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

294 PQCB Meeting

Date: 20-11-2025

Time: 11:00 AM

Venue

DIRECTORATE GENERAL HEALTH SERVICES, 24-COOPER ROAD LAHORE

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Enteric coated Tablet U-Tran 50mg]	K17	M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhupura road, Lahore.	01- 171000129/DTL Dated. 11-01-2022	<p><u>Analysis with specifications applied:</u> BP 2021.</p> <p><u>Physical Description:</u></p> <p>Yellow brown coloured, round coated biconvex tablet with “UNEXO” and a logo engraved on either side of line of bisection and other side plain in a blister of 10 units.</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 (DICLOFENAC SODIUM IDENTIFIED).</p> <p><u>Assay of Diclofenac Sodium:</u></p> <p>Stated: 50mg/ Tab.</p> <p>Determined: 41.96 mg/ Tab</p> <p>Percentage: 83.93% (Does not Comply)</p> <p>Limit: 95.0-105.0%</p> <p><u>Result:</u></p> <p>The above sample is Sub-standard on the basis of assay of DICLOFENAC SODIUM, performed as per BP.</p>
Mfg Date:				
July 2021				
Exp Date:				
June 2024				
Registration No.				
012496				

- iii. M/s Javed Medical Store, Kot Abdul Malik, Ferozewala provided Invoice/warranty No. 710, dated 05-11-2021 issued by M/S Kohinoor Medicine Company, Muhammad Ali Amin Medicine Market, Chowk Urdu Bazar Lahore-Pakistan as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/s Javed Medical Store, Kot Abdul Malik, Ferozewala.
- v. M/S Kohinoor Medicine Company, Muhammad Ali Amin Medicine Market, Chowk Urdu Bazar Lahore-Pakistan provided invoice/ warranty no. 001010INV000656 dated 29-10-2021 issued by M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhupura road, Lahore.
- vi. A copy of test/analysis report was sent to M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhupura road, Lahore.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
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Tablet. U Tran- 50 mg	k17	M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhupura road, Lahore.	0205-P/2022 dated 13 th October, 2022.	<p><u>Analysis with specifications applied: BP 2017</u></p> <p>Assay Test:</p> <p>Stated: 50 mg/ Tablet.</p> <p>Found: 41.38 mg/ Tablet</p> <p>Limit: 95-105%</p> <p>Percentage: 82.76%</p> <p>Does not comply with BP-2017</p> <p>Result: The sample is of Sub-standard quality on the basis of tests performed..</p>
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viii. A copy of NIH Report was sent to M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhupura road, Lahore with directions to explain their position and provide requisite information in this regard.

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

Sr.	Accused	Offence
1.	<p>1. M/S Unexo Laboratories, Sheikhupura road, Lahore through its Chief Executive Officer Muneeb Shafqat Malik</p> <p>2. Muneeb Shafqat Malik Chief Executive Officer</p> <p>3. Wasim Ahmed Production In-charge</p> <p>4. Arsalan Javed Quality Control In-charge</p> <p>5. Aqeel Ahmad Warrantor</p> <p>of M/S Unexo Laboratories, Sheikhupura road, Lahore.</p>	<p>i. Manufacture for sale/Sale of Substandard drug</p> <p>ii. Issuance of false warranty</p>
2.	<p>1. Muhammad Riaz Proprietor</p> <p>2. Ch. Muhammad Saeed Riaz Qualified Person</p> <p>of M/S Kohinoor Medicine Company, Amin Medicine Market, Lahore.</p>	<p>i. Stock and sale of drugs without valid warranty</p> <p>ii. Issuance of false warranty</p>

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

REPLY OF SHOW CAUSE NOTICE BY FIRM:

With reference to the subject matter. We would like to respectfully submit the following:

1- As per **NIH REPORT NO: 0205-P/2022 (DATED: 13th OCTOBER 2022)**, **B.P 2017** is used as a reference for analysis protocol, whereas **B.P 2021** (product manufacturing date being July 2021) or **B.P 2022** (13-10-2022 being date of analysis by NIH) should have been used which is a clear contradiction to drug act 1976 (Chapter 1, section 3 under sub section Z (ii)), that clearly mentions that most recent edition of reference pharmacopoeia must have been used.

3. In **NIH REPORT NO: 0205-P/2022(DATED: 13th OCTOBER 2022)** "Under system suitability" no details of system suitability test are provided, just claiming that "The System Suitability is performed as required" does not fulfill the requirement in true essence of test as B.P 2017 describes certain conditions to be fulfilled for System Suitability to be valid as follows:

SYSTEM SUITABILITY

The assay is not valid unless, in the chromatogram obtained with solution (3), the resolution between the peaks corresponding to diclofenac and diclofenac impurity A is at least 2.0.

4. Further in **NIH REPORT NO: 0205-P/2022(DATED: 13th OCTOBER 2022)** nothing is mentioned about solution (3), a clear requirement in Assay protocol and System suitability test. We have severe reservations about this report and believe that protocol is not followed properly. **Therefore, we request that detail data / chromatograms must be provided regarding this analysis report.**

5. Our product U-tran 50 Tablets are enteric coated tablets. That coating material is not readily soluble or dispersible in Methanol/ 50% Methanol solution specially when mixed for prescribed 30 minutes mixing time as per official method. It is obvious that, this solubility property of coating material hinders the dispersion of Tablets completely causing low assay results. On the other hand this coating material is very well soluble/ dispersible in pure water as compared to 50% or pure methanol.

We are sure that low assay results in NIH Report is due to this solubility/ dispersibility issue. Therefore, we request to retest our product following suggested method with slight modification in solution preparation to solve the issue.

Official B.P Method of assay / sample preparation:

Shake 10 tablets (equivalent to 500mg of Diclofenac Sodium) with 700ml of 50% Methanol, and sonicate for about 30 minutes. Dilute with mobile phase to volume (1000ml), and mix. Centrifuge a portion of this solution and filter supernatant liquid through a filter having a 0.45- μ m or finer porosity, and collect the filtrate. Dilute 5.0 mL of the filtrate with Mobile Phase to 50 mL, and mix well. (Conc. 0.05 mg per mL).

Suggested Method of assay / sample preparation:

[Note: Enteric coating is not soluble in 50% methanol. Therefore, tablets are disintegrated in 350ml of water by shaking/ sonication and then 350ml of methanol is added to make it 700ml of 50% methanol as prescribed in official method]

Shake 10 tablets (equivalent to 500mg of Diclofenac Sodium) with 350ml of water in a 1000-mL volumetric flask till tablets disintegrate. Add 350ml. of Methanol, and sonicate for about 30 minutes. Dilute with mobile phase to volume, and mix. Centrifuge a portion of this solution and filter supernatant liquid through a filter having a 0.45- μ m or finer porosity, and collect the filtrate. Dilute 5.0 mL of the filtrate with Mobile Phase to 50mL, and mix well (Conc. 0.05 mg per mL)

Alternate Method for Assay Preparation:

Weigh and Powder 20 tablets. Transfer an accurately weighed portion of the powder, equivalent to about 500mg of Diclofenac Sodium (10 tablets), to a 1000-mL volumetric flask, add 700mL of 50% Methanol, and sonicate for about 30 minutes. Dilute with mobile phase to

volume, and mix. Pass a portion of this solution through a filter having a 0.45- μ m or finer porosity, and collect the filtrate. Dilute 5.0 mL of the filtrate with Mobile Phase to 50 mL, and mix well. (**Conc. 0.05 mg per mL**)

It can be noted that in the first suggested method half quantity 350ml water is added to disintegrate the tablets followed by addition of 350 ml of pure methanol making it 700ml of 50% methanol, followed by addition of mobile phase to make up the volume, and no deviation occurred in final solution preparation.

In 2nd alternate method tablets are triturated instead of using intact tablets, followed by exactly 700ml methanol (50%)..... as follows:
Weigh and Powder 20 tablets.

Transfer an accurately weighed portion of the powder, equivalent to about 500mg of Diclofenac Sodium (10 tablets), to a 1000-mL volumetric flask, add 700 mL of 50% Methanol, and sonicate for about 30 minutes. Dilute with mobile phase to volume, and mix. Pass a portion of this solution through a filter having a 0.45-um or finer porosity, and collect the filtrate. Dilute 5.0 mL of the filtrate with Mobile Phase to 50 mL, and mix well.

NIH did not intimate us for sending the assay method for U-tran Tablet 50 mg or we would had sent the slightly modified method to them and thus this fluctuation/deviation in result could had been avoided.

To justify our point an in house study analysis test reports are being enclosed, where one test was performed using suggested method of sample preparation. i.e using 350ml of water to disperse tablets/coating first and then adding 350ml 100% Methanol later to make it 700ml of 50% methanol solution instead of adding 700ml of 50% methanol at once. Result was 100.48% by this method.

Whereas in second test in which 10 tablets were directly dissolved in 700ml of 50% methanol as per official method resulted 82.73% with part of undissolved tablets remaining in solution.

Another option is to use triturated tablets powder and dissolve in 700ml of 50% methanol and perform the analysis. This method is used always at granular stage of all batches of Utran 50 tablets.

1- We are performing the analysis on qualified HPLC system and using working standards duly calibrated against reference standard.

2- We are manufacturing Tablet U-Tran 50 mg for a number years with consistent results, which are always within the stated official BP limits (95-105%). We are enclosing results of the past one year.

3- The results reported by NIH are near the borderline lower limits.

Considering the above stated facts, we request a lenient view be taken regarding this case.

REPLY OF SHOW CAUSE NOTICE BY DISTRIBUTOR:

In respect to your letter No. **PQCB/R-375/2022**, dated **16-05-2023** received on **27-05-2023**, I would like to inform you that I being a distributor of the company 'Unexolabs (Pvt) Ltd., purchased the drug U-Tran 50 tabs Batch No. K17 on Invoice No. **0010101NV000656** dated **29-10-2021**. I sold it to Javed Medical Store, Kot Abdul Malik, Ferozewala on Invoice No. **710** dated: **05-11-2021**.

As I was informed by the company to recall the above mentioned drug on basis of substandard I forwarded a recall letter to all the customers to whom the drug was sold but none had it in stock.

In regards to your request to submit the names of the accused I have no information regarding the employees of the factory. The concerned sales manager of the company is only in contact with me.

4. Personal hearing notice(s) issued to the accused persons(s)

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **272nd meeting** held on **22.11.2023** under the Chairpersonship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice Chairperson. Dr. Asma, Secretary DQCB District Sheikhpura attended the meeting online via Zoom Link and Bilal Yaseen, Drug Inspector Ferozewala was present along with original case record. Among nominated accused Arsalan Javed (QCM) along with Ishtiaq Javed (Advocate) appeared before the Board on the behalf of M/s Unexolabs (Pvt.) Ltd., 9.5-Km Sheikhpura road, Lahore and Muhammad Riaz appeared before the Board on behalf of M/S Kohinoor Medicine Company, Amin Medicine Market, Lahore and the firm submitted that As per NIH report, B.P 2017 is used as a reference for analysis protocol, whereas B.P 2021 (product manufacturing date being July 2021) or B.P 2022 (13-10-2022 being date of analysis by NIH) should have been used which is a clear contradiction to Drug Act 1976 (Chapter 1, section 3 under sub section Z (ii)), that clearly mentions that most recent edition of reference pharmacopoeia must have been used.

6. Keeping in view forgoing facts of the case and submissions of firm, the Board after due deliberation and discussion decided to **pend** the case and seek clarification form NIH regarding edition of British Pharmacopoeia used as reference for analysis of said sample.

Clarification of NIH

Reference letter No.PQCB/R-375,434/2022, dated 22-12-2023 regarding sample name Tablet U-Tran 50mg Batch No. K17, it is to clarify that the method of specification of British Pharmacopoeia 2017 and British Pharmacopoeia 2021 are exactly the same. Therefore, the protocol for assay and conclusion remains same. However, on page 1 and 2 "British Pharmacopoeia 2017" should be replaced and read as "British Pharmacopoeia 2021".

This correction does not affect the validity or conclusions of the original report.

Summary:

Manufacturing Date: 12.2019

Expiry Date: 12.2021

Sampling Date (Form 4): 30.06.2021

Sent to DTL (Form 6): 05.07.2021

Date of receipt in DTL: 09.07.2021

DTL Report Date (Form 7): 30.08.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 28.10.2021

Date of Retesting Request of Firm: 01.11.2021

Fate of Retesting Request: Turn Down in 235th meeting dated 30.11.2021 (Review Upheld in 245th meeting dated 16.06.2022)

Investigation Report Dated: 04.02.2022

Permission of SCN:

SCN issued: 16.05.2023

Reply of firm: 03.06.2023

History (Last 03 Years): Product: 03 case reported, Firm: 04 cases reported.

4. 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. 2

PQCB/R-889/2021

(Tehsil & District Sheikhupura)

ATTENDENCE

Secretary DQCB	<u>Accused Persons involved in subject case</u> 1. M/S Unexolabs (Pvt.) Ltd., 9.5-Km Sheikhupura Road, Lahore through its CEO, Muneeb Shafqat Malik. 2. Muneeb Shafqat Malik CEO 3. Waseem Ahmed Production Incharge 4. Arsalan Javed Quality Control Incharge 5. Aqeel Ahmed Warrantor of M/S Unexolabs (Pvt.) Ltd., 9.5-Km Sheikhupura Road, Lahore.
Drug Inspector	

BRIEF FACTS OF THE CASE

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

- i. The then Provincial Inspector of Drugs, on 21.12.2020, inspected the business premises of M/s Saeed Medical Store, Railway Road, Farooqabad, District Sheikhupura and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 80427 dated 23.12.2020.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Lahore, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
Capsule Axalyn (Amoxicillin Trihydrate equal to Amoxicillin: 500mg) Mfg. Date: Exp. Date: Registration No. 01.2020 12.2022 013356	P73	M/S Unexolabs (Pvt.) Ltd., 9.5-Km Sheikhupura Road, Lahore	01-166000044/DTL Dated. 20.02.2021
DTL Test Report Result Specification applied: USP 2020			

Physical Characteristics: Pale yellow colored powder in hard gelatin capsule shell with yellow body and maroon cap in blister pack of 10 units.

IDENTIFICATION: Amoxicillin identified.

ASSAY: Stated: 500mg/Caps, **Determined: 432.48mg/Caps, Percentage: 86.5% (Not Complies)**, Limit: 90-120% of the stated amount

RESULT: The above sample is **Substandard** on the basis of "Assay" performed as per USP

- iii. M/S Saeed Medical Store, Railway Road, Farooqabad, District Sheikhupura provided invoice/ warranty no. 1010 dated 15.08.2020 issued by M/S Aamer Medicine Company, 21-A Muslim Masjid, Lohari Gate, Lahore as proof of purchase.
 - iv. Warrantor portion of drug sample was sent to M/s Aamer Medicine Company, 21-A Muslim Masjid, Lohari Gate, Lahore.
 - v. M/S Aamer Medicine Company, 21-A Muslim Masjid, Lohari Gate, Lahore provided invoice/ warranty no. 001010INV002764 dated 30.01.2020 issued by M/S Unexolabs (Pvt.) Ltd., 9.5-Km Sheikhupura Road, Lahore as proof of purchase.
- iii. A copy of test/analysis report was sent to M/S Unexolabs (Pvt.) Ltd., 9.5-Km Sheikhupura Road, Lahore and they were directed to explain their position and to provide the requisite information in this regard. In response the firm submitted retesting request which was allowed by the Committee of the Board in its 16th meeting dated 16.06.2021 and sample was sent to NIH. 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	test Report	NIH Test Report Results
Axalyn-500 Capsules	P73	M/s Unexolabs (Pvt.) Ltd., 9.5-Km Sheikhupura Road, Lahore	0247-P/2021 Dated: 23.08.2021	Assay: Amoxicillin (as Trihydrate) Stated: 500mg/capsule, Found: 424.6mg/ capsules , Limit: 90-120%, Percentage: 84.92% (Does not Comply with USP-39) Conclusion: The sample is of Substandard quality on the basis of tests performed.

- vi. A copy of test/analysis report of NIH was sent to M/S Unexolabs (Pvt.) Ltd., 9.5-Km Sheikhupura Road, Lahore.

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

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

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. The case was placed in 285th meeting dated 26.09.2024 and the case was left over due to time constraints.

Summary:

Manufacturing Date: 01.2020

Expiry Date: 12.2022

Sampling Date (Form 4): 21.12.2020

Sent to DTL (Form 6): 23.12.2020

Date of receipt in DTL: 23.12.2020

DTL Report Date (Form 7): 20.02.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 09.03.2021

Date of Retesting Request of Firm: 22.03.2021

Fate of Retesting: Allowed (Substandard by NIH)

Investigation Report Dated: 05.12.2023

Permission of SCN: 275-M

SC/PHN issued: 11.09.2024

Reply of firm:

History (Last 03 Years): Product: 00 subject reported case, Firm: 04 cases reported.

5. The Personal Hearing Notice was issued to the accused person (s)

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case No. 3

PQCB/R-803/2022

(Tehsil Safdarabad, District Sheikhpura)

ATTENDENCE

Secretary DQCB Drug Inspector	<p><u>Accused Persons involved in subject case</u></p> <p>1. M/s Murfy Pharmaceuticals (Pvt.) Ltd., 8-Km Raiwind Road, Lahore through its Chief Executive, Mian Shafiq-ur-Rehman.</p> <p>2. Mian Shafiq-ur-Rehman Chief Executive</p> <p>3. Nazia Arif Production Incharge</p> <p>4. Shazia Qadeer Quality Control Incharge</p> <p>5. Syed Sibtain Asghar Zaidi Warrantor/ Sales Manager</p> <p>of M/s Murfy Pharmaceuticals (Pvt.) Ltd., 8-Km Raiwind Road, Lahore.</p> <p>6. Abdul Rehman S/o M. Ashraf Proprietor/ Warrantor</p> <p>7. Shan Ali S/o M. Mushtaq Proprietor</p> <p>8. Maqsood Ahmed Proprietor</p> <p>of M/S Arslan Traders, House # 4, St # 4, Mashallah Bazaar, Madina Park, Near Sheesh Mahal, Sheikhpura.</p> <p>9. M. Imran S/o M. Sabir Proprietor</p> <p>10. Khurram Javid Qualified Person</p> <p>of M/s Cheema Pharmacy situated at Khanqa Dogran Road, Butter Market UBL Bank Tehsil Safdarabad District Sheikhpura.</p>
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BRIEF FACTS OF THE CASE

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

- i. The then Provincial Inspector of Drugs, on 15.04.2022, inspected the business premises M/s Cheema Pharmacy situated at Khanqa Dogran Road, Butter Market, UBL Bank, Tehsil Safdarabad, District Sheikhpura and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 123967 dated 17.04.2022.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Lahore, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	TRA No. & Date	DTL Test Report Result

Tablet Normax 5mg 203 (Amlodipine as Besylate USP: 5mg)	M/S Murfy Pharmaceuticals (Pvt.) Ltd., 8-Km Raiwind Road, Lahore	01-177000809/DTL Dated: 16.06.2022	<p><u>Analysis with specifications applied:</u> USP 2021</p> <p><u>Physical Description:</u> White oblong tablets with line of bisection on one side and MURFY engraved on other side packed in blue opaque blister packing of 10 units.</p> <p><u>Identification:</u> The retention time of the major peak in sample chromatogram corresponds to the retention time of major peak in standard chromatogram. (Amlodipine besylate identified).</p> <p><u>Assay of Amlodipine:</u></p> <p>Stated: 5mg/tab</p> <p>Limit: 90%-110% of labeled amount</p> <p>Determined: 4.025mg/tab</p> <p>Percentage: 80.50% (Does not Comply)</p> <p><u>RESULT:</u> The above sample is <u>Substandard</u> on the basis of the Assay performed as per BP.</p>
Mfg. Date: 10.2021			
Exp. Date: 10-2023			
Regn. No.: 062644			

- iii. M/s Cheema Pharmacy situated at Khanqa Dogran Road, Butter Market, UBL Bank, Tehsil Safdarabad, District Sheikhpura provided Invoice/warranty No. 006294 dated 13.02.2022 issued by M/s Arslan Traders, House # 4, St # 4, Mashallah Bazaar, Madina Park, Near Sheesh Mahal, Sheikhpura and asked to provide requisite information in this regard.
- iv. Warrantor portion of drug sample was provided to M/s Arslan Traders, House # 4, St # 4, Mashallah Bazaar, Madina Park, Near Sheesh Mahal, Sheikhpura along with a copy of test/analysis report who in turn provided invoice/warranty No. 22135 dated 11.12.2021 issued by M/s Murfy Pharmaceuticals (Pvt.) Ltd., 8-Km Raiwind Road, Lahore as a proof of its purchase.
- v. A copy of test/analysis report was sent to M/s Murfy Pharmaceuticals (Pvt.) Ltd., 8-Km Raiwind Road, Lahore and they were asked to provide the requisite information in this regard.

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

Accused Person	Offences
<ol style="list-style-type: none"> 1. M/s Murfy Pharmaceuticals (Pvt.) Ltd., 8-Km Raiwind Road, Lahore through its Chief Executive, Mian Shafiq-ur-Rehman. 2. Mian Shafiq-ur-Rehman, Chief Executive 3. Nazia Arif, Production Incharge 	<ol style="list-style-type: none"> a. Manufacture for sale/ Sale of Substandard drug b. Issuance of false warranty

<p>4. Shazia Qadeer, Quality Control Incharge 5. Syed Sibtain Asghar Zaidi, Warrantor/ Sales Manager</p> <p>of M/s Murfy Pharmaceuticals (Pvt.) Ltd., 8-Km Raiwind Road, Lahore.</p>	
<p>6. Abdul Rehman S/o M. Ashraf, Proprietor/ Warrantor 7. Shan Ali S/o M. Mushtaq, Proprietor 8. Maqsood Ahmed, Proprietor</p> <p>of M/S Arslan Traders, House # 4, St # 4, Mashallah Bazaar, Madina Park, Near Sheesh Mahal, Sheikhpura.</p>	<p>a. Sale/ stock/ exhibition for sale of Substandard drug b. Issuance of false warranty</p>
<p>9. M. Imran S/o M. Sabir, Proprietor 10. Khurram Javid, Qualified Person</p> <p>of M/s Cheema Pharmacy situated at Khanqa Dogran Road, Butter Market UBL Bank Tehsil Safdarabad District Sheikhpura.</p>	<p>a. Sale/ stock/ exhibition for sale of Substandard drug b. Sale/ Stock/ exhibition for sale of drugs in the absence of qualified person</p>

3. The Show-Cause Notices were issued to the accused person (s).
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 Drug Act 1976 in its **283rd Special Meeting** held on **20.08.2024** under the Chairmanship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice-Chairperson PQCB. Dr. Asma, Secretary DQCB District Sheikhpura attended the meeting online via Zoom Link along and Imran Anwar, Drug Inspector, Safdarabad was present along with original case record. Among nominated accused persons Shazia (QCM) appeared before the Board behalf of M/s Murfy Pharmaceuticals (Pvt.) Ltd., 8-Km Raiwind Road, Lahore and M. Imran (Proprietor) of M/s Cheema Pharmacy situated at Khanqa Dogran Road, Butter Market UBL Bank Tehsil Safdarabad District Sheikhpura appeared before the Board.
6. The Board decided to **adjourn the case** on request of firm and also decided to provide another opportunity of personal hearing in best interest of justice.

Summary:

Manufacturing Date: 10.2021

Expiry Date: 10.2023

Sampling Date (Form 4): 15.04.2022

Sent to DTL (Form 6): 17.04.2022

Date of receipt in DTL: 18.04.2022

DTL Report Date (Form 7): 16.06.2022

Time Extension: N/A

1ST DI Communication with firm on dated: 27.07.2022

Date of Retesting Request of Firm: N/A

Fate of Retesting: N/A

Investigation Report Dated: 18.03.2024

Permission of SCN: 279-M dated 24.04.2024

SCN issued: 12.08.2024

Reply of firm:

History (Last 03 Years): Product: 03 case reported, Firm: 12 cases reported.

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

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 4

PQCB/R-723/2021

(Tehsil Pattoki District Kasur)

ATTENDENCE

Secretary DQCB Drug Inspector	<u>Accused Persons involved in subject case</u> 1. M/s Unexo Labs (Pvt) Ltd. 9.5 K.M. Sheikhpura Road, Lahore-Pakistan through its Chief Executive Officer Munib Shafqat Malik 2. Munib Shafqat Malik Chief Executive Officer 3. Waseem Ahmed Production Manager 4. Arslan Javed Quality Control Manager 5. Aqeel Ahmed Warrantor Of M/s Unexo Labs (Pvt) Ltd. 9.5 K.M. Sheikhpura Road, Lahore-Pakistan.
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BRIEF FACTS OF THE CASE

Provincial Inspector of drugs, Tehsil Pattoki, District Kasur reported that: -

- i. The then drug inspector, on 10-02-2021, inspected the business premises M/s Ashraf Pharmacy, situated at Market Bazar Phool Nagar Tehsil Pattoki, District Kasur, took sample of two different types of drugs on Form No.04 for the purpose of test/analysis and sent the sample to Drug Testing Laboratory, Lahore vide memorandum no. 85153 dated 12-02-2021.
- ii. Following drug sample, after test/analysis, was declared **Substandard** by Government Analyst, Drug Testing Laboratory, **Lahore** as detailed below:
- iii. M/s Ashraf Pharmacy, situated at Market Bazar Phool Nagar Tehsil Pattoki, District Kasur provided Invoice/warranty No. 076687 dated 10-01-2021 issued by M/s Shan Elahi & Sons situated at Rehman Plaza Railway Road, Kasur as a proof of its purchase of the said drug.
- iv. Warrantor portion of the drug sample was sent to M/s Ashraf Pharmacy, situated at Market Bazar Phool Nagar Tehsil Pattoki, District Kasur with directions to supply the warrantor portion to the concerned warrantor.
- v. M/s Shan Elahi & Sons situated at Rehman Plaza Railway Road, Kasur in turn submitted invoice/warranty No. 001010INV003113 dated 03-10-2020 issued by M/s Unexo Labs (Pvt) Ltd. 9.5 K.M. Sheikhpura Road, Lahore-Pakistan as a proof of its purchase of the said drug.
- vi. A copy of test/analysis report was sent to M/s Unexo Labs (Pvt) Ltd. 9.5 K.M. Sheikhpura Road, Lahore-Pakistan with directions 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.
- vii. Pursuant to firm's retesting request the Provincial Quality Control Board in its 238th meeting held on 09-02-2022 **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	DTL Report TRA No. & Date	DTL Test Report Results
Sugar Coated Tablet. COBLA [Mecobalamin 500 mcg] Mfg.date: Aug-2020 Exp. date: July-2022 Regn No. 059770	V 97	M/s UNEXOLABS (Pvt) Ltd. 9.5 K.M. Sheikhupura Road, Lahore- Pakistan	01- 73007649/DTL Dated: 07-04- 2021	<u>Analysis with specifications applied:</u> MS <u>PHYSICAL DESCRIPTION:</u> WHITE COLORED, ROUND BICONVEX, SUGAR TABLET PLAIN ON BOTH SIDES PACKED IN ALU-ALU PACKING OF TEN TABLETS. <u>DISINTEGRATION TEST:</u> All 6 units comply the limits. <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 (MECOBALAMIN IDENTIFIED) <u>ASSAY OF MECOBALAMIN:</u> Stated: 500 mcg / Tab Determined: 390.75 mcg / Tab Percentage: 78.15% (DOES NOT COMPLY) Limit: 90.0 – 110.0% of the stated amount RESULT: The above sample is SUB-STANDARD on the basis of Assay of MECOBALAMIN, performed as per MS.

Name of Drug	Batch No.	Name of Manufacturer	NIH Test Report No.	NIH Test Report Result
Tablet Cobla (S.C) (Mecobalamin ...500 mcg)	V 97	M/s Unexolab (Pvt) Ltd. 9.5 K.M. Sheikhupura Road, Lahore- Pakistan	030-P/2022 dated 25- 04-2022	Analysis with specifications applied: Manufacture Specification <u>Identification:</u> Mecobalamin identified. <u>ASSAY:</u> Mecobalamin

Stated	Found	Limit	Percentage
500 mcg/ Tablet	342.7 mcg/ Tablet	90-110%	68.54%
Does not comply with manufacturer specification.			
CONCLUSION: The sample is of Sub-Standard quality on the basis of the tests performed.			

viii. A copy of NIH report was sent to M/s Unexo Labs (Pvt) Ltd. 9.5 K.M. Sheikhpura Road, Lahore-Pakistan.

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

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

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

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

4. 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 and Laiq-ur-Rehman, Drug Inspector was present along with original case record. No among nominated accused appeared before the Board on the behalf of M/s Unexo Labs (Pvt) Ltd. 9.5 K.M. Sheikhpura Road, Lahore-Pakistan.
5. The Board decided to adjourn the case on written request of firm and also decided to provide another opportunity of personal hearing in best interest of justice.
6. Personal hearing notice(s) issued to accused person(s).

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

7. The case was placed in 285th meeting dated 26.09.2024 and the case was **Left over** due to time constrains.

Summary:

Manufacturing Date: 08.2020

Expiry Date: 07.2022

Sampling Date (Form 4): 10.02.2021

Sent to DTL (Form 6): 12.02.2021

Date of receipt in DTL: 12.02.2021

DTL Report Date (Form 7): 07.04.2021

Time Extension: N/A

1ST DI Communication with firm on dated: 18.11.2021

Date of Retesting Request of Firm: 22.11.2021

Fate of Retesting: Substandard by NIH

Investigation Report Dated: 24.03.2023

Permission of SCN: 258-M

SCN issued: 04.09.2023

Reply of firm: No Reply

History (Last 03 Years): Product: 0 case reported, Firm: 4 cases reported.

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

Case is placed before the Board for decision.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

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Case No. 5

Case No.

PQCB/R-434/2022

(Ferozewala, Sheikhpura)

ATTENDENCE:

Secretary DQCB	<u>Accused Persons involved in subject case</u>
Drug Inspector	
	<ol style="list-style-type: none">1. M/S Unexo Laboratories, Sheikhpura Road, Lahore through its Chief Executive Officer Muneeb Shafqat Malik2. Muneeb Shafqat Malik Chief Executive Officer3. Wasim Ahmed Production In-charge4. Arsalan Javed Quality Control In-charge5. Aqeel Ahmad Warrantor <p>of M/S Unexo Laboratories, Sheikhpura road, Lahore.</p>

BRIEF FACTS OF THE CASE

Provincial Inspector of Drugs, Ferozewala, District Sheikhpura reported that: -

- i. He, on 16-11-2021, inspected the business premises of M/s Chishtia Medical Store, Main Bazar, Nain Sukh, Ferozewala and took below mentioned drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide Memo. No.111044, dated 16-11-2021.
- ii. Following Drug sample after test/analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory **Lahore**, as detailed below:

Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL Test Report Result
Enteric coated Tablet U-Tran 50mg] Mfg Date: July 2021	K17	M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhpura road, Lahore.	01-171000128/DTL Dated. 11-01-2022	<u>Analysis with specifications applied:</u> BP 2021. <u>Physical Description:</u> Yellowish brown coloured, round coated biconvex tablet with "UNEXO" and a logo engraved on either side of line of bisection and other side plain in a blister of 10 units.. <u>Identification:</u> The retention time of the major peak in the sample chromatogram

Exp Date: June 2024				<p>corresponds to the retention time of the major peak in standard chromatogram (DICLOFENAC SODIUM IDENTIFIED).</p> <p>Assay of Diclofenac Sodium:</p> <p>Stated: 50mg/ Tab.</p> <p>Determined: 41.18 mg/ Tab</p> <p>Percentage: 82.36% (Does not Comply)</p> <p>Limit: 95.0-105.0%</p> <p><u>Result:</u></p> <p>The above sample is Sub-standard on the basis of assay of DICLOFENAC SODIUM, performed as per BP.</p>
Registration No. 012496				

- iii. M/s Chishtia Medical Store, Main Bazar, Nain Sukh, Ferozewala provided Invoice/warranty No. 449, dated 13-11-2021 issued by M/S Good Luck Medicine Company, Wholesale Medicine Dealer 8-Amim Medicine Market, Chowk Urdu Bazar Lahore as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/s Chishtia Medical Store, Main Bazar, Nain Sukh, Ferozewala.
- v. M/S Good Luck Medicine Company, Wholesale Medicine Dealer 8-Amim Medicine Market, Chowk Urdu Bazar Lahore provided invoice/ warranty no. 001010INV000658 dated 20-10-2021 issued by M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhpura road, Lahore.
- vi. A copy of test/analysis report was sent to M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhpura road, Lahore.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
Tablet. U Tran-50 mg	k17	M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhpura road, Lahore.	0292-P/2022 dated 25 th January,2023.	<p><u>Analysis with specifications applied: BP 2017</u></p> <p>Assay Test:</p> <p>Stated: 50 mg/ Tablet.</p> <p>Found: 41.74 mg/ Tablet</p> <p>Limit: 95-105%</p>

				<p>Percentage: 83.48%</p> <p>Does not comply with BP-2017</p> <p>Result: The sample is of Sub-standard quality on the basis of tests performed.</p>
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viii. A copy of NIH Report was sent to M/S Unexo Labs (Pvt. Ltd., 9.5 km, Sheikhpura road, Lahore with directions to explain their position and provide requisite information in this regard.

2. Drug Inspector requested for grant of permission for prosecution against the 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**

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

REPLY OF SHOW CAUSE NOTICE:

With reference to the subject matter. We would like to respectfully submit the following:

1. *As per NIH REPORT NO: 0292-P/2022(DATED: 25th JANUARY 2023), B.P 2017 is used as a reference for analysis protocol, whereas B.P 2021 (product manufacturing date being July 2021) or B.P 2022 (25-01-2023 being date of analysis by NIH) should have been used which is a clear contradiction to drug act 1976 (Chapter 1, section 3 under sub section Z (ii)), that clearly mentions that most recent edition of reference pharmacopoeia must have been used.*

2. *In NIH REPORT NO: 0292-P/2022(DATED: 25th JANUARY 2023) "Under system suitability" no details of system suitability test are provided, just claiming that "The System Suitability is performed as required" does not fulfill the requirement in true essence of test as B.P 2017 describes certain conditions to be fulfilled for System Suitability to be valid as follows:*

SYSTEM SUITABILITY

The assay is not valid unless, in the chromatogram obtained with solution (3), the resolution between the peaks corresponding to diclofenac and diclofenac impurity A is at least 2.0.

3. *Further in NIH REPORT NO: 0292-P/2022(DATED: 25th JANUARY 2023) nothing is mentioned about solution (3), a clear requirement in Assay protocol and System suitability test. We have severe reservations about this report and believe that protocol is not followed properly. Therefore, we request that detail data/ chromatograms must be provided regarding this analysis report.*

4. *Our product U-tran 50 Tablets are enteric coated tablets. That coating material is not readily soluble or dispersible in Methanol/ 50% Methanol solution specially when mixed for prescribed 30 minutes mixing time as per official method. It is obvious that, this solubility property of coating material hinders the dispersion of Tablets completely causing low assay results. On the other hand this coating material is very well soluble/ dispersible in pure water as compared to 50% or pure methanol.*

We are sure that low assay results in NIH Report is due to this solubility/ dispersibility issue. Therefore, we request to retest our product

following suggested method with slight modification in solution preparation to solve the issue.

Official B.P Method of assay / sample preparation:

Shake 10 tablets (equivalent to 500mg of Diclofenac Sodium) with 700ml of 50% Methanol, and sonicate for about 30 minutes. Dilute with mobile phase to volume (1000ml), and mix. Centrifuge a portion of this solution and filter supernatant liquid through a filter having a 0.45- μ m or finer porosity, and collect the filtrate. Dilute 5.0 mL of the filtrate with Mobile Phase to 50 mL, and mix well. (Conc. 0.05 mg per mL).

Suggested Method of assay / sample preparation:

[**Note:** Enteric coating is not soluble in 50% methanol. Therefore, tablets are disintegrated in 350ml of water by shaking/sonication and then 350ml of methanol is added to make it 700ml of 50% methanol as prescribed in official method]

Shake 10 tablets (equivalent to 500mg of Diclofenac Sodium) with 350ml of water in a 1000-mL volumetric flask till tablets disintegrate. Add 350mL of Methanol, and sonicate for about 30 minutes. Dilute with mobile phase to volume, and mix. Centrifuge a portion of this solution and filter supernatant liquid through a filter having a 0.45- μ m or finer porosity, and collect the filtrate. Dilute 5.0 mL of the filtrate with Mobile Phase to 50mL, and mix well. (Conc. 0.05 mg per mL)

Alternate Method for Assay Preparation:

Weigh and Powder 20 tablets. Transfer an accurately weighed portion of the powder, equivalent to about 500mg of Diclofenac Sodium (10 tablets), to a 1000-mL volumetric flask, add 700mL of 50% Methanol, and sonicate for about 30 minutes. Dilute with mobile phase to volume, and mix. Pass a portion of this solution through a filter having a 0.45- μ m or finer porosity, and collect the filtrate. Dilute 5.0 mL of the filtrate with Mobile Phase to 50 mL, and mix well. (Conc. 0.05 mg per mL)

It can be noted that in the first suggested method half quantity 350ml water is added to disintegrate the tablets followed by addition of 350 ml of pure methanol making it 700ml of 50% methanol, followed by addition of mobile phase to make up the volume, and no deviation occurred in final solution preparation.

In 2nd alternate method tablets are triturated instead of using intact tablets, followed by exactly 700ml methanol (50%).....as follows:
Weigh and Powder 20 tablets.

Transfer an accurately weighed portion of the powder, equivalent to about 500mg of Diclofenac Sodium (10 tablets), to a 1000-mL volumetric flask, add 700 mL of 50% Methanol, and sonicate for about 30 minutes. Dilute with mobile phase to volume, and mix. Pass a portion of this solution through a filter having a 0.45- μ m or finer porosity, and collect the filtrate. Dilute 5.0 mL of the filtrate with Mobile Phase to 50 mL, and mix well.

NIH did not intimate us for sending the assay method for U-tran Tablet 50 mg or we would had sent the slightly modified method to them and thus this fluctuation/deviation in result could had been avoided.

To justify our point an in house study analysis test reports are being enclosed, where one test was performed using suggested method of sample preparation. i.e using 350ml of water to disperse tablets/coating first and then adding 350ml 100% Methanol later to make it 700ml of 50% methanol solution instead of adding 700ml of 50% methanol at once. Result was 100.48% by this method.

Whereas in second test in which 10 tablets were directly dissolved in 700ml of 50% methanol as per official method resulted 82.73% with part of undissolved tablets remaining in solution.

Another option is to use triturated tablets powder and dissolve in 700ml of 50% methanol and perform the analysis. This method is used

always at granular stage of all batches of Utran 50 tablets.

- 1. We are performing the analysis on qualified HPLC system and using working standards duly calibrated against reference standard.*
- 2. We are manufacturing Tablet U-Tran 50 mg for a number of years with consistent results, which are always within the stated official BP limits (95-105%). We are enclosing results of the past one year.*
- 3. The results reported by NIH are near the borderline lower limits.*

Considering the above stated facts, we request a lenient view be taken regarding this case.

4. Personal hearing notice(s) issued to the accused persons(s)

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 **272nd meeting** held on **22.11.2023** under the Chairpersonship of Special Secretary (Operations), Primary and Secondary Healthcare Department, Punjab/ Vice Chairperson. Dr. Asma, Secretary DQCB District Sheikhpura attended the meeting online via Zoom Link and Bilal Yaseen, Drug Inspector Ferozewala was present along with original case record. Among nominated accused Arsalan Javed (QCM) along with Ishtiaq Javed (Advocate) appeared before the Board on the behalf of M/s Unexolabs (Pvt.) Ltd., 9.5-Km Sheikhpura road, Lahore and Muhammad Riaz appeared before the Board on behalf of M/S Kohinoor Medicine Company, Amin Medicine Market, Lahore and the firm submitted that As per NIH report, B.P 2017 is used as a reference for analysis protocol, whereas B.P 2021 (product manufacturing date being July 2021) or B.P 2022 (13-10-2022 being date of analysis by NIH) should have been used which is a clear contradiction to Drugs Act 1976 (Chapter 1, section 3 under sub section Z (ii)), that clearly mentions that most recent edition of reference pharmacopoeia must have been used.

6. Keeping in view forgoing facts of the case and submissions of firm, the Board after due deliberation and discussion decided to **pend the case** and seek **clarification form NIH** regarding edition of British Pharmacopoeia used as reference for analysis of said sample.

Clarification of NIH

Reference letter No.PQCB/R-375,434/2022, dated 22-12-2023 regarding sample name Tablet U-Tran 50mg Batch No. K17, it is to clarify that the method of specification of British Pharmacopoeia 2017 and British Pharmacopoeia 2021 are exactly the same. Therefore, the protocol for assay and conclusion remains same. However, on page 1 and 2 "British Pharmacopoeia 2017" should be replaced and read as "British Pharmacopoeia 2021".

This correction does not affect the validity or conclusions of the original report.

Summary:

Manufacturing Date: 07.2021

Expiry Date: 06.2024

Sampling Date (Form 4): 16.11.2021

Sent to DTL (Form 6): 16.11.2021

Date of receipt in DTL: 19.11.2021

DTL Report Date (Form 7): 11.01.2022

Time Extension: N/A

1ST DI Communication with firm on dated: 28.10.2021

Date of Retesting Request of Firm: 27.01.2022

Fate of Retesting Request: Allowed in 253rd meeting dated 29.11.2022, (NIH Substandard)

Investigation Report Dated: 08.03.2023

Permission of SCN:

SCN issued: 16.05.2023

Reply of firm: 03.06.2023

History (Last 03 Years): Product: 03 case reported, Firm: 04 cases reported.

4. 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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