, Rawat, Islamabad and they were asked to provide the requisite information in this regard. In response the firm challenged the Drug Testing Laboratory report and the office of Provincial Quality Control Board place the said retesting request in the 12th Committee Meeting of Retesting dated 25-08-2020 and Board after unanimous decision decided to turn down the said retesting request. The company file review petition against the decision of PQC Board Order dated 25-08-2020 on 17-11-2020 and the said Review Petition was placed in 15th Committee Meeting dated 10-04-2021 and unanimous decision is decided to uphold its previous decision taken in 12 meeting.
2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -
 - a. Manufacture for sale/Sale of Substandard drug
 - b. Issuance of false warranty
 3. Show-cause notice(s) issued to accused person(s).
 4. Personal hearing notice(s) issued to the accused persons(s)

Summary	
Sampling Date (Form 4):	08-10-2019
Sent to DTL (Form 6):	09-10-2019
Date of receipt in DTL	11-10-2019
DTL Report Date (Form 7):	28-11-2019
1st DI Communication with firm dated	24-12-2019
Date of Retesting Request of Firm:	13-01-2020
Fate of Retesting Request:	12 th dated 25-08-2020 Turn Down (Time Barred) 15 th dated 10-04-2021 RP turn down
Investigation Report Dated	14-09-2022
Firm History 3 years	Firm: 25 Product: nil

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board under section 11 of the Drug Act 1976 in its **274th meeting** held on **21.12.2023** under the chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab (Vice-Chairperson Ahmad Awais, Secretary DQCB District Sahiwal attended the meeting online via Zoom and Mst. Rouqia Parveen, Drug Inspector Tehsil Sahiwal was present along with original case record. No one among nominated accused, appeared before the Board on the behalf of M/s Caraway Pharmaceuticals, Plot No. 12, street No. 3, National Industrial Zone, RCCI, Rawat, Islamabad however, the firm submitted written request for adjournment.

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

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

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 56

PQCB/R-777/2020

Allama Iqbal Memorial Teaching Hospital, District Sialkot

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<ol style="list-style-type: none">1. M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad through its Managing Director Umer Farooq.2. Umer Farooq Managing Director3. Noor Fraz Quality Control Incharge4. Arifullah Production Incharge5. Arif Ullah Khan Warrantor <p>of M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad.</p>

BREIF FACTS OF THE CASE:

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

- He, on 08-01-2020, inspected the premises of Main Medicine Store Allama Iqbal Memorial Hospital, District Sialkot and took two different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo no. 0000055617 dated. 08-01-2020.
- 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 Carafenac-P [Each Tablet contains: Diclofenac Pottasium USP.....75mg] Mfg Date: Nov-2019 Exp Date: Oct-2021	9L629	M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad	01- 68001876/DTL Dated. 05-03- 2020	<u>Analysis with specifications applied:</u> MS/USP 2019. <u>Description:</u> White Color, Oval Shape, Biconvex Tablet plain from one side and scored from other side packed in ALU-PVC blister of 10's. <u>Uniformity of Dosage Unit (Weight Variation):</u> Does not comply the acceptance Criteria of uniformity of dosage unit (weight variation) as per USP 2019. (Average weight of Tablet: 147.133mg) Acceptance Criteria:

Registration No.

050019

- Acceptance value of First 10 dosage units is less than or equal to L1% (i.e 15%)
- Final Acceptance value of 30 dosage units is $\leq L1\%$ and no individual content of any dosage unit is less than $[1-(0.01)(L2)] M$ nor more than $[1+(0.01)(Ls)] M$.

Determined:

- **Acceptance value of 10 dosage units (L1)=20.846 (Does not comply).**
- **Acceptance value of 30 dosage units =25.936 (Does not comply).**

Note: Contents of two individual units is found less than $[1-(0.01)(L2)] M$, Therefore, given sample does not comply uniformity of Dosage Unit Test.

Identification Test:

Diclofenac Pottasium identified

Stated	75mg/Tablet
Determined	73.701mg/tablet
Percentage	98.268%
Limit	90-110% (USP 2019)

Dissolution Test: Complies with the manufacturer's specifications as detailed below:

Tolerance Limit: Not less than 80% (Q) of the labelled amount of Azithromycin is dissolved in 30 minutes.

Level	Number Tested	Acceptance Criteria	Remarks												
S1	06	Each unit is not less than Q+5%	Complies												
	Time	<table border="1"> <tr> <td>Unit 1</td> <td>Unit 2</td> <td>Unit 3</td> <td>Unit 4</td> <td>Unit 5</td> <td>Unit 6</td> </tr> <tr> <td>99.26%</td> <td>98.97%</td> <td>96.92%</td> <td>96.63%</td> <td>99.72%</td> <td>97.63%</td> </tr> </table>		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	99.26%	98.97%	96.92%	96.63%	99.72%	97.63%
	Unit 1	Unit 2		Unit 3	Unit 4	Unit 5	Unit 6								
99.26%	98.97%	96.92%	96.63%	99.72%	97.63%										
After 60 Minutes															

Result:

Given sample is **Substandard** on the basis of Uniformity of Dosage unit (Weight variation).

iii. Drug Inspector also directed the store keeper not to dispose off stock vide Form No. 3. Dated 25-03-

2020 & 16-03-2020 respectively.

- iv. Store keeper of Main Medicine Store Allama Iqbal Memorial Hospital, District Sialkot provided Invoice/warranty No AIMH/003, dated. 12-11-2019 issued by M/S M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad as a proof of its purchase.
- v. Warrantor Portion was sent to M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad and they were asked to provide the requisite information in this regard.
- vi. A copy of test/analysis report was sent to M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad and they were asked to provide the requisite information in this regard.

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

a. Manufacture for sale/Sale of Substandard drug

b. Issuance of false warranty

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

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad submitted written reply vide reference no. 326/CP/ISB as follows:

Respectfully submitted,

That on 18-01-2020, the Drug Inspector of Allama Iqbal Memorial Teaching Hospit, district Sialkot, took two samples of

(1) Cream Betawis-N, batch no. 238 and

(2) Tablet Carafenac-P, 75mg, batch no. 9L629

Both the samples were sent to DTL Faisalabad, where the same were declared sub standard on the basis of assay test and weight variation test respectively.

1- Reply on Cream Betawis-G, Batch no. 238

That the test report no. 01-68001867/DTL dated 10-03-2020 pertaining to the drig sample of cream Betawis-N, reveals that one of its constituent i.e. Betamethaso: (as Valerate) is determined to the extent of 42.20% which is lower than the stato limit of 90 to 115%, whereas the second ingredient Neomycin qualifies its ass, test.

In this regard it is presumed that the product is of multi-ingredients and chances interference may have causes the one of the ingredient to be deteriorated. It is a presumed that there might be error while calculating/formulating the results tests applied. If the raw data was provided to us, then we would be in a better position to defend the case.

However after the receipt of said DTL report, the Quality Control retention sample of the said drug was tested and the results were as of standard quality including the assay test.

That we are of the opinion that the said test report is incomplete, unauthentic and non-con-conclusive on the following:

GROUND S

(a)- That the protocols of tests applied are not mentioned on the said test report and the absence of the full protocols of test in the above is crystal clear violation f Drug Laws. Reports of Analyst have to be conclusive and must disclose the protoc s of tests applied to formulate opinion of Government Analyst. The description of tie testing procedure must be crystal clear whenever report would be dispute ! **Reliance PLD 2003**

Lahore 115.

(b)- That noncompliance to section 19(3) related to statutory of sending warrantor's portion within stipulated time, is an illegality. The warrantor's portion has not been sent to the manufacturer within statutory period as prescribed under section 19(3) (iii) of the Drug Act 1976 and rules framed there under. The non-observance to said procedure is highly doubtful and is an illegality; in the recent years, the PQCB has unanimously dropped a case no. PQCB-R577-09/2016 related to infusion Dorcep Batch no. DC-075 declared as Adulterated and substandard by the Government Analyst DTL Rawalpindi vide DTL report no. 1077/DTL dated 22-09-2016. The PQC has observed that this case was fit for prosecution on the basis of report. But, this case was dropped as PQCB had observed that the case would fail in court because warrantor portion was not sent to the manufacturer within statutory period as prescribed under section 19(3)(iii) of the Drug Act 1976 and rules framed there under.

2- Reply on Tablet Carafenac-P, Batch no. 91629

That the test report no. 01-68001876/DTL dated 05-03-2020 pertaining to the drug sample Tablet Carafenac-P, Batch no. 9L629 reveals that the sample has been declared substandard on the basis of Uniformity of dosage unit (weight variation) test. However all other tests such as identification, Assay and Dissolution tests etc. The report of Government Analyst is on physical attribute, whereas the product is perfect chemically. If the raw data was provided to us, then we would be in a better position to defend the case.

On careful examination of test report it is understood that the assay figures of dissolution test indicate that the drug is fit for use as the API is within normal limit. Similarly if all individual tablets of weight variation were tested chemically, then it would definitely produce the required quantitative results.

Moreover after the receipt of said DTL report, the Quality Control retention sample of the said drug was tested and the results were as of standard quality including the assay and other tests.

That we are of the opinion that the said test report is incomplete, unauthentic and non-conclusive on the following;

GROUND

(a) That the protocols of tests applied are not mentioned on the said test report and the absence of the full protocols of test in the above is crystal clear violation of Drug Laws. Reports of Analyst have to be conclusive and must disclose the protocols of tests applied to formulate opinion of Government Analyst. The description of the testing procedure must be crystal clear whenever report would be dispute. Reliance PLD 2003 Lahore 115.

(b)- That noncompliance to section 19(3) related to statutory of sending warrantor's portion within stipulated time, is an illegality. The warrantor's portion has not been sent to the manufacturer within statutory period as prescribed under section 19(3) (iii) of the Drug Act 1976 and rules framed there under. The non-observance to said procedure is highly doubtful and is an illegality; in the recent years, the PQCB has unanimously dropped a case no. PQCB-R577-09/2016 related to infusion Dorcep Batch no. DC-075 declared as Adulterated and substandard by the Government Analyst DTL Rawalpindi vide DTL report no. 1077/DTL dated 22-09-2016. The PQC3 has observed that this case was fit for prosecution on the basis of report. But, this case was dropped as PQCB had observed that the case would fail in court because "warrantor portion was not sent to the manufacturer within statutory period as prescribed under section 19(3)(iii) of the Drug Act 1976 and rules framed there under.

That the Government Analyst declared the said Drug sample as SUB-STANDARD vide TRA No, 01-68001876/DTL dated 05-03-2020 on the basis of weight variation.

However it has been determined in chemical assay that therapeutic ingredient Diclofenac potassium is 98.268% which is within the Pharmacopoeia limit of 90% to 110%. "A drug could not be declared as substandard when it meets the chemical specification." Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183

PRAY

1. Under the circumstances explained above it is respectfully prayed that the instant case may kindly be dropped/warned in the interest of justice.
2. The chance of PSI may be kindly be allowed so as to observe the improvement made in the overall system, by the honorable Board's members to produce the quality products.

Sr.	Summary of the case R-777/2020	
1.	Date of sampling	08-01-2020
2.	Sent to DTL	08-01-2020
3.	Date of receipt in DTL	13-01-2020
4.	Issuance of DTL Report	05-03-2020
5.	Time Extension	N/A
6.	DI 1st communication with firm	17-04-2020
7.	Retesting Request	No
8.	Fate of retesting request	N/A
9.	Investigation Report of DI	25-09-2023
10.	Permission of SCN	272 nd meeting dated 22-11-2023
11.	SC Notice Issued	31-01-2024
12.	Reply of the firm	14-03-2024
13	History (3 years)	25 cases of the firm No case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 57

PQCB-R-775/2020

Allama Iqbal Memorial Teaching Hospital, District Sialkot

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<ol style="list-style-type: none">1. M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad through its Managing Director Umer Farooq.2. Umer Farooq Managing Director3. Noor Fraz Quality Control Incharge4. Arifullah Production Incharge5. Arif Ullah Khan Warrantor <p>of M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad.</p>

BREIF FACTS OF THE CASE:

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

- He, on 08-01-2020, inspected the premises of Main Medicine Store Allama Iqbal Memorial Hospital, District Sialkot and took two different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Faisalabad vide Memo no. 0000055665dated. 08-01-2020.
- 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		
Cream Betawis-N [Each gram contains: Betamethasone (as valerate).....1mg, Neomycin (as Sulphate).....5mg]	238	M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad	01- 68001867/DTL Dated. 10-03- 2020	<u>Analysis with specifications applied:</u> MS. <u>Description:</u> White colored, semi solid cream, contained in collapsible aluminum tube, sealed and capped with white colored screw cap, packed in an outer unit carton. <u>Assay:</u> <u>Betamethasone (as Valerate):</u> <table border="1" data-bbox="730 1960 1476 2060"><tr><td>Stated</td><td>1mg Betamethasone/gram</td></tr></table>	Stated	1mg Betamethasone/gram
Stated	1mg Betamethasone/gram					

Nov-2021 Registration No. 089581	Determined	0.422mg/gram
	Percentage	42.20% (Does not comply)
	Limit	90-115%
<u>Neomycin (As Sulphate):</u>		
	Stated	5mg Neomycin/gram
	Determined	5.2085mg/gram
	Percentage	104.13% (Does not comply)
	Limit	90-120%
<u>Result:</u>		
Given sample is Substandard on the basis of Chemical Assay of Betamethasone.		

- iii. Drug Inspector also directed the store keeper not to dispose off stock vide Form No. 3. Dated 25-03-2020 & 16-03-2020 respectively.
- iv. Store keeper of Main Medicine Store Allama Iqbal Memorial Hospital, District Sialkot provided Invoice/warranty No AIMH/003, dated. 12-11-2019 issued by M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad as a proof of its purchase.
- v. Warrantor Portion was sent to M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad and they were asked to provide the requisite information in this regard.
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2. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

a. Manufacture for sale/Sale of Substandard drug

b. Issuance of false warranty

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

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/S Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone Rawat, Islamabad submitted written reply vide reference no. 326/CP/ISB as follows:

Respectfully submitted,

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(1) Cream Betawis-N, batch no. 238 and

(2) Tablet Carafenac-P, 75mg, batch no. 9L629

Both the samples were sent to DTL Faisalabad, where the same were declared sub standard on the basis of assay test and weight variation test respectively.

1- Reply on Cream Betawis-G, Batch no. 238

That the test report no. 01-68001867/DTL dated 10-03-2020 pertaining to the drig sample of cream Betawis-N, reveals that one of its constituent i.e. Betamethaso: (as Valerate) is determined to the extent of 42.20% which is lower than the stato limit of 90 to 115%, whereas the second ingredient Neomycin qualifies its ass, test.

In this regard it is presumed that the product is of multi-ingredients and chances interference may have causes the one of the ingredient to be deteriorated. It is a presumed that there might be error while calculating/formulating the results tests applied. If the raw data was provided to us, then we would be in a better position to defend the case.

However after the receipt of said DTL report, the Quality Control retention sample of the said drug was tested and the results were as of standard quality including the assay test.

That we are of the opinion that the said test report is incomplete, unauthentic and non-con-conclusive on the following:

GROUND

(a)- That the protocols of tests applied are not mentioned on the said test report and the absence of the full protocols of test in the above is crystal clear violation f Drug Laws. Reports of Analyst have to be conclusive and must disclose the protoc s of tests applied to formulate opinion of Government Analyst. The description of tie testing procedure must be crystal clear whenever report would be dispute !. **Reliance PLD 2003 Lahore 115.**

(b)- That noncompliance to section 19(3) related to statutory of sending warrantor's portion within stipulated time, is an illegality. The warrantor's portion has not bee sent to the manufacturer within statutory period as prescribed under section 19(3 (iii) of the Drug Act 1976 and rules framed there under. The non-observance to sai procedure is highly doubtful and is an illegality; in the recent years, the PQCB has unanimously dropped a case no. PQCB-R577-09/2016 related to infusion Dorcep Batch no. DC-075 declared as Adulterated and substandard by the Government Analyst DTL Rawalpindi vides DTL report no. 1077/DTL dated 22-09-2016. The PQC has observed that this case was fit for prosecution on the basis of report. But, this case was dropped as PQCB had observed that the case would fail in court because warrantor portion was not sent to the manufacturer within statutory period as prescribed under section 19(3)(iii) of the Drug Act 1976 and rules framed there under.

2- Reply on Tablet Carafenac-P, Batch no. 91629

That the test report no. 01-68001876/DTL dated 05-03-2020 pertaining to the dru sample Tablet Carafenac-P, Batch no. 9L629 reveals that the sample has been declared substandard on the basis of Uniformity of dosage unit (weight variation) test. However all other tests such as identification, Assay and Dissolution tests etc. The report of Government Analyst is on physical attribute, whereas the product is perfect chemically. If the raw data was provided to us, then we would be in a better position to defend the case.

On careful examination of test report it is under stood that the assay figures of dissolution test indicate that the drug is fit for use as the API is within normal limit. Similarly if all individual tablets of weight variation were tested chemically, then it would definitely produce the required quantitative results.

Moreover after the receipt of said DTL report, the Quality Control retention sample of the said drug was tested and the results were as of standard quality including the assay and other tests.

That we are of the opinion that the said test report is incomplete, unauthentic and non-conclusive on the following:

GROUND

(a) That the protocols of tests applied are not mentioned on the said test report and the absence of the full protocols of test in the above is crystal clear violation of Drug Laws. Reports of Analyst have to be conclusive and must disclose the protocols of tests applied to formulate opinion of Government Analyst. The description of the testing procedure must be crystal clear whenever report would be dispute. Reliance PLD 2003 Lahore 115.

(b)- That noncompliance to section 19(3) related to statutory of sending warrantor's portion within stipulated time, is an illegality. The warrantor's portion has not been sent to the manufacturer within statutory period as prescribed under section 19(3) (iii) of the Drug Act 1976 and rules framed there under. The non-observance to said procedure is highly doubtful and is an illegality; in the recent years, the PQCB has unanimously dropped a case no. PQCB-R577-09/2016 related to infusion Dorcep Batch no. DC-075 declared as Adulterated and substandard by the Government Analyst DTL Rawalpindi vide DTL report no. 1077/DTL dated 22-09-2016. The PQCB has observed that this case was fit for prosecution on the basis of report. But, this case was dropped as PQCB had observed that the case would fail in court because " warrantor portion was not sent to the manufacturer within statutory period as prescribed under section 19(3)(iii) of the Drug Act 1976 and rules framed there under.

That the Government Analyst declared the said Drug sample as SUB-STANDARD vide TRA No, 01-68001876/DTL dated 05-03-2020 on the basis of weight variation.

However it has been determined in chemical assay that therapeutic ingredient Diclofenac potassium is 98.268% which is within the Pharmacopoeia limit of 90% to 110%. "A drug could not be declared as substandard when it meets the chemical specification." Reliance on 1992 MLD 481 1992. 1996 PCr. LJ 1183

PRAY

1. Under the circumstances explained above it is respectfully prayed that the instant case may kindly be dropped/warned in the interest of justice.
2. The chance of PSI may be kindly be allowed so as to observe the improvement made in the overall system, by the honorable Board's members to produce the quality products.

Sr.	Summary of the case	R-775/2020
1.	Date of sampling	08-01-2020
2.	Sent to DTL	08-01-2020
3.	Date of receipt in DTL	13-01-2020
4.	Issuance of DTL Report	10-03-2020
5.	Time Extension	N/A
6.	DI 1st communication with firm	17-04-2020
7.	Retesting Request	No
8.	Fate of retesting request	N/A

9.	Investigation Report of DI	26-09-2023
10.	Permission of SCN	272 nd meeting dated 22-11-2023
11.	SC Notice Issued	31-01-2024
12.	Reply of the firm	14-03-2024
13	History (3 years)	25 cases of the firm No case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 58

PQCB-R-633/2020

Benazir Bhutto Hospital, Rawalpindi

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<ol style="list-style-type: none">1. M/s Caraway Pharmaceutical Plot 12, St N-3 National Industrial Zone (RCCI), Rawat, Islamabad through its Managing Director, Umer Farooq2. Umer Farooq Managing Director3. Arif-u-Allah Plant Manager/Warrantor4. Syed Naveed Abbass Production Manager5. Noor Faraz Quality Control Manager <p>Of M/s Caraway Pharmaceutical Plot 12, St N-3 National Industrial Zone (RCCI), Rawat, Islamabad.</p>

BREIF FACTS OF THE CASE:

Provincial Inspector of Drugs, Benazir Bhutto Hospital, Rawalpindi reported that:-

- His predecessor, on 10-02-2020 inspected the premises of Main Medical Store Benazir Bhutto Hospital, Rawalpindi, took sample of the subject drug on Form No. 4 for the purpose of test and analysis and sent to Drug Testing Laboratory, Rawalpindi vide memo no. 58024 dated 10-02-2020.
- The following drug sample, after test/analysis was declared as **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Injection. KOLBI [Nalbuphine HCl...10mg/ml] Mfg. Date:01-2020 Exp. Date:12-2021 Reg.# 093271	2A036	M/s CARAWAY PHARMACEUTICALS, PLOT 12, ST N-3, NATIONAL INDUSTRIAL ZONE (RCCI), RAWAT, Islamabad	01-72000357/ DTL dated: 11 Apr 2020	Result of test/ analysis with specifications applied MS/USP 2019 <u>PHYSICAL DESCRIPTION:</u> Visibly clear, colourless solution, filled in transparent glass ampoule packed in plastic tray of 1*5 ampules, further packed in outer labeled carton containing two trays (10 ampules). Manufacturer specifications state that the solution will be filled in transparent glass ampoule with green printing and yellow cut mark while in actual the ampule has affixed label and there was no cut mark on the ampule. (DOES NOT COMPLY). <u>PH:</u>

				<p>Observed: 3.605</p> <p>Limit: 3.5-4.5 (MS).</p> <p><u>ASSAY:</u></p> <p>Stated: 10mg/ml</p> <p>Determined: 9.398mg/ml</p> <p>Percentage 93.98%</p> <p>Limit: 90-110% (MS)</p> <p><u>STERILITY TEST:</u> Sterile (USP 2019)</p> <p><u>RESULT:</u></p> <p><u>The above sample is Sub-Standard on the basis of Physical description.</u></p>
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- iii. The Storekeeper of Main Medical Store Benazir Bhutto Hospital, Rawalpindi provided invoice/ Delivery Challan bearing No. BBH/7 dated 07-02-2020 issued by M/s Caraway Pharmaceutical Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan.
- iv. Warrantor Portion was sent to M/s Caraway Pharmaceutical Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan.
- v. A copy of Test/ Analysis report was sent to M/s Caraway Pharmaceutical Plot 12, St. N-3 National Industrial Zone (RCCI), Rawat, Islamabad-Pakistan and they were directed to provide requisite information in this regard. In response the firm requested for retesting of subject drug sample from Appellate laboratory, National Institute of Health (NIH), Islamabad. But the request of the firm was turned down by the Provincial Quality Control Board in its 231st meeting dated 13-03-2021.
- vi. The firm filed the review petition against the orders dated 13-03-2021 which was adjourned by the Committee of Provincial Quality Control Board in its 18th meeting dated 13-09-2021 and the same was returned to the firm vide letter dated 26-11-2021

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

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

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

Sr.	Summary of the case	
1.	Date of sampling	10-02-2020
2.	Sent to DTL	10-02-2020
3.	Date of receipt in DTL	11-02-2020

4.	Issuance of DTL Report	11-04-2020
5.	Time Extension	N/A
6.	DI 1st communication with firm	16-04-2020
7.	Retesting Request	17-04-2020
8.	Fate of retesting request	Turn-Down 231 st meeting dated 13-03-2021, Retesting review of the firm was placed at 18 th Committee meeting dated 13-09-2021 and all the reviews/ revisions were adjourned in light of the orders of Honorable Drug Court dated 25-08-2021. Retesting review of the firm was returned vide letter dated 26-11-2021.
9.	Investigation Report of DI	14-01-2022
10.	Permission of SCN	244 th meeting dated 31-05-2022
11.	SC/PH Notice Issued	26-08-2024
12.	Reply of the firm	Not received
13	History (3 years)	25 cases of the firm No case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 59

PQCB-R-792/2022

Aziz Bhatti Shaheed Teaching Hospital, Gujrat

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<p>1. M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan through its Chief Executive Officer Farhat Munawar Bajwa</p> <p>2. Farhat Munawar Bajwa Chief Executive Officer/ Warrantor</p> <p>3. Farkhanda Shaheen Production Manager</p> <p>4. Sulman Aslam Quality Control Manager</p> <p>Of M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan .</p>

BREIF FACTS OF THE CASE:

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

- i. He, on 05-08-2022, inspected the premises of Main Medicine Store Aziz Bhatti Shaheed Teaching Hospital, Gujrat and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memo number 136100 dated 05-08-2022.
- ii. The drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:
- iii. Store keeper of Main Medicine Store Aziz Bhatti Shaheed Teaching Hospital, Gujrat provided invoice/ warranty no. 6839 dated 22-06-2022 issued by M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan as a proof of its purchase of the said drug.
- iv. Warrantor portion of the drug samples were sent M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan .
- v. A copy of test reports of the drug samples were sent to M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan with directions to provide the requisite information and to explain their position in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 259th meeting held on 18-04-2023 **turn-down** the retesting request of the firm. The retesting review of the firm was turn-down by the Board in its 266th meeting dated 24-08-2023.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection Synostat	SS-0522	M/s Bajwa Pharmaceuticals	TRA 01-68017647/DTL	<u>Specification applied: bp 2022</u>

<p>[Each ml contains :Tranexamic Acid BP...100mg]</p> <p>Mfg Date: June-2022</p> <p>Exp. Date: May-2024</p> <p>Reg. No. 098162</p>	<p>Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan .</p>	<p>dated 14-09-2022</p>	<p>DESCRIPTION:</p> <p>Colorless solution having particles visible to naked eye filled in transparent glass ampoules. (Does not Comply)</p> <p>IDENTIFICATION: Tranexamic Acid is identified</p> <p>ASSAY</p> <p>Stated: 500mg / 5ml</p> <p>Determined: 493.289 mg / 5ml</p> <p>Percentage: 98.658 % (Complies)</p> <p>Limit: 95 – 105 % (BP 2022)</p> <p>pH</p> <p>Stated: 6.5 - 8.0 (BP 2022)</p> <p>Determined: 7.37 (Complies)</p> <p>Extractable Volume</p> <p>Stated: Not less than nominal Volume (BP 2022)</p> <p>Determined: 5.0 ml (Complies)</p> <p>Sterility</p> <p>Stated: Must be Sterile (BP2022)</p> <p>Determined: Sterile (Complies)</p> <p>Particulate Contamination: Visible Particles</p> <p>Stated: According to BP, “Injections must be clear and practically free from particles when observed for about 5s in front of the white panel. Repeat the procedure in front of the black panel. Record the presence of any particles. (BP 2022)</p> <p>Determined: Particles visible to naked eye were observed in two out of twenty inspected ampoules. (Does Not Comply).</p> <p>RESULT: Given sample is Sub-Standard with regards to presence of visible particles in ampoules.</p>
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2. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

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

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

Sr.	Summary of the case	
1.	Date of sampling	05-08-2022
2.	Sent to DTL	05-08-2022
3.	Date of receipt in DTL	06-08-2022
4.	Issuance of DTL Report	14-09-2022
5.	Time Extension	N/A
6.	DI 1st communication with firm	27-09-2022
7.	Retesting Request	01-10-2022
8.	Fate of retesting request	Turn-Down 259 th meeting dated 18-04-2023 Retesting review, turn down 266 th meeting dated 24-08-2023
9.	Investigation Report of DI	07-05-2024
10.	Permission of SCN	281 st meeting dated 06-06-2024
11.	SC Notice Issued	08-07-2024
12.	Reply of the firm	Not received
13	History (3 years)	35 cases of the firm 04 case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 60

PQCB-MSS-176736/2023

Allied Hospital, Faisalabad

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<p>1. M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan through its Chief Executive Officer Farhat Munawar Bajwa</p> <p>2. Farhat Munawar Bajwa Chief Executive Officer</p> <p>3. Farkhanda Shaheen Production In-charge</p> <p>4. Sulman Aslam Quality Control Manager/ warrantor</p> <p>Of M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan .</p>

BREIF FACTS OF THE CASE:

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

- i. She, on 28-09-2023, inspected the premises of Central Pharmacy, Allied Hospital, Faisalabad and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memo number 176736 dated 28-09-2023.
- ii. The drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:
- iii. Medical Superintendent Allied Hospital, Faisalabad provided invoice/ warranty no. 50679 dated 24-09-2023 issued by M/s Tanveer Enterprises 289-C, Gulberg Colony Faisalabad as a proof of its purchase of the said drug.
- iv. Warrantor portion of the drug samples was sent M/s Tanveer Enterprises 289-C, Gulberg Colony Faisalabad.
- v. M/s Tanveer Enterprises 289-C, Gulberg Colony Faisalabad provided invoice/ warranty number provided invoice/ warranty number 10189 dated 23-09-2023 issued by M/s Bajwa Pharmaceuticals (Pvt.) Ltd. 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan.
- vi. A copy of test reports of the drug samples were sent to M/s Bajwa Pharmaceuticals (Pvt.) Ltd. 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan with directions to provide the requisite information and to explain their position in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its 37th committee meeting held on 30-04-2024 **turn-down** the retesting request of the firm.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
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Injection
Relocurium
[Each 5 ml
ampoule
contains:
Atracurium
Besylate
USP...50mg]

RC-
1323

M/s Bajwa
Pharmaceuticals
Pvt. Ltd., 36-km
Lahore-
Gujranwala
Road, Kohri
District
Sheikhupura
Pakistan

TRA 01-
68026390/DTL
dated 16-12-2023

Specification applied: USP 2023

DESCRIPTION: _____

Clear colorless liquid filled in transparent glass ampoule, placed in plastic tray, packed in outer hard carton.

IDENTIFICATION Atracurium Besylate isomers are identified.

ASSAY

Stated: 50 mg / 5 ml

Determined: 54.448 mg / 5 ml

Percentage: 108.896 % (Complies)

Limit: 90.0 – 115.0 %

Isomers	Limit	Determined
<i>trans-trans</i> isomer	NLT 5.0% & NMT 6.5 %	5.914 %
<i>cis-trans</i> isomer	NLT 34.5% & NMT 38.5 %	36.399 %
<i>cis-cis</i> isomer	NLT 55.0% & NMT 60.0 %	57.687 %

pH TEST

Stated: 3.00 – 3.65

Determined: 3.47 at 23.5 °C (Complies)

CONTAINER CONTENT

Stated: Not less than nominal volume (5ml)

Determined: 5.0 ml (Complies)

STERILITY TEST

Stated: Must be Sterile

Determined: Non-Sterile (by membrane filtration method) (Does not Comply)

BACTERIAL ENDOTOXIN TEST

Stated: Not more than 5.56 USP Endotoxin Units/mg of atracurium Besylate

				<p style="text-align: right;">Determined: Less than 5.56 USP Endotoxin Units/mg as no gel formation observed (Complies).</p> <p>PARTICULATE MATTER IN INJECTIONS</p> <p>Stated:</p> <p>1. Average no. of particles does not exceed 6000/ container \geq 10μm</p> <p>2. Average no. of particles does not exceed 600/ container \geq 25μm</p> <p>Determined: 1. 873.6667 particles/ container \geq 10μm (Complies)</p> <p>2. 12.6667 particles/ container \geq 25μm (Complies)</p> <p>NOTE: Time Extension required for the analysis of given sample was granted by the Provincial Quality Board Punjab, Lahore vide Order No. PQCB/TEX-FSD-29/2023 dated 30-11-2023.</p> <p>RESULT: Given sample is Sub-Standard with regards to Sterility Test.</p>
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2. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

a. Manufacture for sale/Sale of Substandard drug

b. Issuance of false warranty

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

REPLY OF FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan submitted written reply in response to show-cause notice as follows:

With reference to letter No. PQCB/MSS-176736/2023 dated: Lahore 09-08-2024 and received us on August 15, 2024, we are explaining our position about the drug injection Relocurium 50mg/5ml Batch No.RC-1323 declared Substandard vide report No. 01-68026497/DTL Faisalabad dated 16-12-2023.

FIRM EXPLANATION

1. DTL used membrane filtration method while our product is preservative free and direct inoculation method of sterility is required for our product. Dear Sir, method of sterility used for our product is "Direct inoculation" as it is preservative free.i.e. Chances of test invalidity more in membrane filtration as compare to direct inoculation.

2. As per USP (USP45 NF41 Vol.06) Microbiological tests (71) Page 6487 i.e. "Observation and interpretation of Results" Test may be considered invalid only if one or more of the following conditions are fulfilled. The data of the microbiological monitoring of the sterility testing

i. facility show fault.

ii. A review of the testing procedure used during the test in question reveals a fault.

iii. Microbial growth is found in the negative controls.

iv. After determination of the identity of the microorganisms isolated from the test, the growth of this species (or these species) may be ascribed unequivocally to faults with respect to the material and or the technique used in conducting the sterility test procedure.

3. Dear Sir, we have was Pharmaceutical retained Pvt. samples they comply Bajwa sterility testing. On basis of our investigation our samples are sterile.(Report has attached)

4. We received 1 pack of 5ml x 5 Ampoules as warrantor portion, but for sterility test 20 ampoules required.

(Informed DI but yet no sample received, Letter Has Attached)

We are sending your requisite,

Sr.	Summary of the case	
1.	Date of sampling	28-09-2023
2.	Sent to DTL	28-09-2023
3.	Date of receipt in DTL	28-09-2023
4.	Issuance of DTL Report	19-01-2024
5.	Time Extension	30-11-2023
6.	DI 1st communication with firm	03-01-2024
7.	Retesting Request	08-01-2024
8.	Fate of retesting request	Turn-Down 37 th Committee meeting dated 30-04-2024
9.	Investigation Report of DI	28-06-2024
10.	Permission of SCN	282 nd meeting dated 24-07-2024
11.	SC Notice Issued	09-08-2024
12.	Reply of the firm	16-08-2024
13	History (3 years)	35 cases of the firm 02 case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 61

PQCB-MSS-180554/2024

Allama Iqbal Memorial Teaching Hospital, Sialkot

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<p>1. M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan through its Chief Executive Officer Farhat Munawar Bajwa</p> <p>2. Farhat Munawar Bajwa Chief Executive Officer</p> <p>3. Farkhanda Shaheen Production Manager</p> <p>4. Sulman Aslam Quality Control Manager/ warrantor</p> <p>Of M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan .</p>

BREIF FACTS OF THE CASE:

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

- i. Her Predecessor, on 02-11-2023, inspected the premises of Main Medicine Store Allama Iqbal Memorial Teaching Hospital, Sialkot and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memo number 180554 dated 02-11-2023.
- ii. The drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:
- iii. Medical Superintendent Allama Iqbal Memorial Teaching Hospital, Sialkot provided invoice/warranty no. 10193 dated 25-09-2023 issued by M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan as a proof of its purchase of the said drug.
- iv. Warrantor portion of the drug samples were sent M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan.
- v. A copy of test reports of the drug samples were sent to M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan with directions to provide the requisite information and to explain their position in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 36^h committee meeting held on 17-04-2024 **turn-down** the retesting request of the firm.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection Suxathon 2 ml [Suxamethonium	SX-0523	M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-	TRA 01-10194004591/DTL dated 19-01-2024	Specification applied: BP 2023 <u>PHYSICAL DESCRIPTION:</u>

<p>Chloride...100mg/ 2ml]</p> <p>Mfg Date: May- 2023</p> <p>Exp. Date: April- 2025</p> <p>Reg. No. 078953</p>	<p>km Lahore- Gujranwala Road, Kohri District Sheikhupura Pakistan</p>		<p>Colorless liquid in sealed amber glass ampoule with label printed on it placed in plastic transparent tray of 10 units, further packed in unit carton. Claimed volume= 2 mL</p> <p><u>pH TEST:</u></p> <p>Limit: 3.0 - 5.0</p> <p>Determined: 3.4 at 23.5°C</p> <p><u>EXTRACTABLE VOLUME:</u></p> <p>Limit NLT Nominal Volume: i.e. 2 mL</p> <p>Determined Volume: 2.0 mL</p> <p>(Complies)</p> <p><u>IDENTIFICATION:</u></p> <p>Suxamethonium Chloride is identified.</p> <p><u>ASSAY OF SUXAMETHONIUM CHLORIDE:</u></p> <p>Stated: 100 mg/2 mL</p> <p>Determined: 103.78 mg/2 mL</p> <p>Percentage: 103.78%</p> <p>Limit: 90.0-107.5% of the stated amount</p> <p><u>STERILITY TEST:</u></p> <p>The Sample Is Non-Sterile</p> <p>(Does not comply)</p> <p>RESULT: The above sample is SUB-STANDARD on the basis of Sterility Test performed as per BP.</p>
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2. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

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

b. **Issuance of false warranty**

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

REPLY OF FIRM IN RESPONSE TO SHOW-CAUSE NOTICE:

M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhupura Pakistan submitted written reply in response to show-cause notice as follows:

1. Same product of batch SX-0523 declared standard quality by DTL Faisalabad and Bahawalpur

2. We used "Direct Inoculation" procedure of sterility test, as our product is preservative free and chance of sterility failure is minimum as compare to membrane filtration test.

3. As per USP (USP45 NF41 Vol.06) Microbiological tests (71) Page 6487 i.e. "Observation and interpretation of Results" Test may be considered invalid only if one or more of the following conditions are fulfilled.

i. The data of the microbiological monitoring of the sterility testing facility show fault.

ii. A review of the testing procedure used during the test in question reveals a fault.

iii. Microbial growth is found in the negative controls.

iv. After determination of the identity of the microorganisms isolated from the test, the growth of this species (or these species) may be ascribed unequivocally to faults with respect to the material and or the technique used in conducting the sterility test procedure.

4. We have received 01 pack of 2ml x 10 ampoules warrantor portion of Suxathon injection 2.0ml (SX-0523) but for sterility test we required 20 ampoules (02 packs)

Moreover our finished product testing report reveals that mention batch comply with sterility testing. We have tested our quality control retained samples whose comply with sterility testing.

Kindly review our matter and grant us retest of sample as, same product declared standard quality with four standard quality reports, we have not received subject product proper warrantor portion and our Quality Control retained samples comply with sterility test.

Sr.	Summary of the case	
1.	Date of sampling	02-11-2023
2.	Sent to DTL	02-11-2023
3.	Date of receipt in DTL	03-11-2023
4.	Issuance of DTL Report	19-01-2024
5.	Time Extension	31 st Committee meeting dated 04-01-2024
6.	DI 1st communication with firm	13-02-2024
7.	Retesting Request	21-02-2024
8.	Fate of retesting request	Turn-Down 36 th Committee meeting dated 17-04-2024
9.	Investigation Report of DI	31-05-2024
10.	Permission of SCN	282 nd meeting dated 24-07-2024
11.	SC Notice Issued	26-07-2024

- iv. Warrantor portion of the drug samples were sent M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan.
- v. A copy of test reports of the drug samples were sent to M/s Bajwa Pharmaceuticals Pvt. Ltd., 36-km Lahore-Gujranwala Road, Kohri District Sheikhpura Pakistan with directions to provide the requisite information and to explain their position in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- vi. Pursuant to firm's retesting request the Provincial Quality Control Board in its 36th committee meeting held on 17-04-2024 **turn-down** the retesting request of the firm.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection ISOBAJ 10MG/10ML [Isosorbide dinitrite...1mg/ml] Mfg Date: May- 2023 Exp. Date: April- 2025 Reg. No. 078953	IB-0523	M/s Bajwa Pharmaceuticals Pvt. Ltd., 36- km Lahore- Gujranwala Road, Kohri District Sheikhpura Pakistan	TRA 01- 10194004577/DTL dated 30-12-2023	<p>Specification applied: BP 2023</p> <p><u>PHYSICAL DESCRIPTION:</u></p> <p>Colourless liquid in transparent glass ampoule with label pasted on it. Claimed volume=10mL.</p> <p><u>EXTRACTABLE VOLUME:</u></p> <p>Determined: 11mL</p> <p>Limit: NLT Nominal Volume, i.e., 10mL</p> <p><u>pH:</u></p> <p>Determined: 4.9 AT 23.0°C</p> <p>Limit: 3.5-7.0</p> <p><u>IDENTIFICATION:</u></p> <p>The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram (Isosorbide dinitrate identified).</p> <p><u>ASSAY OF ISOSORBIDE DINTRATE:</u></p> <p>Stated = 1mg/mL</p> <p>Determined = 1.0mg/mL</p> <p>Percentage = 100.5%</p> <p>Limit = 95.0%-105.0% of the stated amount</p> <p><u>STERILITY TEST:</u></p> <p>The sample is non-sterile.</p> <p>(DOES NOT COMPLY)</p>

				RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of Sterility test performed as per BP.on the basis of Sterility Test performed as per BP.
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2. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

a. Manufacture for sale/Sale of Substandard drug

b. Issuance of false warranty

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

Sr.	Summary of the case	
1.	Date of sampling	02-11-2023
2.	Sent to DTL	02-11-2023
3.	Date of receipt in DTL	03-11-2023
4.	Issuance of DTL Report	30-12-2023
5.	Time Extension	N/A
6.	DI 1st communication with firm	15-01-2024
7.	Retesting Request	18-01-2024
8.	Fate of retesting request	Turn-Down 36 th committee meeting dated 17-04-2024
9.	Investigation Report of DI	30-05-2024
10.	Permission of SCN	281 st meeting dated 06-06-2024
11.	SC Notice Issued	10-07-2024
12.	Reply of the firm	Not received
13	History (3 years)	35 cases of the firm 04 case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 62

PQCB/R-657/2022

THQ Hospital Sambrial, District Sialkot

ATTENDENCE

<p>Secretary DQCB</p> <p>Drug Inspector</p>	<p><u>Accused Persons involved in subject case</u></p> <p>1. M/S Kohinoor Industries, 160-B Small Industrial Estate, Sahiwal through its Managing Director Noman Shahid.</p> <p>2. Noman Shahid Managing Director</p> <p>3. Khurram Shahzad Production Incharge</p> <p>4. Naveed Iqbal Abid Quality Control Incharge</p> <p>5. Nadeem Akram Warrantor</p> <p>of M/S Kohinoor Industries, 160-B Small Industrial Estate, Sahiwal.</p>
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BRIEF FACTS OF THE CASE:

Provincial Inspector of drugs, THQ Hospital Sambrial, District Sialkot reported that: -

- i. She, on 11-06-2022, inspected the premises of THQ Hospital Sambrial and took following drug sample on Form No. 04 for the purpose of test and analysis and sent to Government Analyst Drug Testing Laboratory, Faisalabad vide memorandum no. 129867 dated 12-06-2022.
- ii. The subject drug sample 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 No. & Date	DTL Test Report Result
<p>Cotton, Leader Kohinoor Absorbent Cotton wool [Absorbent Cotton Wool (BPC), Wt. ±5%: 500gm with packing]</p> <p>Mfg Date May 2022</p> <p>Expiry Date May-2025</p> <p>Regn No.</p>	105502	M/s Kohinoor Industries, 160-B Small Industries Estate, Sahiwal.	<p>01-68016347/ DTL</p> <p>Dated 28-07-2022</p>	<p><u>Analysis with specifications applied:</u> BPC 1973</p> <p><u>DESCRIPTION:</u> Well carded cotton, fibers, <u>not properly bleached, having foreign pieces of pink, blue and brown threads</u> and reasonably free from leaf shell, <u>it does not offer appreciable resistance when pulled and shed appreciable quantity of dust when gently shaken</u> and it is almost odorless. (Does not comply)</p> <p><u>SOLUBILITY:</u></p> <p>Stated: Soluble at 20°, in 66% v/v sulphuric acid. (BPC 1973 and F.6-6/2005-Reg-II (South))</p> <p>Determined: Dissolve in 66 % v/v sulphuric acid. (Complies)</p> <p>Stated: Soluble in ammoniacal copper oxide solution (BPC 1973 and F.6-6/2005-Reg-II (South))</p> <p>Determined: Dissolve in ammoniacal copper oxide solution</p>

005416

(Complies)

Stated: Insoluble in dilute (1.25 M) Sodium hydroxide solution (BPC 1973 and F.6-6/2005-Reg-II (South))

Determined: Insoluble in dilute (1.25 M) Sodium hydroxide solution. (Complies)

ABSORBENCY:

Sinking Time:

Stated: NMT 10 seconds at 20-25 °C (BPC 1973) NMT 15 seconds at 20-25 °C (F.6-6/2005-Reg-II (South))

Determined: Average of 3 tests= 29.67 seconds (Does not Comply)

Water Holding Capacity:

Stated: NLT 23 gm per gm of sample (BPC 1973)

NLT 20 gm per gm (F.6-6/2005-Reg-II (South))

Determined: Average of 3 tests= 24.13 gm per gm (Complies)

ACIDITY/ALKALINITY:

Stated: Should be Neutral in reaction with phenolphthalein solution and methyl orange solution.

Determined: Pink color appears upon addition of phenolphthalein solution (Does not Comply)

FLUORESCENCE TEST:

Stated: No intense blue fluorescence except that which may be shown by a few isolated fibers. (BPC 1973)

Determined: Intense blue fluorescence was observed in the given sample at 365nm. (Does not Comply)

RESULT: Given sample is Sub-Standard with regards to Description (physical characteristics), Absorbency (Sinking time), alkalinity and fluorescence tests of Absorbent Cotton Wool.

- iii. Store keeper THQ Hospital Sambrial provided Invoice/Warranty bearing number 01-21-3057 dated 24-05-2022 issued by M/s Kohinoor Industries, 160-B Small Industries Estate, Sahiwal as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent M/s Kohinoor Industries, 160-B Small Industries Estate, Sahiwal.
- v. A copy of test/analysis report was sent to M/s Kohinoor Industries, 160-B Small Industries Estate, Sahiwal, with directions to explain their position and provide requisite information in this regard. In response, the firm requested for retest/ analysis of the drug sample from Appellate Laboratory.

vi. Pursuant to the request of the firm, the sample was sent to Appellate Laboratory for the purpose of retest/ analysis, from where, the drug was declared **Substandard**, as follows:

Name of Drug	Batch No.	Name of Manufacturer	NIH Report No. & Date	DTL Test Report Result
Kohinoor Absorbent Cotton wool BPC	105502	M/s Kohinoor Industries, 160-B Small Industries Estate, Sahiwal.	01-P/2023 dated 8 th May 2023.	<p><u>Analysis with specifications applied:</u> BPC 1973</p> <p><u>SINKING TIME:</u> 22 seconds</p> <p>Limit: Not more than 10 seconds</p> <p>Does not comply with BPC-73</p> <p><u>ALKALINITY:</u></p> <p>Determined: Solution showed yellow color</p> <p>Limit: Solution shows yellow color</p> <p>Complies with BPC-73</p> <p><u>REMARKS:</u> Fluorescent test could not be performed due to non-availability of facility.</p> <p>RESULT: The sample is Sub-Standard quality on the basis of tests performed.</p>

vii. A copy of NIH test/analysis report was sent to M/s Kohinoor Industries, 160-B Small Industries Estate, Sahiwal, with directions to explain their position and provide requisite information in this regard.

2. The Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused person(s), who have contravened the Schedule II & III of DRAP Act 2012 by the way of:

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

3. Show-cause notice(s) issued to accused person(s) dated 13-10-2023

Reply of the firm to show cause notice vide letter no. KCi/961073 dated 24-10-23:

Respected Sir,

With reference to letter no. PQCB/R-657/2022, we are providing the following details regarding the Leader Absorbent Cotton Wool 500 gm Roll Batch No. 105502, which has been substandard Vide TRA No. 01-68016347/DTL which are mentioned below.

1. Name of the Technical Staff,

i Noman Shahid S/O Sheikh Shahid Hameed. (Managing Director)

ii. Dr Khuram Shehzad S/O Muhammad Saleem, (Production Incharge)

iii. Naveed Iqbal Abid S/O Ch Basir Ahmad (Quality Control Incharge)

2. Attested copy of Drug Manufacturing License.

3. Copy of Registration Certificate of Absorbent Cotton wool BPC 500 gm.

4. Personal hearing notice(s) issued to accused person(s) dated 15-04-2024

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

279th meeting dated 24-04-2024:

5. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **279th** meeting held on **24-04-2024** under the chairmanship of Special Secretary (operations) vice chairperson PQCB Primary and Secondary Health Care Department. Ms. Farah Majeed Secretary DQCB Sialkot attended meeting via zoom link. No one among the nominated accused person of M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Lahore Pakistan was present. Firm submitted written adjournment request vide letter no. Kci/961074 dated 22-04-2024.

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

7. Personal hearing notice(s) issued to accused person(s) on 27-05-2024.

281st meeting dated 06-06-2024:

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **281st** meeting held on **06-06-2024** under the chairmanship of Special Secretary (Operations)/ Vice chairperson PQCB Primary & Secondary Healthcare Department Punjab. Ms. Farah Majeed, Secretary DQCB, District Sialkot attended the meeting online via zoom link and Ms. Asma Hanif Drug Inspector THQ Hospital Sambrial District Sialkot was present along with the original case record. No one among the nominated accused persons of M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan was present. However, firm submitted written request for adjournment vide letter no. KCi/961043 dated 05-06-2024.

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

10. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 05-2022**
- **Exp. Date: 05-2025**
- **Sampling date (Form 4): 11-06-2022**
- **Sent to DTL (Form 6): 12-06-2022**
- **Date of receipt in DTL: 14-06-2022**
- **DTL Report Date (Form 7): 28-07-2022**
- **DI 1st intimation to firm: 06-08-2022**
- **Retesting request if any: 18-08-2022**

- **Fate of Retesting: Allowed in 255th meeting dated 29-12-2022. NIH substandard (118 days)**
- **Investigation report Dated: 19-09-2023**
- **Permission of SCN: 269th meeting dated 03-10-2023**
- **SCN Issued: 13-10-2023**
- **Reply of the firm: Yes**
- **History (3 years) Firm: 24 cases**
- **Product: 09 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 63

PQCB/R-569/2022

Tehsil & District Hafizabad

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">1. M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan through its Chief Executive Officer, Noman Shahid2. Noman Shahid Chief Executive Officer3. Khurram Shahzad Production Incharge4. Naveed Iqbal Abid Quality Control Incharge5. Muhammad Nadeem Akram Warrantor/ GM <p>Of M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan.</p>
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BRIEF FACTS OF THE CASE:

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

- i. The then drug inspector, on 29-06-2022 inspected the premises of Main Medicine Store CEO (DHA) Office District Complex Hafizabad, took four different types of drug samples on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memorandum no. 132456 dated 04-07-2022.
- ii. The subject drug sample, 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 No. & Date	DTL Test Report Result
Cotton. Leader Absorbent Cotton Wool [Absorbent Cotton Wool (BPC) Wt ± 5%: 500gm with Packing] Mfg Date: May-2022 Exp. Date: May-2025	105503	M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan.	01-68017015/ DTL dated 18-08-2022	<p>Analysis with specifications applied: BPC 1973</p> <p>DESCRIPTION: Well carded cotton fibers, bleached to a good white, free from foreign pieces of thread and reasonably free from leaf shell and foreign matter. It offers appreciable resistance when puled and does not shed appreciable quantity of dust when gently shaken & it is almost odorless.</p> <p>SOLUBILITY:</p> <p>Stated: Soluble at 20°C, in 66% v/v sulphuric acid. (BPC 1973 and F.6-6/2005-Reg-II (South))</p> <p>Determined: Dissolve in 66% v/v sulphuric acid. (Complies)</p> <p>Stated: Soluble in ammoniacal copper oxide solution (BPC 1973 and F.6-6/2005-Reg-II (South))</p> <p>Determined: Dissolve in ammoniacal copper oxide solution. (Complies)</p>

Regn. No: 005416

Stated: Insoluble in dilute (1.25 M) Sodium hydroxide solution (BPC 1973 and F.6-6/2005-Reg-II (South))

Determined: Insoluble in dilute (1.25 M) Sodium hydroxide solution. (Complies)

ABSORBENCY:

Sinking Time:

Stated: NMT 10 seconds at 20-25°C (BPC 1973)

NMT 15 seconds at 20-25°C (F.6-6/2005-Reg-II (South))

Determined: Average of 3 tests=31.33 seconds (Does Not Comply)

Water Holding Capacity:

Stated: NLT 23 gm per gm of sample (BPC 1973)

NLT 20 gm per gm (F.6-6/2005-Reg-II (South))

Determined: Average of 3 tests= 23.73 gm per gm (Complies)

ACIDITY/ALKALINITY:

Stated: Should be Neutral in reaction with phenolphthalein solution and methyl orange solution.

Determined: Pink color appears upon addition of phenolphthalein solution (Does Not Comply)

FLUORESCENCE TEST:

Stated: No intense blue fluorescence except that which may be shown by a few isolated fibers. (BPC 1973)

Determined: Intense blue fluorescence was observed in the given sample at 365 nm. (Does Not Comply)

RESULT: Given sample is Sub-Standard with regards to Absorbency (Sinking Time), Alkalinity and fluorescence tests of Absorbent Cotton Wool

- i. Storekeeper Main Medicine Store CEO (DHA) Office District Complex Hafizabad provided Invoice/ warranty No. 01-21-2425 dated 29-05-2022 issued by M/Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan as a proof of its purchase.
- ii. Warrantor portion of the subject drug sample was sent to M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan.
- iii. A copy of test/ analysis report was sent to M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan with directions to explain their position and provide requisite information in this regard. 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.
- iv. Pursuant to the request of M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal

Pakistan the retesting request of the subject drug sample was considered in the 255th Meeting of the Board held on 29-12-2022 and the subject drug sample was sent to NIH, Islamabad, from where the sample was declared **Sub-standard** as detailed below:

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Kohinoor Absorbent Cotton Wool BPC 500gm	105503	M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan	No. 02-P/2023 dated 8 th May, 2023	<p>Analysis with Specifications Applied: BPC-73</p> <p><u>SINKING TIME:</u></p> <p>Determined: 20 Seconds</p> <p>Limit: Not more than 10 Seconds</p> <p>Does not Comply with BPC-73</p> <p><u>ACIDITY OR ALKALINITY:</u></p> <p>Determined: Solution showed yellow colour</p> <p>Limit: Solution shows yellow colour.</p> <p>Complies with BPC-73</p> <p><u>REMARKS:</u> Fluorescent test could not be performed due to non-availability of facility.</p> <p><u>CONCLUSION:</u> The sample is of Sub-Standard quality on the basis of tests performed.</p>

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

3. Show cause/Personnel hearing notice was issued to accused person(s) vide dated 04-09-2023.

4. Personnel hearing notice issued vide dated 15-04-2024.

PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:

279th meeting dated 24-04-2024:

5. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its 279th meeting held on 24-04-2024 under the chairmanship of Special Secretary (operations) vice chairperson PQCB Primary and Secondary Health Care Department. Miss Anum Lodhi Secretary DQCB Hafizabad attended meeting via zoom link. And Mr. Awais Younis DI Hafizabad was present along with original case record. No one among the nominated accused person of M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan was present. Firm submitted written adjournment request vide letter no. Kci/961074 dated 22-04-2024.

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

7. Personal hearing notice(s) issued to accused person(s) on 27-05-2024.

281st meeting dated 06-06-2024:

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **281st** meeting held on **06-06-2024** under the chairmanship of Special Secretary (Operations)/ Vice chairperson PQCB Primary & Secondary Healthcare Department Punjab. Ms. Anum Lodhi, Secretary DQCB, District Hafizabad attended the meeting online via zoom link and Mr. M. Awais Drug Inspector Tehsil & District Hafizabad was present along with the original case record. No one among the nominated accused persons of M/s Kohinoor Industries, 160-B Small Industrial Estate Sahiwal Pakistan was present. However, firm submitted written request for adjournment vide letter no. KCi/961043 dated 05-06-2024.

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

10. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 05-2022**
- **Exp. Date: 05-2025**
- **Sampling date (Form 4): 29-06-2022**
- **Sent to DTL (Form 6): 04-07-2022**
- **Date of receipt in DTL: 07-07-2022**
- **DTL Report Date (Form 7): 18-08-2022**
- **DI 1st intimation to firm: 06-10-2022**
- **Retesting request if any: 19-10-2022**
- **Fate of Retesting: Allowed in 255th meeting dated 29-12-2022. NIH Substandard (118 days)**
- **Investigation report Dated: 06-06-2023**
- **Permission of SCN: 262nd meeting dated 13-06-2023**
- **SCN Issued: 04-09-2023**
- **Reply of the firm: No**
- **History (3 years) Firm: 24 cases**
- **Product: 09 cases**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 64

PQCB/R-319/2023

Tehsil and District Lodhran

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan through its Managing Director Noman ShahidNoman Shahid Managing DirectorKhuram Shehzad Production InchargeNaveed Iqbal Abid Quality Control InchargeMuhammad Nadeem Akram Warrantor <p>Of M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan.</p>
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BRIEF FACTS OF THE CASE:

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

- He, on 29-04-2023, inspected the premises of Main Medicine Store, office of CEO (DHA) Lodhran, took sample of three different types of drugs on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Multan vide memorandum no. 0000165121 dated 29-04-2023.
- Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Multan** as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Leader Kohinoor Absorbent Cotton Wool 500g Mfg.date: Apr-2023 Exp. date: Apr-2026 Regn No. MDME-0000086	105564	M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan	TRA No. 01-105002594/DTL Dated:-08-06-2023	<u>Result of test/ analysis with specifications applied:</u> BPC 1973 <u>Description:</u> Well-carded cotton fibers bleached to good white, free from pieces of thread and reasonably free from leaf, shell and foreign matter. It does not shed any appreciable quantity of dust when gently shake. <u>Sinking Time:</u> Limit: NMT 15 seconds (BPC/MOH) Determined:32 seconds (Does Not Comply) <u>Water Holding Capacity:</u> Limit: NLT 20g/g

				<p>(BPC/MOH)</p> <p>Determined: 19.79 g/g (Does Not Comply)</p> <p>Alkalinity: Limit: Should show no pink color with phenolphthalein indicator (BPC/MOH)</p> <p>Determined: Filtrate gives no pink color with phenolphthalein indicator. (Complies)</p> <p>Acidity: Limit: Should show yellow color with methyl orange indicator. (BPC/MOH)</p> <p>Determined: Filtrate gives yellow color with methyl orange. (Complies)</p> <p>Color of aqueous extract: (Complies)</p> <p>RESULT:</p> <p>The above sample is Sub-Standard on the basis of Sinking Time & Water Holding Capacity.</p>
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- iii. Store Keeper, Main Medicine Store, office of CEO (DHA) Lodhran submitted Invoice/warranty no. 01-21-9600 dated 03-04-2023 issued by M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan as a proof of its purchase of the said drug.
- iv. Warrantor portion of the drug sample was sent to M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan and they were asked to provide the requisite information in this regard.
- v. A copy of test/analysis report was sent to M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal-Pakistan and they were asked to provide the requisite information in this regard.

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

- a. **Manufacture for sale/sale of the Substandard drug**
- b. **Issuance of false warranty**
- c. **Disobeying the lawful authority of drug inspector by non-provision of requisite information and documents within given time**

3. Show-cause notice(s) issued to accused person(s) vide 28-11-2023.

Personal Hearing notice(s) issued to accused person(s) dated 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date:04-2023**
- **Exp. Date: 04-2026**
- **Sampling date (Form 4): 29-04-2023**
- **Sent to DTL (Form 6): 29-04-2023**
- **Date of receipt in DTL: 02-05-2023**
- **DTL Report Date (Form 7): 08-06-2023**
- **Time Extension to DTL: report not Time Barred**
- **DI 1st intimation to firm: 08-07-2023**
- **Retesting request if any: NO**
- **Investigation report Dated: 14-10-2023**
- **Permission of SCN: 271st meeting dated 01-11-2023**
- **SCN Issued: 28-11-2023**
- **Reply of the firm No**
- **History (3 years) Firm: 24 case**
- **Product: 09 case**

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 65

PQCB/R-249/2022

Govt. Haji Abdul Qayyum Hospital Sahiwal

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Pharmasol (Pvt.) Ltd., 549, Sundar Industrial Estate, Lahore through its Chief Executive, Akbar Ali. 2. Akbar Ali Chief Executive 3. Javed Iqbal Production Incharge/ Warrantor 4. Muhammad Shoaib Quality Control Incharge of M/S Pharmasol (Pvt.) Ltd., 549, Sundar Industrial Estate, Lahore
Drug Inspector	

BRIEF FACTS OF THE CASE

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

- i. He, on 26.03.2022, inspected the premises of Main Medicine Store, Govt. Haji Abdul Qayyum Teaching Hospital Sahiwal and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Bahawalpur vide memorandum no. 206No./GHAQ dated 26.03.2022
- ii. Following Drug samples after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Bahawalpur, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
Injection Dexapro (Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate: 4mg/ml) Mfg Date: 02.2022 Expiry Date: 01.2024	EGO65	M/S Pharmasol (Pvt.) Ltd., 549, Sundar Industrial Estate, Lahore	01-85001590/ DTL dated 26.04.2022	Specifications applied: USP 2021 Composition: Each ml contains: Dexamethasone Sodium Phosphate USP eq. to Dexamethasone Phosphate: 4mg Description: Colorless liquid in transparent sealed glass ampules with green printing. Enclosed in outer carton. (Stated Volume is 01ml). Four (04) ampules out of Twenty (20) ampules contain Undissolvable visible material with following descriptive appearance: 01 ampule contain fibrous mass with black particles. 02 ampules contain undissolved white precipitated material in shape of flakes

Regn No. 090491			visible with naked eyes. 01 ampule contain black particle. (Does not comply with the parenteral specifications) <u>Volume (USP):</u> Complies <u>pH (USP):</u> Complies <u>Sterility (USP):</u> The product is sterile. <u>Identification:</u> Dexamethasone phosphate is identified. <u>Assay:</u> percentage: 100.06% limit: 90-115% Complies <u>Result:</u> The sample is declared Sub-standard on the basis of Physical Test.
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iii. Store Keeper of Medicine Store, Govt. Haji Abdul Qayyum Teaching Hospital Sahiwal provided Invoice/warranty PHL/INV/22/Mar/2821, Dated 12.03.2022 issued by M/S Pharmasol (Pvt.) Ltd., 549, Sundar Industrial Estate, Lahore as a proof of its purchase.

iv. Warrantor portion of drug sample was sent to M/S Pharmasol (Pvt.) Ltd., 549, Sundar Industrial Estate, Lahore.

v. A copy of test/analysis report was sent to M/S Pharmasol (Pvt.) Ltd., 549, Sundar Industrial Estate, Lahore and they were asked to provide the requisite information in this regard. **In response the firm submitted retesting requests which was turned down by the Provincial Quality Control Board in its 251st meeting dated 20.10.2022. The firm submitted Review Petitions which were also turned down by Provincial Quality Control Board in its 262th meeting dated 13.06.2023.**

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, selling of Substandard drug**
- ii. **Issuance of false warranty**

3. Show cause notice(s) issued to the accused dated 20-03-2024

Firm submitted reply of show cause notice dated 08-04-2024

Please refer to your Letter No. PQCB/R-249/2022 dated 20.03.2023 received on 04.04.2024 of the above cited subject.

1. We have checked the retained samples of the batch in question and found it of standard quality with regards to Physical appearance as well as sterility, identification, extractable volume, Ph, and assay of the product. None of the retention sample was found contaminated with any fibrous matter, black particles or any undissolved precipitate.

2. We had supplied our product Dexapro Injection Batch No. EG065 (same product and batch) to Teaching Hospital D.G. Khan. The Government Analyst Drug Testing Laboratory Multan declared

our product of standard quality.

3. Since the identified particles or mass has not been identified by the analyst in order to reach a just conclusion whether these circumstances are foreign particles or any precipitated substance.

4. Therefore, it is strongly apprehended by the company that these particles or mass has been created due to improper storage conditions at the final end. As per your requirement, we furnishing following documents/information for your kind perusal.

Name of Chief Executive Officer: Mr. Akbar Ali

Name of Production Incharge & Warrantor: Javed Iqbal

Name of Quality Control Incharge: Muhammad Shoaib

In view of the above submission and clarification, we therefore request you to take a lenient view and file the matter please.

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

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

5. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **281st** meeting held on **06-06-2024** under the chairmanship of Special Secretary (operations) vice chairperson PQCB Primary and Secondary Health Care Department. Mr Ahmad Awais Secretary DQCB Sahiwal attended meeting via zoom link. No one among the nominated accused person of M/s Pharmasol (Pvt.) Ltd., 549, Sundar Industrial Estate, Lahore appeared before the Board. Firm submitted written adjournment request vide letter no. PPL/G-37-5/24 dated 01-06-2024.

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

Director DTLBahawalpur clarified /submitted vide letter no. 1619/DTLB dated 27-06-2024 that there is a typographical error on 1st page of form 7 serial no. 1038 in Batch no. as “EGO65” was written instead of EG065”. The corrected and attested copy is sent for record

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

	Summary of the case	
1	Sampling Date: (Form 4)	26-03-2022
2	Sent to DTL (Form 6):	26-03-2022
3	Date of receipt in DTL	28-03-2022

4	DTL Report date	26-04-2022
5	Time extension granted	N/A
6	1 ST DI Communication with firm	09-05-2022
7	Retesting Request of Firm	19-05-2022
8	Fate of Retesting Request:	Turn down 252 M dated 20-10-2022 Review petition turn down 262-M dated 13-06-2023
9	Investigation Report of DI	08-08-2023
10	SCN permission	267-M dated 07-09-2023
11	Show cause notice issued	20-03-2024
12	Firm History: (3years)	Firm: 18 Product: 3

CURRENT PROCEEDING & DECISION BY THE BOARD:

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<p>Ophthalmic Suspension Tobracort (Each ml contains:Tobramycin (USP)...3mg, Dexamethasone (USP)...1mg)</p> <p>Mfg.date: May-2022</p> <p>Exp. date: May-2024</p> <p>Regn No. 090423</p>	<p>OD039</p>	<p>M/s Pharmasol Private Limited Plot # 549,Sundar industrial Estate, Lahore, Pakistan</p>	<p>TRA No. 01-68017465/DTL</p> <p>Dated:-18-10-2022</p>	<p><u>Result of Test/ Analysis with specifications applied:</u> USP 2022</p> <p><u>Description:</u> Off white color suspension contained in plastic bottle with nozzle and plastic screw cap, packed in outer hard carton.</p> <p><u>Identification:</u> Dexamethasone and Tobramycin are identified.</p> <p><u>Assay:</u></p> <table border="1" data-bbox="836 443 1509 898"> <thead> <tr> <th>Generic</th> <th>Stated</th> <th>Determined</th> <th>Percentage</th> <th>Limit (USP 2022)</th> </tr> </thead> <tbody> <tr> <td>Dexamethasone</td> <td>1 mg/ml</td> <td>1.0102 mg/ml</td> <td>101.02%</td> <td>90-110%</td> </tr> <tr> <td>Tobramycin</td> <td>3mg/ml</td> <td>3.509mg/ml</td> <td>116.967%</td> <td>90-120%</td> </tr> </tbody> </table> <p>(Complies)</p> <p><u>PH:</u> Stated: 5.0-6.0 (USP 2022)</p> <p>Determined: 5.64 (Complies)</p> <p><u>Sterility:</u> Stated: Must be Sterile (membrane filtration method) (USP 2022)</p> <p>Determined: Non-sterile (Does not comply)</p> <p><u>RESULT:</u> Given sample is Sub-Standard with regards to Sterility Test.</p>	Generic	Stated	Determined	Percentage	Limit (USP 2022)	Dexamethasone	1 mg/ml	1.0102 mg/ml	101.02%	90-110%	Tobramycin	3mg/ml	3.509mg/ml	116.967%	90-120%
Generic	Stated	Determined	Percentage	Limit (USP 2022)															
Dexamethasone	1 mg/ml	1.0102 mg/ml	101.02%	90-110%															
Tobramycin	3mg/ml	3.509mg/ml	116.967%	90-120%															

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

- i. **Manufacturing for Sale / Sale of Sub-standard Drug.**
- ii. **Issuance of false warranty.**

3. Showcause was issued to accused person(s) vide dated 11-08-2023

REPLY OF SHOW CAUSE NOTICE

Firm replied to the show cause notice vide letter Reference no. PPL/G-47-3/2022 dated 19-08-2023 stating that:

Please refer to your Letter No. PQCB/R-576/2022 dated 11.08.2023 received on subject.

1. we checked the retained samples of the batch in question and found it of standard quality

regards to Physical appearance, identification, extractable volume, pH, assay and especially the sterility of the product.

2. We had supplied our product Tobracort Ophthalmic Suspension Batch No. OD039 (same product and batch) to CEO (DHA) Lodhran. The Government Analyst Drug Testing Laboratory Multan, declared our product of standard quality (copy of report attached herewith for ready reference).

3. We had supplied our product Tobracort Ophthalmic Suspension Batch No. OD039 (same product and batch) to CEO (DHA) Rajanpur. The Government Analyst Drug Testing Laboratory Multan, declared our product of standard quality (copy of report attached herewith for ready reference).

4. Even otherwise the report Of DTL Faisalabad TRA. 01-68017465/DTL dated is a time barred report and can't be relied upon/considered against the interest of the company and cannot be further made basis for any action against the company.

5. As per your requirement, we furnishing following documents/information for your kind perusal.

Copy of Drug Manufacturing License Enclosed Copy Of Drug Registration Certificate Enclosed

III. Batch manufacturing and sales record Enclosed

IV. Name of Chief Executive Officer Mr. Akbar Ali

V. Name of Production IIICharge Mr. Javed Iqbal Name of Quality Control Incharge. Kamal Subhani copies of CNIC Enclosed

VII. Copies of appointment letter Enclosed

Moreover, the concerned person is Mr. Kamal Subhani (Quality Control Incharge) on the behalf of the company is ready to reply to all the queries raised by the board as and when required and his contact and WhatsApp number 0333-4178594.

Assuring you our best cooperation and attention all the times.

Personnel hearing notice(s) issued to accused person(s) vide dated 26-08-2024

Case is placed before the Board.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	29-07-2022
2	Sample Sent to DTL (Form-6)	29-07-2022
3	Receipt Date in DTL	03-08-2022

4	Issuance of DTL Report	18-10-2022
5	Time Extension	251 meeting dated 24-10-2022
6	DI First Communication with Firm	23-11-2022
7	Retesting Request	29-11-2022
8	Investigation Report by DI	06-06-2023
9	SCN Permission	264 th meeting
10	Show Cause Notice Issued	11-08-2023
12	History (3 years)	Firm's Reported: 24
		Product's Reported: 07

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 67

PQCB/R-437/2023

Nishtar Hospital, Multan

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/s Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan through its Managing Director, M. Ashar Khurram 2. M. Ashar Khurram Managing Director 3. Khalid Iqbal Production Incharge/Warrantor 4. Saeed Ahmed Quality Control Incharge of M/S Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Nishtar Hospital, Multan reported that: -

- i. He, on 24-01-2023, inspected the premises of Main Drug Store, Nishtar Hospital, Multan and took 03 different types of drug samples on Form No.04 and sent to Drug Testing Laboratory Multan for the purpose of test/analysis.
- ii. Following drug sample, sent vide memorandum no. 154988, dated 24-01-2023, 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
Injection MINI KCL 25ml (Potassium Chloride 74.6mg/ml) Mfg. Date: Dec-2022 Exp. Date: Nov-2025 Reg# 076882	058022	M/S Frontier Dextrose Limited, Plot No 18/3, Phase 1 Hattar Industrial Estate, Haripur Pakistan.	TRA. 01-105000802/DTL, Date: 25-03-2023

Specifications: BP 2023

Description: Colorless solution filled in a sealed, labelled, transparent, plastic ampoule of 25mL with green printed label.

Visible Particles:

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

Determined: "When examined against white and black background, 02(Two) out of 20 ampoules contain visible particles".
(DOES NOT COMPLY)

Extractable Volume	Limit:	NLT stated	
	Determined:	25.0 mL	(Complies)
Sterility	It conforms to sterility test		(Complies)
Identification	Potassium Chloride Identified.		
Assay			
Potassium Chloride	Stated:	74.6 mg/ mL	
	Determined:	74.61 mg/ mL	
	Percentage:	100.01%	
	Limit:	95-105%	(Complies)

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

- iii. Store Keeper, Main Medicine Store, Nishtar Hospital, Multan provided invoice/ warranty no. 14705 dated 17-01-2023, issued by M/S Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan as a proof of its purchase.
- iv. Warrantor portion of the subject sample was sent to M/S Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan.
- v. A copy of test/analysis report was sent to M/S Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan, with directions to explain their position and provide requisite information in this regard.
- vi. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad.
- vii. The retesting request was placed in PQCB's 25th Committee meeting, dated: 13-09-2023. The Board after due deliberation unanimously decided to **Turn Down** the subject request for retesting of the sample under Section 22 (4) of the Drugs Act, 1976 (as amended).

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

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

b. **Issuance of false warranty**

3 Show cause/personal hearing notice issued to the accused

Reply of show cause notice:

This is in response to your Show Cause/Personal hearing notice via letter No. PQCB/R-437/2023, dated 06-05-2024 on the subject cited above which is received on 11-05-2024. We, Frontier dextrose Limited would like to submit our compliance to this as follows:

1. First and foremost, we must assert our right to due process, as guaranteed by our legal system. The Committee of the Provincial OQuality Control Board Punjab turned down request in PQCB's 25th Committee meeting dated 13-09-2023, to the subject drug sample, which is a fundamental step in ensuring fairness and accuracy in any proceedings.
2. Our contention lies in the fact that both the samples of warrantor portion as well as QC retained samples of our Injection Mini KCl 25 mL (Potassium Chloride 74.6 mg/mL, 25 mL),

B. No. 058022 has passed the visible and sub visible particles tests. We have meticulously adhered to the necessary protocols and standards to ensure the accuracy and reliability of these tests as per British Pharmacopoeia. However, without the opportunity to retest the sample in the Appellant Laboratory, the possibility of inaccuracies or misunderstandings cannot be ruled out. We have studied Batch Manufacturing Record of said Batch No. 058022 and found no deviation from our standard manufacturing procedure. Copy of Batch Manufacturing Record is attached.

We have world best company Liquid particle counter to check the invisible particles and its reports are well within the Limits. Copies of reports are attached as Annex B.

5. We have state of the art production facilities with world best Company Rommelag BFS Machine. This machine is designed on the principle of aseptic filling. In BES process formation of ampoules, filling and sealing, all steps are done within enclosed mold and there is no exposure of product from external environment. We also installed series of online cartridge filters 1um, 0.45um from compound tank to filling machine and 0.2um filter terminally at filling point, which ensures that our product is clean, safe, and free of all narticles. There is no chance of any particle to enter in ampoule as product passes through 0.2um filter.

6. In addition to all above mentioned measures before final packing each and every ampoule is optically inspected on white and black background, by well trained staff, and then packed. As a precaution clear instructions are mentioned on the label as, Donot use if ampoule is leaking, solution is cloudy or contains any visible solid particles.

7. We have Quality Assurance department who monitor each and every step of manufacturing in process as well as all our products have validated procedures and there is no chance of any lapse. Moreover, we strictly follow GMP practices on plant to assure quality products.

We are fully prepared to cooperate with any additional inquires or discussions necessary to address this matter satisfactory.

9. In addition to the aforementioned justifications, we have re-supplied complete stock as replacement free of cost to the Nishtar Hospital Multan, so that hospital as well as patient should not suffer. As a proof copy of delivery challan is attached.

We earnestly request that please close this case by taking into account the successful test results of warrantor samples and based upon the fact that our right to due process for retesting of samples as guaranteed by our legal system was not given to us & we firmly believe that this step is crucial in ensuring a fair and comprehensive evaluation of the situation before any further legal action is pursued.

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

4. The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its 280th meeting held on 16-05-2024 under the chairmanship of Special Secretary (operations) vice chairperson PQCB Primary and Secondary Health Care Department. Dr. Imran DQCB member Multan attended meeting via zoom link and Mr. M. Nasir Drug Inspector Nishtar Hospital Multan was present along with original case record. No one among the nominated accused person of M/s Frontier Dextrose Limited, Plot No 18/3, Phase 1 Hattar Industrial Estate, Haripur Pakistan was present. Firm submitted written request for adjournment vide letter ref no. FDL/1505/24/2 dated 15-05-2024. The Board after due deliberation and discussion, unanimously decided to **adjourn** the case on request of the firm in the best interest of justice and provide another chance of hearing to the accused.

Moreover, the drug inspector is directed to retain an appropriate portion for Court proceeding and dispose-off the case property from Drug Disposal Committee (EDDC) of health facilities already constituted vide PSHD notification No. SO (HP) 2-9(2)/ 2021 dated 14-February, 2022 and PQCB order dated 06-05-2023 on guidelines regarding fate of

case properties and report to the office of Secretary PQCB within 7 days positively.

5 Personal hearing notice issued to the accused

Summary:

Sampling Date: 24-01-2023

Sent to DTL (Form 6): 24-01-2023

Date of receipt in DTL: 25-01-2023

DTL Report Date: 25-03-2023

Time extension granted: N/A

1ST DI Communication with firm on dated: 4-4-2023

Date of Retesting Request of Firm: 15-04-2023

Fate of Retesting Request: turn down 25th CM dated 13-09-2023

Investigation Report Dated: 7-2-2024

SCN permission: 276-M 29-02-2024

SCN/PH issued: 06-05-2024

Reply of SCN of firm: no

Firm history (3 years)

Firm: 10, Product: 1

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

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Case No. 68

PQCB/MSS- 162794/2023

Nishtar Hospital, Multan

ATTENDANCE:

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/s Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan through its Managing Director, M. Ashar Khurram 2. M. Ashar Khurram Managing Director 3. Khalid Iqbal Production Incharge/Warrantor 4. Saeed Ahmed Quality Control Incharge of M/S Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan
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BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Nishtar Hospital, Multan reported that: -

- i. He, on 04-04-2023, inspected the premises of Main Drug Store, Nishtar Hospital, Multan and took 03 different types of drug samples on Form No.04 and sent to Drug Testing Laboratory Multan for the purpose of test/analysis.
- ii. Following drug sample, sent vide memorandum no. 162794, dated 04-04-2023, after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Multan as detailed below:
- iii. Store Keeper, Main Medicine Store, Nishtar Hospital, Multan provided invoice/ warranty no. 15072 dated 29-03-2023, issued by M/S Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan as a proof of its purchase.
- iv. Warrantor portion of the subject sample was sent to M/S Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan.
- v. A copy of test/analysis report was sent to M/S Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan, with directions to explain their position and provide requisite information in this regard.

Name of Drug	Batch No.	Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Infusion Sterifluid-N/3 1000ml [Each 100ml contains: Dextrose Monohydrate....3.3, Sodium Chloride...0.3g]	161723	M/S Frontier Dextrose Limited, Plot no 18/3, Phase -1, Hattar Industrial Estate, Haripur, Pakistan.	01- 105002114/DTL Dated: 27-07- 2023	Analysis with specifications applied: USP 2023 Description: Stated: Colorless, Clear Solution filled in a sealed, labeled, transparent plastic infusion bottle. Identification: Dextrose Monohydrate & Sodium Chloride identified.

Mfg. date:

March-2023

Exp. date:

Feb-2026

Reg.# 064077

Analytical Technique: Polarimetry

Assay (Dextrose Monohydrate)

Stated	3.3g/100ml
Determined	3.65g/100ml
Percentage	110.66%
Limit	95-105%

(Does Not Comply)

Analytical Technique: Titration

Assay (Sodium Chloride)

Stated	0.3g/100ml
Determined	0.308g/100ml
Percentage	102.72%
Limit	95-105%

(Complies)

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

Extractable Volume:

Limit	NLT stated
Determined	1000ml

(Complies)

pH:

Limit	3.2-6.5
Determined	5.04

				<p>(Complies)</p> <p>Result: The above-mentioned sample is “Substandard” on the basis of Assay of Dextrose Monohydrate.</p>
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2. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: --

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

3 Show cause/personal hearing notice issued to the accused

PREVIOUS PROCEEDING & DECISION BY THE BOARD:

4 The subject case was considered by Provincial Quality Control Board under section 11 of the Drugs Act 1976 in its **280th** meeting held on **16-05-2024** under the chairmanship of Special Secretary (operations) vice chairperson PQCB Primary and Secondary Health Care Department. Dr. Imran DQCB member Multan attended meeting via zoom link and Mr. M. Nasir Drug Inspector Nishtar Hospital Multan was present along with original case record. No one among the nominated accused person of M/s Frontier Dextrose Limited, Plot No 18/3, Phase 1 Hattar Industrial Estate, Haripur Pakistan was present. Firm submitted written request for adjournment vide letter ref no. FDL/1505/24/3 dated 15-05-2024. The Board after due deliberation and discussion, unanimously decided to **adjourn** the case on request of the firm in the best interest of justice and provide another chance of hearing to the accused.

5 Personal hearing notice issued to the accused

Summary:

sampling date: 04-04-2023

Sent To DTL (form 6): 04-04-2023

Date Of Receipt In DTL: 04-04-2023

DTL Report Date: 27-07-2023

Time Extension Granted: 21CM dated 6-6-2023

1st DI Communication with Firm On dated: 10-08-2023

Date of retesting request of firm: No

Fate of retesting request: N/A

Investigation report dated: 7-2-2024

SCN permission: 276-M dated 29-02-2024

SCN/PH issued: 06-05-2024

firm history (3 years):

firm: 10

product: 1 subject case

Case is placed before the Board for the decision

CURRENT PROCEEDING & DECISION BY THE BOARD:

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Case No. 69

PQCB/R-662/2019

Tehsil and District Rahim Yar Khan

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/s Bosch Pharmaceuticals (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area, Karachi-Pakistan , through its Chief Executive Officer/ Warrantor, S.M Chawla 2. S.M Chawla 3. Muhammad Ishaq 4. Imtiaz Ahmed 5. Muhammad Amir Javed Of M/s Bosch Pharmaceuticals (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area, Karachi-Pakistan.
Drug Inspector	

BRIEF FACTS OF THE CASE:

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

- i. He, on 02-07-2019 inspected the Medicine Store of District manager PHFMC District Office Gulshan e Ravi Rahim Yar Khan and took four different type of drug samples of on Form No.04 for the purpose of test/analysis.
- ii. One out of 4 drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Bahawalpur**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Injection. Btrol [Tranexamic Acid..... 500mg/5ml]	BT19014	M/S Bosch Pharmaceutical (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area, Karachi-Pakistan	01-65002262/DTL Dated 28-08-2019	Analysis with specifications applied: MS/BP 2018 DESCRIPTION: Colorless liquid in sealed glass ampoule. Visible particulate matter is seen in 01 ampoule out of 20 ampoules with naked eye. (Does not comply with the parenteral specifications) VOLUME: Limits: NLT Nominal volume; i.e. 5 mL Determined Volume: 5.2 mL

				<p>pH:</p> <p>Limit.....6.5-8.0</p> <p>Determined... 7.311</p> <p><u>STERILITY:</u> THE PRODUCT IS STERILE.</p> <p><u>ASSAY OF TRANEXAMIC ACID:</u></p> <table border="1"> <tr> <td>Stated</td> <td>500 mg/ 5mL</td> </tr> <tr> <td>Determined</td> <td>499.11 mg/ 5mL</td> </tr> <tr> <td>Percentage</td> <td>99.822%</td> </tr> <tr> <td>Limit</td> <td>90-105.0%</td> </tr> </table> <p>RESULT: The above sample is Substandard on the basis of physical test.</p>	Stated	500 mg/ 5mL	Determined	499.11 mg/ 5mL	Percentage	99.822%	Limit	90-105.0%
Stated	500 mg/ 5mL											
Determined	499.11 mg/ 5mL											
Percentage	99.822%											
Limit	90-105.0%											

- iii. District Manager PHFMC Rahim Yar Khan provided invoice/warranty bearing No. 19060923 dated 12-06-2019 issued by M/S Bosch Pharmaceuticals (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area, Karachi-Pakistan as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S Bosch Pharmaceuticals (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area, Karachi-Pakistan.
- v. A copy of test/analysis report was sent to M/S Bosch Pharmaceuticals (Pvt) Ltd. 221, Sector 23, Korangi Industrial Area, Karachi-Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

3. Personal hearing notice(s) issued to accused person(s) dated 26-08-2024.

Reply of the firm to show cause notice

Respected Sir,

We have received your show cause notice dated: 20-05-2021 on 26-05-2021.

In such respects we would like to inform to that

That the PQCB, Lahore letter no. PQCB/P-975-08/19, Order dated: 16-11-2019, (Rahim Yar Khan) copy attached regarding above cited drug and test report No. TRA # 01-65002262/DTL, Bahawalpur, dated 28:08 2019, purporting to declare sample of Btrol injection (Tranexamic Acid), Batch No. 8T19014, as Sub-Standard on ground of visible particulate matter is seen in 01 ampoule out of 20 ampoules.

We have appeared in the personal hearing of Provincial Quality Control Board, Lahore on 16-11-2019 to defend our case and request for retesting through Appellate Laboratory which was turn down by the honorable Board. The Board further directed the following

- i. Regulatory Recall of subject Drug.
- ii. Public awareness notice through Newspaper regarding recall of concerned batch.
- iii. Company will inform Chief Drug Controller Office regarding the recall of stated drug.

In this regard Bosch Pharmaceuticals (Pvt.) Ltd. would like to inform you that voluntary and precautionary

we recalled Btrol Injection (Tranexamic Acid) 500 mg/5 ml. Batch No. BT-19014, Exp. Date 04-2022, through advertisement in Daily Dawn and Daily Jang Newspaper dated 14/01/2020 (Copy of the advertisement is attached for your record). This recall is in line with our commitment of patient safety and ethical practices.

That in the meanwhile we have also rechecked and reassessed our keeping samples of Batch No BT19014 of Btrol injection and have pleasure in declaring that the same is as per standard quality and is free from any visible or foreign particles.

We further inform you that to avoid such incident in future, we have arranged extensive training of our staff along with double optical check and give you assurance that this will not be repeated.

To cater the needs and requirements of Punjab Health Facilities management Company (PHFMC) Rahim Yar Khan we have replaced all available stock of Btrol Injection, Batch No. BT19014 lying with the Hospital and informed to Chief Drug Controller Office, Lahore, PQCB, Lahore & e & D.I. Rahim Yar Khan. (Copies attached).

We have appeared second time in the 229th meeting of Provincial Quality Control Board, Lahore on 02-02-2021 to defend our case and informed the Board about the current situation & replacement of stock with copy of acknowledgement. The Board desires to verify the replacement of stock of Btrol Injection lying in the Hospital from the Drug Inspector Rahim Yar Khan which is still unresolved.

Since we have proceeded upon the advice as per order dated 16-11-2019. Therefore we request the honorable Board to close the said case and inform us through letter.

The required documents are attached/submitted herewith for your perusal.

Summary:

Date of sampling: 02-07-2019

Date of DTL: 02-07-2019

Date of receipt in DTL: 06-07-2019

Issuance date of DTL Report: 28-08-2019

Time Extension: Not Time Barred

1st DI Communication with firm on dated: 13-09-2019

Retesting Request of Firm: Firm requested Retesting Request dated 25-09-2019

Fate of Retesting Request: Turn down in 213 meeting dated 16-11-2019

Investigation Report Dated: 29-10-2020

Show Cause Notice Date: 20-05-2021

Reply of the firm: Received

History of the firm of last 3 years:

Firm: 15 cases of the subject firm

Product: 03 cases of the subject product

Manufacturing Date: 05-2019

Expiry Date: 04-2022

PROCEEDINGS & DECISION BY THE BOARD:

Case No. 70

PQCB/R-266/2023

Tehsil & District Sialkot

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <ol style="list-style-type: none">1. M/s Bio-Labs Pvt. Ltd. , Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad through its Managing Director Usman Shaukat2. Usman Shaukat Managing Director3. Yasir Habib Production Manager4. Haroon ur Rasheed Quality Control Incharge/ Warrantor5. Muhammad Shahazad Rasheed Quality Assurance Manager <p>of M/s Bio-Labs Pvt. Ltd. , Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad .</p>
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BRIEF FACTS OF THE CASE:

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

- She, on 16-01-2023, inspected the premises of Zila Council Dispensary Circular Road Sialkot and took following drug sample on Form No. 04 for the purpose of test and analysis and sent to Government Analyst Drug Testing Laboratory, Faisalabad vide memorandum no. 154337 dated 16-01-2023
- The subject drug sample 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 No. & Date	DTL Test Report Result
Cream Bio-Sul [Each 100 gm contains: Silver Sulphadiazine USP...1% w/w] Mfg Date 06-2022 Expiry Date 05-2024 Regn No. 054842	22F017	M/s Bio-Labs Pvt. Ltd. , Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.	01-68021959/ DTL Dated 21-03-2023	<p><u>Analysis with specifications applied:</u> USP 2022</p> <p><u>DESCRIPTION:</u> white color shiny viscous cream filled in printed aluminum tube with white plastic cap packed in outer hard carton.</p> <p><u>IDENTIFICATION:</u> Silver sulphadiazine is identified</p> <p><u>ASSAY:</u></p> <p>Stated: 10 mg/ gram</p> <p>Determined: 9.257 mg/ gm</p> <p>Percentage: 92.57% (Complies)</p> <p>Limit: 90-110%</p>

				<p>pH:</p> <p>Stated: 4.0-7.0 (U.S.P. 2022)</p> <p>Determined: 8.06 (Does not Comply)</p> <p>RESULT: Given sample is Substandard with regards to pH Test.</p>
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- iii. On 30-03-2023, she ordered not to dispose-off the stock on Form-3.
 - iv. Zila Council Dispensary Circular Road Sialkot provided Invoice/Warranty bearing number 225094 dated 05-07-2022 issued by M/s Bio-Labs Pvt. Ltd. , Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad, as a proof of its purchase.
 - v. Warrantor portion of drug sample was sent M/s Bio-Labs Pvt. Ltd. , Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad,.
 - vi. A copy of test/analysis report was sent to M/s Bio-Labs Pvt. Ltd. , Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad, with directions to explain their position and provide requisite information in this regard. In response, the firm requested for re-test/ analysis. The request of the firm was placed at the agenda of PQCB 23rd Committee meeting dated 18-07-2023 and the Committee approved the request of with-drawl of retesting request of the firm.
2. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of :-

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

3. Show cause notice(s) issued to accused person(s) on 13-10-2023.

Reply of the firm to show cause notice vide letter no. Ref: BL/087/2023 dated 30-10-2023:

Reply to the show cause notice bearing reference No. PQCB/R-266/2023 dated 13-10- 2023.

Dear Sir,

1. By way of the instant response, we, M/s Bio-Labs (Private) Limited (the "Company" or "Bio- Labs") seek to show cause as to why any legal action, including but not limited to initiation of prosecution before the Honorable Drug Court and the cancellation/suspension of the Drug Manufacturing License, Drug Sale License and Drug Registration, may not be taken against us for allegedly manufacturing a substandard product, namely, Cream Bio-Sul Batch No. 22F017 (the "Product") in contravention of the Drug Laws and the rules framed thereunder.

2. In response to the allegations levelled against us in the subject show cause notice, we would like to submit the following:

i. The Product has already been declared of standard quality by the National Institute of Health, Islamabad in terms of the pH test (the "NIH") vide TRA No. 04-P/2023 dated 16-02-2023 (the "NIH Report"). Therefore, the findings furnished by the Government Analyst of the Drug Testing Laboratory, Faisalabad (the "Government Analyst") are wholly defective, unreliable and incapable of being relied upon. In this regard, please note that since the NIH has already declared the Product to be of standard quality, no case is made out against the Company and/or its officials and the present proceedings are liable to be dropped/withdrawn.

[Copy of the TRA No. 04-P/2023 dated 16-02-2023 is enclosed herewith as "Enclosure I"]

ii. Without any prejudice to the fact that no case is made out against the Company and/or its officials, we would like to submit

that we employ stringent testing mechanisms in relation to all of our products which are only released subsequent to the confirmation of the quality control department that the same are in compliance with the prescribed pharmacopeial guidelines. In this regard, the excellent quality, safety and efficacy of our pharmaceutical products is evinced from the fact that the same are increasingly being prescribed by healthcare practitioners across the country and no complaint with respect to the same has been received from any quarter whatsoever.

iii. Please note that we have carried out an extensive investigation on our retention samples wherein it has been affirmed that the Product does not suffer from any discrepancy and/or infirmity. The results of the tests conducted on the retention samples are in consonance with the findings of the NIH Report which conclusively establish that the Product is of standard quality and completely safe for usage.

[Copies of the Certificate of Analysis are enclosed herewith as Enclosure II

iv. Even otherwise the variation observed by the Government Analyst may have occurred due to his inability to carry out the test in a proper manner. It is a matter of fact that variations observed in testing the pH of parenteral solutions are attributable to several external reasons including but not limited to the following:

a) Temperature

i) pH values along with the voltage signal measured in a pH meter are temperature dependent. A deviation shall be observed in the value of pH if the temperature of the sample is not properly maintained.

b) Equipment & Procedure

i) Inadequate standardization of the equipment results in the variation in the value of pH.

ii) The pH of the Product is also highly dependent upon the calibration of the measuring system i.e., pH meter and pH electrode.

iii) Improper selection of the pH electrode and inability to select a suitable reference electrolyte and diaphragm.

iv) Improper cleaning of pH electrode at regular intervals with a suitable cleaning solution. [accumulation and buildup of excess materials are likely to result in faulty readings.

v) Improper use of medium [deionized, distilled, demineralized water are likely to increase the electrical resistance in the measurement medium which alters the pH measurements.

vi) Moreover, it is worth mentioning that, USP method for pH determination of topical dosage form (i.e Silver Sulphadiazine cream) involve centrifugation to collect the supernatant and pH is determined from that supernatant. Therefore, might be the DTL analyst deviate from best method, use different methodology to collect supernatant, leading to variation in result. Also the pH meter proper calibration, verification prior to use can lead to variation in result.

[Copy of USP Monograph is attached "Enclosure III"]

With regards to the present case, we are certain that the discrepancy observed by the Government Analyst has occurred as a result of the aforementioned reasons. The foregoing variation observed by the Government Analyst however holds no value in view of the NIH Report wherein the Product has been held as compliant with the specifications. Accordingly, the Company and/or its officials cannot be deemed to have contravened the provisions of the Drugs Act.

3. In view of the foregoing, it is submitted that the Product has already been declared of standard quality by the NIH hence no case in terms of Section 23 of the Drugs Act is made out against the Company and/or its officials. All allegations levelled against us vis-à-vis the manufacturing of a substandard drug and issuing a false warranty in respect thereof are baseless and without any merit. In this regard, any subsequent proceedings against the Company and/or its officials shall be against the dictates of justice specially in presence of conclusive findings vis-à-vis the compliance of the Product with the requisite specifications i.e., USP.

4. Accordingly, as no case is made out against the Company and/or its officials it is very kindly requested that the show cause

notice under reply and all subsequent proceedings may be withdrawn in the interest of justice and the case be consigned to record.

Regards,

Muhammad Shahzad Rasheed

Manager Quality Assurance

For & on behalf of M/s Bio-Labs (Pvt) Ltd, Islamabad

4. Personal hearing notice(s) issued to accused person(s) on 26-08-2024.

Case is placed before the board for decision.

Summary of the case:

- **Mfg. date: 06-2022**
- **Exp. Date: 05-2024**
- **Sampling date (Form 4): 16-01-2023**
- **Sent to DTL (Form 6): 16-01-2023**
- **Date of receipt in DTL: 21-01-2023**
- **DTL Report Date (Form 7): 21-03-2023**
- **DI 1st intimation to firm: 04-05-2023**
- **Retesting request if any: 18-10-2023 (Received in o/o PQCB dated 23-05-2023)**
- **Fate of Retesting: Committee of the Board decided to accept the firm's appeal for withdrawal of the retesting request in 23rd Committee Meeting held on 18-07-2023.**
- **Investigation report Dated: 07-09-2023**
- **Permission of SCN: 269th meeting dated 03-10-2023**
- **SCN Issued: 13-10-2023**
- **Reply of the firm: Yes**
- **History (3 years) Firm: 25 cases**
- **Product: 01 case**

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 71

PQCB/ R-747/2019

Lahore General Hospital, Lahore

ATTENDANCE

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/s Helix Pharma, A-56 S.I.T.E. Karachi, Pakistan through its Managing Director, Naveed Nawazish Hakim 2. Naveed Nawazish Hakim Managing Director 3. Muhammad Tariq Production Manager 4. Shakeel Ahmad Quality Control Manager/ Warrantor Of M/s Helix Pharma, A-56 S.I.T.E. Karachi, Pakistan.
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BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Lahore General Hospital, Lahore reported that: -

- i. Her predecessor, on 18-10-2019, inspected the premises of Main Medicine Store of Lahore General Hospital, Lahore and took sample of below-mentioned drug on Form-4 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Lahore.
- ii. The subject drug sample after test/ analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
EyeDrops. NAFEN [NEPAFENAC 1MG/ML]	N001	M/s Helix Pharma, A-56 S.I.T.E. Karachi, Pakistan.	01-139003001/DTL dated: 16-12-2019	Analysis with specifications applied: MS/USP 2019 <u>PHYSICAL DESCRIPTION:</u> YELLOW COLOURED PREPARATION IN OPAQUE WHITE PLASTIC BOTTLE WITH A NOZZLE AND A SEALED SCREW CAP. CLAIMED VOLUME = 5 ML pH: Limits: 5.5 - 8.5 Determined: 6.96 AT 23.7°C <u>IDENTIFICATION:</u> The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (NEPAFENAC

				<p>IDENTIFIED).</p> <p><u>ASSAY OF NEPAFENAC:</u></p> <p>Stated: 1 mg/mL</p> <p>Determined: 0.93 mg/mL</p> <p>Percentage: 93.2%</p> <p>Limit: 90 - 110% of stated amount</p> <p><u>STERILITY: THE PRODUCT IS NON-STERILE.</u></p> <p>(DOES NOT COMPLY)</p> <p>RESULT: The above sample is <u>SUB-STANDARD</u>, on the basis of STERILITY TEST performed as per MS & USP-2019.</p>
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- iii. Storekeeper of Main Medicine Store of Lahore General Hospital, Lahore provided invoice/warranty no. 13102842 dated 31-05-2019 issued by M/s Helix Pharma, A-56 S.I.T.E. Karachi, Pakistan as a proof of its purchase.
- iv. Warrantor portion of the drug sample was sent to M/s Helix Pharma, A-56 S.I.T.E. Karachi, Pakistan.
- v. A copy of test report was sent to M/s Helix Pharma, A-56 S.I.T.E. Karachi, Pakistan with directions to explain their position and provide requisite information in this regard. In response, the firm challenged the test/analysis report and requested to re-test the above mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.

Previous Proceedings and Decision by the Board:

13th Committee Meeting of the Board held on 28-10-2020

Pursuant to the request of M/s Helix Pharma, A-56 S.I.T.E. Karachi, Pakistan, the retesting request of the subject drug sample was considered in the **13th Committee Meeting** of the Board held on **28-10-2020** and after detailed discussion the retesting request **turn down**.

*Firm submitted a review petition in the office of PQCB against the orders of retesting being turned down, **meanwhile firm also filed a Writ Petition No. 66354-20 dated 16-12-2020 in the Lahore High Court, in which following order was passed:***

*Learned counsel for the petitioner relies upon an order passed by this Court in W.P.No.40067/2020. This petition too is allowed in terms of the said order and **it is directed that the Board shall proceed in terms of sub section (5) of Section 22 of the Act, 1976 and cause the sample of the drugs subject matter of this petition to be tested by the Federal Drug Laboratory at the cost of the petitioner.***

Hence, in compliance of Honorable Lahore High Court, Lahore's order dated 16-12-2020, the subject drug sample was sent to NIH, Islamabad, from where the sample was declared **Sub-standard** as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result
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NAFEN Sterile Ophthalmic Suspension	N001	M/s Helix Pharma, A- 56 S.I.T.E. Karachi, Pakistan.	No. 02- P/2021 dated 15-02-2021	<p>Analysis with specifications applied: Manufacturer Specification</p> <p>DESCRIPTION: Light yellow colored suspension contained in white labelled plastic bottle fitted with a dropper further packed in an outer carton.</p> <p>IDENTIFICATION: Nepafenac identified.</p> <p>pH:</p> <p>Determined: 7.0 Limit: 5.5-8.5</p> <p>Complies with manufacturer specifications.</p> <p>VOLUME:</p> <p>Determined: 4.55 ml Limit: 5.0 ml</p> <p>Does not comply with volume stated on the label.</p> <p>STERILITY TEST:</p> <p>Sterile. Complies with BP-2017.</p> <p>ASSAY:</p> <table border="1" data-bbox="791 1025 1458 1267"> <thead> <tr> <th>Assay</th> <th>Stated</th> <th>Found</th> <th>Limit</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Nepafenac</td> <td>1mg/ml</td> <td>0.8194mg/ml</td> <td>90-110%</td> <td>81.94%</td> </tr> </tbody> </table> <p>Does not comply with manufacturer specifications.</p> <p>Result: The sample is of Sub-Standard quality on the basis of the tests performed.</p>	Assay	Stated	Found	Limit	Percentage	Nepafenac	1mg/ml	0.8194mg/ml	90-110%	81.94%
Assay	Stated	Found	Limit	Percentage										
Nepafenac	1mg/ml	0.8194mg/ml	90-110%	81.94%										

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

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

3. Show-cause notice(s) issued to accused person(s) dated 17-03-2022

Firm submitted written reply to the Show Cause Notice vide letter no. RGN-427-05/22 dated 06-05-2022 requesting for the provision of copies of certain documents

Relying on constitutional inalienable right guaranteed under Article 10-A Constitution of Pakistan in respect of disclosure of incriminating material to the accused, on the basis of which allegations have been made in the aforesaid show cause notice. below mentioned documents are essentially required

from your good office for the purpose of addressing aforesaid show cause and submission of our defense reply.

These documents include:

1. Attested copy of Form-4 of this case
2. Attested copy of Form-5 of this case (if any)
3. Attested copy of Form-6 of this case

So, you are humbly requested to provide above mentioned documents on Urgent Basis to the undersigned and Calculate seven days stipulated in the aforesaid show cause notice for submission of reply from the date when above mentioned documents are provided to the undersigned.

Note: Firm was advised by PQCB to approach concerned drug inspector for the provision of above mentioned documents vide letter dated 09-05-2022.

Firm submitted following reply to the show cause notice vide letter no. RGN-427-06/22 dated 16-06-2022

Firm's Reply to the Show Cause Notice

1. First of all, we would like to bring your kind attention on the averment made by your kind self in the aforesaid letter/show cause notice that we have been provided with warrantor portion of the drug sample. **IT IS NOT TRUE. The manufacturer/warrantor has not been provided yet with warrantor portion of the product** taken on form # 4 by the drug inspector in spite of the fact that the manufacturer/warrantor of the company has duly raised this illegality vide its letter dated 09-01-2020 before the drug inspector.

Non-provision of warrantor portion of the product taken on form # 4 to the manufacturer/warrantor/The Company by the drug inspector creates serious doubts upon the entire proceedings conducted by the drug inspector, proprietary and safe transmission of the samples to Drug testing laboratory and NIH laboratory. Furthermore, non-provision of warrantor portion of the product taken on form # 4 is not only clear violation of mandatory provision of law in terms of section 19(3) of Drug Act 1976 (as amended) by the drug inspector but is also violation of the principle of NATURAL JUSTICE i-e; "**WHEN A LAW REQUIRED A THING TO BE DONE IN A PARTICULAR MANNER, THEN IT MUST BE DONE IN THAT MANNER**" Reliance is based on 2018 PLD 189 SUPREME COURT, 2018 SUPREME COURT 97.

2. As far as the allegation of substandard nature of EYE DROP NAFEN Batch NO. NO01 is concerned, the Batch Manufacturing Record prepared at the time of manufacturing of the said batch of the questioned drug by the Production department headed & operated with full independence & sole responsibility by the Production in charge of The Company depicts that they got issued the raw material of Nepafenac through its Manufacturing Order dated 08-02-2019 in the required standard quantity for using in manufacturing and used the same quantity in production of the said batch.
3. While The Quality Control department, headed & operated with full independence & sole responsibility by the Quality Control Incharge of the Company, tested all the required quality parameters including assay and filled volume of the said product during manufacturing and at the time of batch release of EYE DROP NAFEN Batch No. NO01 and found them satisfactory as per Manufacturer specifications. **Relying on these satisfactory reports, this batch was released to be sold.**
4. Later on, upon the receipt of the Impugned DTL Lahore report bearing # 01139003001/DTL dated 16-12-2019, even retained sample of the same batch no. of EYE DROP NAFEN Batch NO. NO01 kept under prescribed conditions was tested at our well-equipped QC Lab, which fully complied with approved specifications and was found of standard quality.
5. As the impugned NIH report is conclusive one u/s 22(5) of the Drugs Act 1976, therefore without prejudice to and in addition to The Company's reply dated 15-07-2020 in respect of the Impugned DTL Lahore report, **only The Impugned NIH report will be discussed here.** So as far as the alleged

abnormalities/contraventions pointed out in The Impugned NIH Report Are Concerned, these are most likely based on deviations from mandatory testing protocol and non-observance to mandatory provisions of Drugs Acts 1976 and rules framed there under by the Federal Government Analyst as follows:

- i. The **Federal Government Analyst tested and analyzed the drug sample when it had got expired.** The expiry date of the drug product sample was 02-2021 as shown on the label of the drug sample and date of test/analysis is 15-02-2021 as shown on the impugned NIH report bearing no, 002-P/2021. So, **the test and analysis of the drug sample after its expiry date has no sanctity in the eye of law** and drug product cannot be declared as substandard on the basis of unlawful testing.
- ii. Furthermore, it is mandatory for Government analyst, who caused the testing/analysis of the sample to be performed and prepared DTL/NIH report, to meet the statutory requirement of section 16 of the Drugs Act 1976. But in the case in hand, no proof of qualifying such statutory requirement by Government Analyst has been provided with the Impugned NIH/DTL report or your show cause. So the impugned DTL/NIH report is illegal and without lawful authority which has no essence in the eye of law.
- iii. The Federal Government Analyst declared the drug sample as substandard on the basis of two parameters as stated on the impugned NIH report bearing no. 002-P/2021 dated 15-02-2021:
 - Volume
 - Assay

The comparison of these two reports issued by the two government analysts is as follows:

Parameter/ Test	Government Analyst DTL Lahore results	Chief Appellate Laboratory NIH, Islamabad
Sterility Test	Failed	Passed
Claimed Volume 5ml	Passed	Failed 4.55ml
Assay Limit 90%-110%	93.2%	81.94%

So, both the impugned reports i.e. DTL Lahore report & NIH report of this case are totally conflicting i.e. at variance to each other which create serious doubts even on the sanctity of the impugned NIH report.

Further the illegalities/deviances committed by the federal government analyst in performing the testing of the questioned drug is discussed below:

Illegalities in determination of filled volume:

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

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

But in this case, the Federal Government Analyst only mentioned the result of volume determination i.e. 4.55ml. He didn't disclose the protocol at all for determination of volume that how many units of drug sampled were used for the volume determination and how he reached to this conclusion that volume of sample is 4.55ml instead of 5ml.

Non provision of full protocol of test analysis makes the impugned NIH report faulty and illegal on account of its non-conformity nature to mandatory requirement of Rule 16 of Drugs (Federal

Inspectors, etc.) Rules 1976.

Illegality in determination of Assay

- *The Federal Government Analyst also didn't disclose the full protocol of assay test performed as follows:*

The federal government analyst didn't mention the value of % RSD he obtained while calculating the areas of Nepafenac peaks from replicate injections of standard solution which must not be more than 2.0 % as stated under the heading of system suitability in method of analysis based on Manufacturer specifications.

Non provision of full protocol of Assay test analysis not only makes the impugned NIH report faulty and illegal on account of its non-Conformity nature to mandatory requirement of Rule 16 of Drugs (Federal Inspectors, etc.) Rules 1976 but also raises serious question on the results credibility of testing apparatus in terms of system suitability.

- *It is also pertinent to point out here that the Federal Government Analyst, while performing the assay test, also deviated from the method of analysis based on Manufacturer specifications as follows:*

*The Federal Government Analyst, as shown in the impugned NIH report, injected 20ul of standard solution in **triplicate** only into HPLC System contrary to procedure devised by Manufacturer whereby he was supposed to inject 20ul of standard solution in **5 replicates**. This deviation renders the system suitability test invalid which in turn makes the whole assay testing invalid and distrustful. So this deviation by the Federal Government Analyst, while performing the assay test, renders this assay testing highly doubtful, invalid and illegal.*

Furthermore, we sold the questioned drug to Lahore General Hospital and they didn't tender any evidence that the same was kept stored in the same state as it was acquired by them. On the other hand, the sample of the drug sampled sent to NIH was kept stored at PQCB for about two years. So the contraventions alleged in the impugned NIH report might be due to improper storage at Lahore General Hospital and PQCB and improper transportation conditions from Drug Inspector after sampling to PQCB and PQCB to NIH laboratory.

- *The allegation of Manufacturing for sale/sale of Substandard drug has been dealt and defended in detail in supra paragraphs and may kindly be considered as reply to this allegation.*
- *As far as allegation of issuance of false warranty is concerned, it is groundless and based upon misreading of relevant law. The warranty was issued after release of standard quality report by Quality Control Department of the Company which was good and sufficient reason available at the time of sale of the product and issuance of warranty for believing the product of standard quality. So **the offence of issuance of false warranty has been added just to manipulate the scenario. Section 27(2)(b) is reproduced below:***

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

For the names of accused persons, please see below mentioned reply of the SCN by Naveed Nawazish Hakim, the Managing Director

REPLY+ EXPLANATION BY NAVEED NAWAZISH HAKIM (MANAGING DIRECTOR):

- *The legal system all over the globe including Pakistan recognizes "company as a "Juristic person" with its own rights, capable of owning property, creating contracts, and conducting litigations with responsibility*

towards wrongdoings an profiting. A company being juristic person having no physical existence is run and managed by human beings/ its board and same is the case with M/S Heli Pharma (Pvt) Ltd (The Company).

- Any company manufacturing pharmaceutical valid drug manufacturing license is liable for all legal acts and omissions of all the prevailing drugs under laws including the Drugs Act 1976 as stated in section 11 & 34 of the Drugs Act 1976 and Rule 5 of the Punjab Drug Rules 2007 reproduced below:

34. OFFENCES BY COMPANIES, etc.- where the person guilty of an offence under this Act, is a company, corporation, firm or institution, every director, partner and employee of the company, corporation, firm or institution with whose knowledge or consent the offence was committed shall be guilty of the offence.

11.(5) (e) to ascertain the names of such directors, partners and employees of the company, corporation, firm or institution who are prima facie responsible for the commission of any offence under this Act or the rules and allow an Inspector to institute prosecution only against such persons;

The Punjab Drugs Rules 2007 5-Procedure for the Board.5.(4) Before referring a case to a Drug Court, the Provincial or the District Board shall ascertain the name of the director, partner and employee of the company, corporation, firm or institution who is prima facie responsible for the commission of the offence under the Act or the rules and may allow an inspector to institute prosecution against such person.

- **Regulatory Compliance** is the central and integral component of M/S Helix Pharma (Pvt) Ltd (The Company). The functionaries of The Company have been given, by the Board of Directors, full autonomy/ power based upon sole responsibility to ensure that all the regulatory requirements (strict compliance to Drugs Act 1976/DRAP Act 2012 and rules framed there under) are strictly fulfilled. For this purpose, in The Company as required under Drug (Licensing, Registratioon & Advertisement) Rules 1976, the production department and quality control department headed and operated by production incharge and quality control hcharge respectively are fully independent and bound by law to exercise all powers and perform all actions required to ensure the strict complhance to all Tegulatory requirements including compliance to Drugs Act 1976/DRAP Act 2012 dnd rules framed there under. The approval/ consent of the Board of Directors, Chier Executive or other Directors is not required at all to exercise such powers and perform actions by the production incharge and quality control incharge for the strict compliance to all regulatory requirements. Meaning thereby that the production incharge and quality control incharge take independent decisions without prior consent and knowledge of the Chief Executive officer, Directors and the Board of Directors.
- The detail of persons (not accused as alleged) who were involved in the manufacturing and checking quality of the said batch of the product, is as follows:

1. Mr. Muhammad Tariq Production Incharge
2. Mr. Shakeel Ahamd Quality Control Incharge
3. Mr. Shakeel Ahamd Warrantor

of M/s Helix Pharma (Pvt) Ltd.

Since in this case, the Managing Director has no nexus with the issues (allegations under consideration in the said show cause as all routine manufacturing and quality control/assurance operations are done without his prior knowledge and consent. So, in the light of above, **it is requested that name of Naveed Nawazish Hakim, The Managing Director may please be deleted from the Show Cause Notice or any other legal proceedings** under the Drug Act 1976 or Rules framed there under in the best interest of justice.

Reliance: That the Honorable Supreme Court of Pakistan has settled the question of liability related to the company in a case reported as PLD 1978 Supreme Court 193 (Superintendent of Police, Federal investigation Agency, Lahore and another--Appellants Versus Akhtar Hussain Bhutta-Respondent) Judgement by Muhammad Akram, Actg. C.J and G. Safdar Shah, **Therefore, it would be difficult to presume that the respondent was guilty**

of the manufacture of the said substandard drug for and on behalf of the Company, just because he happened to be its Managing Director.

But if the prosecution would be disposed to foist liability also then the burden would lie on it to show that the said offence had been committed within their knowledge and consent''

11. Please also note that Mr. Muhamamd Tariq Production Manager has left his job from M/S Helix Pharma (Pvt) Ltd one year ago. So his SHOW CAUSE NOTICES be kindly considered as UNSERVED and is being sent back to along with this reply.

13. That in addition to above, the undersigned reserves its right to submit further assistance/arguments/contradictory evidence to any honorable forum at personal hearing stage if happened.

*So, based on the above discussed **sheer violations** by Provincial Inspector of Drugs, **non-disclosure of protocol** applied and protocol deviances by Federal Government Analyst making the NIH report illegal and unlawful, the impugned NIH Test Report/DTL report has no substance and no legs to stand upon and should be rejected and deemed a nullity in essence and spirit. Therefore, the entire proceedings/actions based on this faulty and inconclusive impugned NIH Report/DTL report are void ab initio and are unlawful and this case deserves to be dropped.*

4. Personal hearing notice(s) issued to accused person(s) dated 19-05-2022

Previous Proceedings & Decision by the Board:

244th meeting held on 31-05-2022

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **244th meeting** held on **31-05-2022** in the presence of Board members as mentioned above. Mr. Hassan Saeed, Secretary DQCB, District Lahore and Miss Sehrish Iqbal, Drug Inspector, Lahore General Hospital was present along with the original case record. No one among the nominated accused persons was present. However, Dr. Imran Mehmood Chaudhry (Advocate), Counsel of M/s Helix Pharma, A-56 S.I.T.E. Karachi, Pakistan appeared before the Board on behalf of the firm. The firm's counsel requested for adjournment stating that they require a copy of Form-4 & 6 in the subject case to proceed further.

6. The Board, keeping in view the firm's request directed the drug inspector to provide the firm with a copy of Form-4 & 6 and further unanimously decided to **adjourn the case** in the best interest of justice.

7. Personal hearing notice(s) issued to accused person(s) dated 12-08-2022

Previous Proceedings and Decision by The Board:

249th meeting held on 23-08-2022

8. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **249th meeting** held on **23-08-2022** under the Chairmanship of Vice-Chairperson, Provincial Quality Control Board, Punjab. Mr. Hassan Saeed, Secretary DQCB, District Lahore and Ms. Sehrish Iqbal, Drugs Inspector, Lahore General Hospital, District Lahore was present along with the original case record. Among the nominated accused persons, Shakeel Ahmad (Quality Control Manager/ Warrantor) along with Dr. Imran Mehmood Chaudhry, Counsel of M/s Helix Pharma, A-56 S.I.T.E. Karachi, Pakistan appeared before the Board. Firm's counsel restated the arguments already presented in its reply to the show cause notice and pointed out a seeming to be calculation ambiguity in the NIH report. The firm was of the view that multiplying with an additional "100" is making the whole calculation imprecise. Furthermore, firm requested to consider the case on sympathetic grounds.

9. The Board upon careful perusal of the case record and scrutiny of the case observed that the subject drug sample i.e. Eye Drops. Nafen [Nepafenac 1mg/ml], Batch No. N001 was declared Substandard from the Drugs Testing Laboratory Lahore being non-sterile. Whereas the sample is declared of substandard quality from NIH also, due to failure of the key parameters of volume and assay test of the subject drug sample. The Board further observed that under the heading of “Protocol for Assay” in the NIH report, the sub-heading “calculation” shows an ambiguous calculation as the figure comes out to be “8194 mg/ml” instead of “0.8194 mg/ml”.

10. Hence, keeping in view the above-mentioned notable observation, the Board after due deliberation and detailed discussion unanimously decided to seek **clarification from NIH** in this case regarding above mentioned calculation.

NIH Submitted a letter no. F.1-20/02-P/2021-DC&TMD dated 08-05-2023 with the subject “Corrigendum of Test Report No. 021-P/2021 dated 15-02-2021

Reference letter No. PQCB/P-747/2019 dated 31-10-2022.

2. It is submitted that the Drug Testing Laboratory declared the sample Sub-Standard on the basis of Sterility Test where as in the NIH report the sample was declared Standard on the basis of Sterility test and Sub-Standard on the basis of Volume and in Assay test.

3. This causes contradiction.

4. In order to avoid such issues, the Federal Drug Appellate Laboratory recently communicated its intention vide letter F.No. 1-20/17-Misc/2021 -DC&TMD dated August 11, 2021, which has been accepted by the board vide letter PQCB/ISU-11/234/21, dated 21-10-2021.

5. Keeping the above into consideration the Provincial Quality Control Board is requested to convey its request whether we decide the fate of the case on the basis of Sterility test only or vice versa

The above-said letter of NIH was responded by the PQCB as follows:



No. POCB/R-747/2019

Government of The Punjab
Primary & Secondary Health Care Department
Provincial Quality Control Board, Punjab
492 R-II Johar Town, Lahore.
Email Address: secretary.pqcb@gmail.com
Dated Lahore 15-06-2023

To,

The Chief/ Authorized Officer/ Government Analyst,
The Appellate Laboratory,
National Institute of Health (NIH),
Drug Control and Traditional Medicines Division,
Islamabad.

SUBJECT: - CLARIFICATION REGARDING TEST/ANALYSIS REPORT

Reference to your letter no. F.1-20/02-P/2021-DC&TMD dated 08-05-2023 regarding NIH test/analysis report No. 02-P/2021 dated 15-02-2021.

2. Under the provision of section 22(5) of the Drugs Act 1976, the case was sent to your esteemed institution for retest vide this office letter no. POCB/P-1358-12/2019 dated 07-01-2021. The NIH Test Report declared the drug sample substandard on the basis of two parameters i.e., Volume & Assay vide Test Report No. 02-P/2021 dated 15-02-2021. It is an established fact that the NIH Test Report is the conclusive evidence as per section 22 (5) of the Drugs Act 1976 and hence, the PQCB will decide the case keeping in view the NIH report.


3. The subject case was considered by Provincial Quality Control Board in its 249th Meeting held on 23-08-2022, wherein the Board decided to request a clarification from NIH as follows:

"The Board further observed that under the heading of "Protocol for Assay" in the NIH report, the sub-heading "calculation" shows an ambiguous calculation as the figure comes out to be "8194 mg/ml" instead of "0.8194 mg/ml".

Hence, keeping in view the above-mentioned notable observation, the Board after due deliberation and detailed discussion unanimously decided to seek clarification from NIH in this case regarding above mentioned calculation"

(copy of Orders and NIH Report enclosed).

4. The above-mentioned clarification in this regard is still awaited. Hence, you are requested to furnish your comments in the subject matter.


DR. MUHAMMAD MUNAWAR HAYAT
Secretary

o/c Provincial Quality Control Board Punjab

Copy forwarded for information to:

1. Master File


DR. MUHAMMAD MUNAWAR HAYAT
Secretary

o/c Provincial Quality Control Board Punjab
PH-31

Subsequently, a copy of Board Orders and Multiple letters dated 15-06-2023, 05-10-2023, 20-05-2024 & 28-08-2024 have been sent to the National Institute of Health Islamabad seeking clarification as per Board Orders but **no reply from NIH has been received regarding the clarification sought.**

Hence, a copy of personal hearing notice has also been sent to the NIH requesting again, to either submit response to Board Orders OR **depute a representative for attending** the case hearing.

11. Personal hearing notice(s) issued to accused person(s) dated 26-08-2024.

12. Case is placed before the Board for decision.

Sr. No.	Summary of the Case
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	Mfg Date	Feb 2019
	Expiry Date	Feb-2021
1	Sampling Date (Form 4)	18-10-2019
2	Sample Sent to DTL (Form-6)	18-10-2019
3	Receipt Date in DTL	21-10-2019
4	Issuance of DTL Report	16-12-2019
5	Time Extension	Not Time Barred
6	DI First Communication with Firm	24-12-2019
7	Retesting Request	09-01-2020
8	Investigation Report by DI	14-12-2021
9	SCN Permission	237-M dated 30-12-2021
10	Show Cause Notice Issued	17-03-2022
11	Reply of Firm to Show Cause Notice	16-06-2022
12	History (3 years)	Firm's Reported: Nil
		Product's Reported: Nil

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 72

PQCB-R-790/2022

Aziz Bhatti Shaheed (DHQ) Teaching Hospital, Gujrat

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<ol style="list-style-type: none">1. M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad through its Chief Executive Officer Chaudhary Pervaiz Ahmad2. Chaudhary Pervaiz Ahmad Chief Executive Officer3. Anees ur Rehman Production In-charge/ Warrantor4. Fazal Wahab Quality Control In-charge <p>Of M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad.</p>

BREIF FACTS OF THE CASE:

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

- He, on 24-08-2022, inspected the premises of Aziz Bhatti Shaheed (DHQ) Teaching Hospital, Gujrat and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Faisalabad vide memo number 138146 dated 26-08-2022.
- The drug samples, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Faisalabad** as detailed below:
- Store keeper Aziz Bhatti Shaheed (DHQ) Teaching Hospital, Gujrat provided invoice/ warranty no. 655 dated 12-08-2022 issued by M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad as a proof of its purchase of the said drug.
- Warrantor portion of the drug samples were sent M M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad.
- A copy of test reports of the drug samples were sent to M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad with directions to provide the requisite information and to explain their position in this regard. In response, the firm challenged the test/analysis report of the drug sample and requested to re-test the above-mentioned drug sample from Appellate Laboratory, National Institute of Health, Islamabad.
- Pursuant to firm's retesting request the Provincial Quality Control Board in its 20th committee meeting held on 17-05-2023 decided to turn-down the request of the firm.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection Aqua-P (Sterile water for injection USP...5ml)	P-634	M/s Ipram International, Plot # 26, S.S-3, National	TRA 01-68018040/DTL dated 27-10-2022	<u>Specs Applied: USP 2022</u> <u>Description:</u>

Mfg Date: Sep-2021 Exp. Date: Sep-2026 Reg. NO. 034290		Industrial Zone, Rawat, Islamabad.		Clear colorless liquid filled in transparent glass ampoule. <u>Tests:</u> <u>Conductivity Test:</u> Stated: NMT 25 µ/cm (USP 2022) Determined: 1.282 µ/cm (Complies) <u>Container Content:</u> Stated: Not less than nominal Volume (USP 2022) Determined: 5.2 ml (Complies) <u>Sterility:</u> Stated: Must be sterile (USP 2022) Determined: Sterile (Complies) <u>Bacterial Endotoxin Test:</u> Stated: Less than 0.25 USP Endotoxin Units/ ml (USP 2022) Determined: Not less than 0.25 EU/ml determined by USP Gel clot technique (Does not comply) <u>RESULT:</u> Given sample is “ Substandard ” with regards to Bacterial Endotoxin Test.
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2. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

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

b. **Issuance of false warranty**

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

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad submitted reply vide Ref no. 190/IPM/ISB dated 14-06-2024

In response to your letter# PQCB/R-790/2022 Dated 10-06-2024, DTL has declared our product

(AQUA-P B# 634) Substandard on the basis of Bacterial Endotoxin Test.

In response to the above mentioned letter under reply, we would like to submit as;

i Ipram International is well reputed organization manufacturing its products as per Good Manufacturing Guidelines, organization and its employees always follow GMP standards.

As the samples of this product retained in our retained in our retain room were tested and found in compliance with

standards

ii. As for as Bacterial Endotoxin Test, there are some possibilities that if reconstitution of Control Standard Endotoxin Test is improper or improper preparation of controls and incorrect pipetting may lead to the fail of BET Test

iii. In regard to these possibilities, this is our legitimate request to retest our sample

iv. Sir, For official Correspondence, kindly contact with Anees ur Rehman WhatsAap No. 0333-5043104

So kindly consider our request for retesting of our Product Aqua-p B#634

We will be highly obliged by the favor at your end.

Sr.	Summary of the case	
1.	Date of sampling	24-08-2022
2.	Sent to DTL	26-08-2022
3.	Date of receipt in DTL	30-08-2022
4.	Issuance of DTL Report	27-10-2022
5.	Time Extension	N/A
6.	DI 1st communication with firm	14-12-2022
7.	Retesting Request	19-12-2022
8.	Fate of retesting request	Turn-Down 20 th committee meeting dated 17-05-2023 Retesting review turn down in PQCB 266 th meeting dated 24-08-2023.
9.	Investigation Report of DI	23-04-2024
10.	Permission of SCN	280 th meeting dated 16-05-2024
11.	SC Notice Issued	10-06-2024
12.	Reply of the firm	14-06-2024
13	History (3 years)	29 cases of the firm 27 case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 73

PQCB/ MSS-174932/2023

Government Kot Khawaja Saeed Teaching Hospital, District Lahore

ATTENDANCE

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

BRIEF FACTS OF THE CASE

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

- i. She, on 06-09-2023, inspected the premises of Main Medicine Store of Government Kot Khawaja Saeed Teaching Hospital, District Lahore, took following drug sample on Form No. 4 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Lahore vide memo no. 174932 dated 06-09-2023.
- ii. The subject drug sample, after test/analysis was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below: -

Name of Drug	Batch No.	Name of Manufacturer	DTL Report	DTL Test Report Result
<p>Injection. AQUA-P [Sterile Water for Injection 5ml]</p> <p>Mfg. Date: Sep-2022</p> <p>Exp. Date: Sep-2027</p>	P-655	M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan	01-10194003359/DTL dated 21-10-2023	<p>Result of test/ analysis with specifications applied: USP 2023</p> <p><u>PHYSICAL DESCRIPTION:</u> Colorless liquid in sealed transparent glass ampoule with label printed on it. Claimed volume= 5mL</p> <p><u>EXTRACTABLE VOLUME:</u></p> <p>Determined: 5 mL</p> <p>Stated: NLT nominal volume i.e., 5.0mL</p> <p><u>WATER CONDUCTIVITY:</u></p> <p>Limit= NMT 25 µ/cm at 25 ± 1°C</p>

<p>Regn. No: 034290</p>			<p>Determined= 13.01μ/cm at 25.9°C</p> <p><u>OXIDIZABLE SUBSTANCES:</u> Complies</p> <p><u>STERILITY TEST:</u> The sample is Sterile.</p> <p><u>BACTERIAL ENDOTOXINS TEST:</u> The sample does not comply the Endotoxin limit of less than 0.25 USP Endotoxin Units/mL. (DOES NOT COMPLY)</p> <p><u>RESULT:</u> The above sample is <u>Sub-Standard</u>, on the basis of Bacterial Endotoxin test performed as per USP.</p>
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- iii. Storekeeper Main Medicine Store of Government Kot Khawaja Saeed Teaching Hospital, District Lahore, provided warranted delivery challan No. Hi-Q-KKSH96 dated 02-09-2023 issued by M/s Hi-Q Medicose Office No. 312, 3rd Floor, PMA Center, Opposite Camp Jail, Ferozpur Road, Lahore as a proof of its purchase.
- iv. Warrantor Portion of drug sample was sent to M/s Hi-Q Medicose Office No. 312, 3rd Floor, PMA Center, Opposite Camp Jail, Ferozpur Road, Lahore who, in-turn- provided invoice/ warranty no. ID-1718 dated 31-08-2023 issued by M/s Amson Vaccines & Pharma (Pvt.) Ltd. 154, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
- v. M/s Amson Vaccines & Pharma (Pvt.) Ltd. 154, Industrial Triangle, Kahuta Road, Islamabad-Pakistan provided warranty no. 5I-23-00029 dated 07-08-2023 issued by M/s Pharmchem Distributor Akbar Khan Plaza College Road Rawalpindi, who, finally provided invoice/ warranty no. T-6264 dated 27-07-2023 issued by M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan.
- vi. A copy of Test/ Analysis report was sent to M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad, Pakistan with directions to explain their position and provide requisite information in this regard.

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

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

3. Show-cause notice(s) issued to accused person(s) dated 10-07-2024

Firm replied to the show cause notice vide letter no. 189/IPM/ISB dated 16-06-2024

REPLY FOR SHOWCAUSE/ REQUEST FOR RETESTING OF PRODUCT AQUA-P B#655

Respected Sir, in response to your letter# P₂CB/MSS-174932/2023 Dated 10-07-2024, DTL has declared our product (AQUA-P B# 655) Substandard on the basis of Bacterial Endotoxin Test. In response to the above-mentioned letter under reply, we would like to submit as;

- i. *Ipram International is well reputed organization manufacturing its products as per Good Manufacturing Guidelines, organization and its employees always follow GMP standards. As the samples of this product retained in our retain room were tested and **found in compliance with standards.***
- ii. *As for as Bacterial Endotoxin Test, there are some possibilities that if **reconstitution of***

Control Standard Endotoxin Test is improper or improper preparation of controls and incorrect pipetting may lead to the fail of BET Test.

iii. *In regard to these possibilities, this is our legitimate request to **retest our sample***

iv. *Sir, for official Correspondence, kindly contact with Anees-ur-Rehman WhatsApp No. 0333-5043104.*

*So kindly **consider our request for retesting** of our Product Aqua-p B#639. We will be highly obliged by the favor at your end.*

4. Personal hearing notice(s) issued to accused person(s) dated 26-08-2024
5. Cases are placed before the Board for decision.

Sr. No.	Summary of the Case	
1	Sampling Date (Form 4)	06-09-2023
2	Sample Sent to DTL (Form-6)	06-09-2023
3	Receipt Date in DTL	08-09-2023
4	Issuance of DTL Report	21-10-2023
5	Time Extension	Not Time Barred
6	DI First Communication with Firm	28-10-2023
7	Retesting Request	Yes but in response to show cause notice on 06-08-2024
9	Investigation Report by DI	24-11-2023
10	SCN Permission	273-M (07-12-2023)
11	Show Cause Notice Issued	10-07-2024
12	Reply of Firm to Show Cause Notice	06-08-2024
13	History (3 years)	Firm's Reported: 29
		Product's Reported: 27

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 74

PQCB-MSS-188771/2024

Holy Family Hospital, Rawalpindi

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<ol style="list-style-type: none">1. M/s Ipram International, Islamabad, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad-Pakistan through its Chief Executive Officer Ch. Pervaiz Ahmed Warraich2. Ch. Pervaiz Ahmed Warraich Chief Executive Officer3. Anees-ur Rehman Production In-charge/ Warrantor4. Sadia Yasmeen Quality Control In-charge <p>Of M/s Ipram International, Islamabad, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad-Pakistan.</p>

BREIF FACTS OF THE CASE:

Provincial Inspector of drugs Holy Family Hospital, Rawalpindi reported that:-

- i. She, on 10-01-2024, inspected the premises of Medical Store (Injection Section) Holy Family Hospital, Rawalpindi and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memo number 188771 dated 11-01-2024.
- ii. The drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below:
- iii. Store keeper of Medical Store (Injection Section) Holy Family Hospital, Rawalpindi provided invoice/warranty no. T 3122 dated 01-11-2023 issued by M/s Ipram International, Islamabad, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad-Pakistan as a proof of its purchase of the said drug.
- iv. Warrantor portion of the drug samples were sent M/s Ipram International, Islamabad, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad-Pakistan.
- v. A copy of test reports of the drug samples were sent to M/s Ipram International, Islamabad, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad-Pakistan with directions to provide the requisite information and to explain their position in this regard.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection Aqua-P [Water for Injection...5ml]	P-657	M/s Ipram International, Islamabad, Plot No. 26, S.S.3,	TRA 01-74009998/DTL dated 11-03-2024	Specs Applied: USP 2023 <u>PHYSICAL DESCRIPTION</u> Visibly clear, colourless liquid filled in transparent sealed labelled glass ampoule. (Complies

Mfg Date: Jul-2023	National Industrial Zone, Rawat, Islamabad-Pakistan	the test)
Exp. Date: Jul-2028		<u>Extractable Volume:</u>
Reg. No. 034290		Observed: 5.0 mL (Complies the test) Limit: 5.0 mL
		<u>Conductivity:</u>
		Observed: 9.2β/ cm (Complies the test) Limit: NMT 25 β/ cm
		<u>Sterility Test:</u>
		Observed: No Visible microbial growth was observed , Product is sterile Limit: no microbial growth must be observed in stipulated incubation time.
		<u>Endotoxin Test:</u>
		Observed: Gel Clot Formed Limit: Less than 0.25 Endotoxin units/ mL (Does not complies)
		<u>RESULT:</u> <u>The sample is being reported as “Sub-Standard” with respect to endotoxin test performed.</u>

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

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

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

Sr.	Summary of the case	
1.	Date of sampling	10-01-2024
2.	Sent to DTL	11-01-2024
3.	Date of receipt in DTL	12-01-2024
4.	Issuance of DTL Report	11-03-2024
5.	Time Extension	N/A

6.	DI 1 st communication with firm	22-05-2024
7.	Retesting Request	No
8.	Fate of retesting request	N/A
9.	Investigation Report of DI	27-06-2024
10.	Permission of SCN	282 nd meeting dated 24-07-2024
11.	SC Notice Issued	30-07-2024
12.	Reply of the firm	Not received
13	History (3 years)	29 cases of the firm 27 case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 75

PQCB-MSS-181101/2024

Holy Family Hospital, Rawalpindi

ATTENDANCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<ol style="list-style-type: none">1. M/s Ipram International, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad through its Chief Executive Officer Ch. Pervaiz Ahmed Warraich2. Ch. Pervaiz Ahmed Warraich Chief Executive Officer3. Anees-ur-Rehman Production In-charge/ Warrantor4. Sadia Yasmeen Quality Control In-charge5. Of M/s Ipram International, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad.

BREIF FACTS OF THE CASE:

Provincial Inspector of drugs Holy Family Hospital, Rawalpindi reported that:-

- i. She, on 04-11-2023, inspected the premises of Medicine store (Injection Section) of Holy Family Hospital, Rawalpindi and took sample of following drug on Form No.04 for the purpose of test/analysis and sent the subject drug sample to Drug Testing Laboratory, Rawalpindi vide memo number 181101 dated 04-11-2023.
- ii. The drug samples, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Rawalpindi** as detailed below:
- iii. Store keeper of Medicine store (Injection Section) of Holy Family Hospital, Rawalpindi provided invoice/ warranty no. T 3120 dated 01-11-2023 issued by M/s Ipram International, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad as a proof of its purchase of the said drug.
- iv. Warrantor portion of the drug samples were sent M/s Ipram International, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad.
- v. A copy of test reports of the drug samples were sent to M/s Ipram International, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad with directions to provide the requisite information and to explain their position in this regard.

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	Results of DTL Report
Injection Aqua-P [Water for injection...5ml] Mfg Date: July-2023 Exp. Date: July-2028	P-657	M/s Ipram International, Plot No. 26, S.S.3, National Industrial Zone, Rawat, Islamabad.	TRA 01-74009178/DTL dated 08-01-2024	<u>Specs Applied: USP 2023</u> <u>Physical Description:</u> Visibly clear, colorless liquid filled in transparent sealed labelled glass ampoule. (complies the test) <u>Extractable Volume:</u> Observed: 5.1ml (Complies the test)

Reg. NO. 034290				<p>Limit: 5.0 ml</p> <p><u>Conductivity:</u></p> <p>Observed: 24.8 μ/cm (Complies the test)</p> <p>Limit: NMT 25 μ/cm</p> <p><u>Sterility Test:</u></p> <p>Observed: no visible microbial growth observed, Product is sterile.</p> <p>Limit: no microbial growth must be observed in stipulated incubation time.</p> <p>(Complies the test)</p> <p>Endotoxin test:</p> <p>Observed: Gel clot formed</p> <p>Limit: Less than 0.25 Endotoxin units/ mL (Does not comply)</p> <p><u>RESULT:</u> The sample is being reported as “Substandard” with respect to endotoxin test performed.</p>
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2. Drug Inspector requested for grant of permission for prosecution against the above- accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

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

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

REPLY OF FIRM IN RESPONSE TO SHOWCAUSE NOTICE:

M/s Ipram International, Plot # 26, S.S-3, National Industrial Zone, Rawat, Islamabad submitted reply vide Ref no. 192/IPM/ISB dated 14-06-2024

In response to your letter# PQCB/MSS-181101/2024 Dated 10-06-2024, DTL has declared our product (AQUA-P B# 657) Substandard on the basis of Bacterial Endotoxin Test.

In response to the above mentioned letter under reply, we would like to submit as;

i. Ipram International is well reputed organization manufacturing its products as per Good Manufacturing Guidelines, organization and its employees always follow GMP standards.

As the samples of this product retained in our retained in our retain room were tested and found in compliance with standards

ii. In this regard we have to say that we are aggrieved by DTL decision of declaring our product substandard as we have tested our product thoroughly before dispatch and found it is of standard quality. Reports of these tests are attached with this letter.

As for as Bacterial Endotoxin Test, there are some possibilities that if reconstitution of Control Standard Endotoxin

Test is improper or improper preparation of controls and incorrect pipetting may lead to the fail of BET Test

iv. In regard to these possibilities, this is our legitimate request to retest our sample

V. Sir, For official Correspondence, kindly contact with Anees ur Rehman WhatsApp No.0333-5043104

So kindly consider our request for retesting of our Product Aqua-p B#657

We will be highly obliged by the favor at your end.

Sr.	Summary of the case	
1.	Date of sampling	04-11-2023
2.	Sent to DTL	04-11-2023
3.	Date of receipt in DTL	10-11-2023
4.	Issuance of DTL Report	08-01-2024
5.	Time Extension	N/A
6.	DI 1st communication with firm	05-03-2024
7.	Retesting Request	No.
8.	Fate of retesting request	Nil
9.	Investigation Report of DI	29-04-2024
10.	Permission of SCN	280 th meeting dated 16-05-2024
11.	SC Notice Issued	10-06-2024
12.	Reply of the firm	14-06-2024
13	History (3 years)	29 cases of the firm 27 case of the product

Personal Hearing notice issued to the accused person(s)

Case is placed before the Board for decision.

PROCEEDINGS & DECISION BY THE BOARD:

