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

**288 Meeting of PQCB**

**Date: 25-02-2025**

**Time: 11:00 AM**

**Venue**

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

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## ITEM No. 1

### REGULAR CASES

#### Case No. 1

PQCB/MSS-172441, 172442/2023

**Bahawalpur City, District Bahawalpur**

#### **ATTENDANCE:**

Secretary DQCB  Drug Inspector	<p><b><u>Accused Persons involved in subject case</u></b></p> <ol style="list-style-type: none"><li>1. M/s Asma Doll House no. 4 Al Baghdad Villas Housing Society Hasil pur Baghdad ul Jaded Road Bahawalpur through its Owner/ Director Asma Akram</li><li>2. Asma Akram Owner/ Director</li><li>3. Asif Akram Production Manager/ Supervisor of Manufacturing and Repackig Operations</li><li>4. Mukhtar Ahmad Servant/ Production Staff working for Manufacturing/ Packing Operations</li></ol> <p><b>of M/s Asma Doll House no. 4 Al Baghdad Villas Housing Society Hasil pur Baghdad ul Jaded Road Bahawalpur.</b></p>
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#### **BREIF FACTS OF THE CASE:**

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

- The then Drug Inspector, on 25-07-2023, inspected the business premises of M/s Asma Doll Bahawalpur situated at Al-Baghdad Villas House no. 4 Housing Society Bahawalpur, took samples of following creams/ cosmetic products on Form No.04 for the purpose of test/analysis and sent the subject samples to Drug Testing Laboratory, Bahawalpur vide memorandum number 172441, 172442, 172444 and 172445 dated 26-07-2023.
- Following samples after test/analysis were declared to **Contain Suspected Ingredients** by Government Analyst Drug Testing Laboratory, Bahawalpur, as detailed below:

Sr.No.	Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
1.	Asma Doll Whitening Cream Zafrani, [Suspected To Contain: Betamethasone+ Clobetasol+ Mercury],	N/A	ASMA DOLL, BAHAWALPUR	01-10097004576/DTL dated 22-09-2023
<b>Specification applied: USP 2023/others/in house</b>				

**DESCRIPTION** Slightly pink color cream packed in a golden-brown plastic container.

**IDENTIFICATION OF BETAMETHASONE VALERATE: (USP-2023)**

**(HPLC-PDA)**

No peak observed at respective retention time of standard peak in sample chromatogram.

**BETAMETHASONE VALERATE NOT IDENTIFIED.**

**IDENTIFICATION OF CLOBETASOL PROPIONATE: (HPLC-PDA)**

No peak observed at respective retention time of standard peak in sample chromatogram.

**CLOBETASOL PROPIONATE NOT IDENTIFIED.**

**IDENTIFICATION OF MERCURY:**

CVAAS (Cold Vapour Atomic Absorption Spectroscopy)

**MERCURY IS IDENTIFIED.**

**QUANTIFICATION OF MERCURY:**

CVAAS (Cold Vapour Atomic Absorption Spectroscopy)

Determined Quantity: **9.901 g/Gram**

**RESULT:** The Sample contain MERCURY as suspected ingredient.

2.	Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
	Asma Doll Whitening Cream Zafrani, [Suspected To Contain: Betamethasone+ Clobetasol+ Mercury],	N/A	ASMA DOLL, BAHAWALPUR	01-10097004577/DTL dated 22-09-2023

**Specification applied: USP 2023/others/in house**

**DESCRIPTION** Pinkish cream packed in a translucent white plastic container.

**IDENTIFICATION OF BETAMETHASONE VALERATE: (USP-2023)**

**(HPLC-PDA)**

No peak observed at respective retention time of standard peak in sample chromatogram.

**BETAMETHASONE VALERATE NOT IDENTIFIED.**

**IDENTIFICATION OF CLOBETASOL PROPIONATE: (HPLC-PDA)**

No peak observed at respective retention time of standard peak in sample chromatogram.

**CLOBETASOL PROPIONATE NOT IDENTIFIED.**

**IDENTIFICATION OF MERCURY:**

CVAAS (Cold Vapour Atomic Absorption Spectroscopy)

**MERCURY IS IDENTIFIED.**

**QUANTIFICATION OF MERCURY:**

CVAAS (Cold Vapour Atomic Absorption Spectroscopy)

Determined Quantity: **7.940 g/Gram**

**RESULT:**

The Sample contain MERCURY as suspected ingredient.

iii. Drug Inspector also seized 20 types of drugs/ therapeutic goods/ medicated cosmetics vide Form-5 dated 26-10-2023.

iv. Copies of test/analysis reports were sent to M/s Asma Doll Bahawalpur situated at Al-Baghdad Villas House no. 4 Housing Society Bahawalpur and they were directed to explain their position and to provide the requisite information in this regard.

**PREVIOUS PROCEEDINGS IN THE CASE**

*The Secretary DQCB Bahawalpur referred the case to PQCB for consideration and decision vide letter No. 3759-60/SDQCB/BWP dated 18-01-2024*

*The Drugs Inspector on direction of Secretary DQCB Bahawalpur forwarded the case to PQCB vide letter no. 14-16/DC/BWP dated 18-01-2024 with the request to grant him permission for prosecution/FIR against the below mentioned accused persons*

- i. *Mr. Asif Akram S/O Muhammad Akram*
- ii. *Ms. Asma Akram D/O Muhammad Akram*

*Of M/S Asma Doll, H. no. 4 Al Baghdad villas Housing scheme Hasilpur Baghdad-Ul-Jaded Bahawalpur*

1. *Manufacturing/repacking of drugs/therapeutic goods/medicated cosmetics without license*
2. *Not registered (unregistered) drugs/therapeutic goods/medicated cosmetics*
3. *Misbranded drugs/therapeutic goods/medicated cosmetics*

*Personal Hearing Notice was issued to the accused persons on 19-01-2024*

**PQCB 32<sup>nd</sup> committee meeting held on 25-01-2024:**

*The subject case was considered by the Committee of Provincial Quality Control Board in its 32<sup>nd</sup> meeting held on 25-01-2024 under the chairmanship of Director General, Drugs Control (Convener), Primary and Secondary Healthcare Department, Punjab. Secretary DQCB Bahawalpur Mr. Jahangir Khan attended the meeting in person and Drug Inspector Bahawalpur City Mr. Adnan Akram appeared before the Committee along with all original record. Both accused persons Ms. Asma Akram & Mr. Asif Akram along with Counsel Mr. Azeem Ashraf Cheema Advocate of M/S Asma Doll H. No. 4 Al Baghdad Villas Housing scheme Hasilpur Baghdad Ul Jaded Bahawalpur appeared before the Committee to plead the case.*

*The Accused person Ms Asma Akram D/O Muhammad Akram apprised the Committee that she is a social media activist and running a beauty Saloon by name of M/S Asma Doll Beauty Bar since last 7 years and all beauty products which are being used are purchased from third party manufacturer through online purchase.*

*She also apprised the committee that purchase from that party was stopped after Drugs Inspector took samples of different products from her premises in presence of her Brother M. Asif S/O Muhammad Akram on 25-07-2023.*

*The counsel apprised the Committee and admitted that his client purchases the manufactured goods/cosmetics in large quantity/container and then repack in small jars/bottles/containers and labelled with the Asma Doll Products. The counsel also submitted two (02) different bills in favor of their argument but Committee didn't agree with them as these bills are not proof of said products.*

*Mr. Adnan Akram, Current Drug Inspector Bahawalpur City apprised the Committee that on first raid eight (08) different products sample were taken and the raiding inspector (Mr. Ali Raza, the then Drugs Inspector Bahawalpur city) also observed that accused persons were manufacturing/repacking the cosmetic products and also took pictorial evidence of all such activity on the time of raid and 4 out of 8 samples were declared to contain the suspected Allopathic ingredient by the Drugs Testing Laboratory (DTL) Bahawalpur. After receiving of DTL reports, I, Mr. Adnan Akram Drugs Inspector Bahawalpur city visited the M/S Asma Doll H.No. 4 Al-Baghdad Villas Housing society Bahawalpur and seized 20 different products/articles/Therapeutic goods on Form 5 and also visited M/S Asma Doll Beauty Bar near Habib Bank Chowk Model Town-A Bahawalpur.*

*The Committee after careful perusal of case record, statement by the accused persons and stance of area Drug Inspector, unanimously decided to grant the **Permission for Registration of FIR** being the cognizable offence under Schedule II of DRAP Act, 2012 and rules framed thereunder, against the below-mentioned accused persons:*

- i. Mr. Asif Akram S/O Muhammad Akram
- ii. Ms. Asma Akram D/O Muhammad Akram

*Of M/S Asma Doll H. No. 4 Al Baghdad villas Housing scheme Hasilpur Baghdad-Ul-Jaded Bahawalpur*

1. Manufacturing/repacking of drugs/therapeutic goods/medicated cosmetics without license
2. Not registered (unregistered) drugs/therapeutic goods/medicated cosmetics
3. Misbranded drugs/therapeutic goods/medicated cosmetics

*The Committee directed the Area Drugs Inspector to launch the complaint against the above-mentioned accused person in concerned Police station at earliest.*

v. On the directions of Committee of Provincial Quality Control Board in 32<sup>nd</sup> Committee Meeting dated 25-01-2024, Drug Inspector registered FIR No. 317/24 dated 25-02-2024 .

vi. Investigating Officer submitted complete challan to concerned drug inspector.

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. **Manufacturing/ Repacking/ Selling of drugs/ therapeutic goods/ medicated cosmetics without license**
- b. **Manufacturing/ Repacking/ Selling of Not registered (Unregistered) drugs/ therapeutic goods/ medicated cosmetics**

**c. Manufacturing/ Repacking/ Selling of Misbranded drugs/ therapeutic goods/ medicated cosmetics**

3. Show-cause notice issued to accused person(s) dated 03-02-2025

<b>Sr.</b>	<b>Summary of the case</b>	
<b>1.</b>	<b>Date of sampling</b>	25-07-2023
<b>2.</b>	<b>Sent to DTL</b>	26-07-2023
<b>3.</b>	<b>Date of receipt in DTL</b>	27-07-2023
<b>4.</b>	<b>Issuance of DTL Report</b>	22-09-2023
<b>5.</b>	<b>Time Extension</b>	N/A
<b>6.</b>	<b>Retesting Request</b>	N/A
<b>7.</b>	<b>Fate of retesting request</b>	N/A
<b>8.</b>	<b>Investigation Report of DI</b>	05-11-2024
<b>9.</b>	<b>Permission of SCN</b>	287 <sup>th</sup> meeting dated 08-01-2025
<b>10.</b>	<b>SC Notice Issued</b>	03-02-2025
<b>11.</b>	<b>Reply of the firm</b>	Not received
<b>12.</b>	<b>History (3 years)</b>	4 cases of the firm (Subject cases)

Personal hearing notice issued to accused person(s)

Case is placed before the Board for decision.

**PROCEEDINGS & DECISION BY THE BOARD:**

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Case No. 2

PQCB/MSS-172444, 172445/2023

Bahawalpur City, District Bahawalpur

**ATTENDANCE:**

Secretary DQCB  Drug Inspector	<p><b><u>Accused Persons involved in subject case</u></b></p> <ol style="list-style-type: none"><li>1. M/s Asma Doll House no. 4 Al Baghdad Villas Housing Society Hasil pur Baghdad ul Jaded Road Bahawalpur through its Owner/ Director Asma Akram</li><li>2. Asma Akram                      Owner/ Director</li><li>3. Asif Akram                      Production Manager/ Supervisor of Manufacturing and Repackig Operations</li><li>4. Mukhtar Ahmad                  Servant/ Production Staff working for Manufacturing/ Packing Operations</li></ol> <p>of M/s Asma Doll House no. 4 Al Baghdad Villas Housing Society Hasil pur Baghdad ul Jaded Road Bahawalpur.</p>
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**BREIF FACTS OF THE CASE:**

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

- The then Drug Inspector, on 25-07-2023, inspected the business premises of M/s Asma Doll Bahawalpur situated at Al-Baghdad Villas House no. 4 Housing Society Bahawalpur, took samples of following creams/ cosmetic products on Form No.04 for the purpose of test/analysis and sent the subject samples to Drug Testing Laboratory, Bahawalpur vide memorandum number 172441, 172442, 172444 and 172445 dated 26-07-2023.
- Following samples after test/analysis were declared to **Contain Suspected Ingredients** by Government Analyst Drug Testing Laboratory, Bahawalpur, as detailed below:

Sr.No.	Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
1.	Name of Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date
	Silent Girl Urgent Beauty Cream, [Suspected To Contain: Betamethasone +Clobetasol +Mercury +Salicylic Acid]	N/A	ASMA                      DOLL, BAHAWALPUR	01-10097004579/DTL dated 22-09-2023
<b>Specification applied: USP 2023/others/in house</b>				
<b><u>DESCRIPTION</u></b> Off white color cream packed in a white plastic container.				
<b><u>IDENTIFICATION OF BETAMETHASONE VALERATE: (USP-2023)</u></b>				

**(HPLC-PDA)**

The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. Further the PDA extracted spectrum of sample peak also corresponds to the PDA extracted spectrum of standard peak.

**BETAMETHASONE VALERATE IS IDENTIFIED.**

**QUANTIFICATION OF BETAMETHASONE VALERATE: (HPLC-PDA)**

Determined Quantity: **0.05 mg/Gram**

**IDENTIFICATION OF SALICYLIC ACID: (HPLC-PDA)**

The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. Further the PDA extracted spectrum of sample peak also corresponds to the PDA extracted spectrum of standard peak.

**SALICYLIC ACID IS IDENTIFIED.**

**QUANTIFICATION OF SALICYLIC ACID: (HPLC-PDA)**

Determined Quantity: **1.399 mg/ Gram**

**IDENTIFICATION OF MERCURY:**

CVAAS (Cold Vapour Atomic Absorption Spectroscopy)

**MERCURY IS IDENTIFIED.**

**QUANTIFICATION OF MERCURY:**

CVAAS (Cold Vapour Atomic Absorption Spectroscopy)

Determined Quantity: **8.72 g/Gram**

**RESULT:**

The Sample contain SALICYLIC ACID, MERCURY, and BETAMETHASONE VALERATE as suspected ingredients

2.	<b>Name of Drug</b>	<b>Batch No.</b>	<b>Name of Manufacturer</b>	<b>DTL Report TRA No. &amp; Date</b>
	Asma Doll Hydrating Face Serum, [Suspected To Contain: Betamethasone+ Clobetasol+ Mercury],	N/A	ASMA DOLL, BAHAWALPUR	01-10097004580/DTL dated 22-09-2023
<b>Specification applied: USP 2023/others/in house</b>				
<b><u>DESCRIPTION</u></b> White viscous lotion filled in transparent glass bottle with plastic dropper cap.				
<b><u>IDENTIFICATION OF BETAMETHASONE VALERATE: (HPLC-PDA)</u></b>				

No peak observed at respective retention time of standard peak in sample chromatogram.

**BETAMETHASONE VALERATE NOT IDENTIFIED.**

**IDENTIFICATION OF CLOBETASOL PROPIONATE: (HPLC-PDA)**

No peak observed at respective retention time of standard peak in sample chromatogram.

**CLOBETASOL PROPIONATE NOT IDENTIFIED.**

**IDENTIFICATION OF MERCURY:**

CVAAS (Cold Vapour Atomic Absorption Spectroscopy)

**MERCURY IS IDENTIFIED.**

**QUANTIFICATION OF MERCURY:**

CVAAS (Cold Vapour Atomic Absorption Spectroscopy)

Determined Quantity: **8.286 g/Gram**

**RESULT:**

The Sample contain MERCURY as suspected ingredient.

iii. Drug Inspector also seized 20 types of drugs/ therapeutic goods/ medicated cosmetics vide Form-5 dated 26-10-2023.

iv. Copies of test/analysis reports were sent to M/s Asma Doll Bahawalpur situated at Al-Baghdad Villas House no. 4 Housing Society Bahawalpur and they were directed to explain their position and to provide the requisite information in this regard.

**PREVIOUS PROCEEDINGS IN THE CASE**

*The Secretary DQCB Bahawalpur referred the case to PQCB for consideration and decision vide letter No. 3759-60/SDQCB/BWP dated 18-01-2024*

*The Drugs Inspector on direction of Secretary DQCB Bahawalpur forwarded the case to PQCB vide letter no. 14-16/DC/BWP dated 18-01-2024 with the request to grant him permission for prosecution/FIR against the below mentioned accused persons*

- i. Mr. Asif Akram S/O Muhammad Akram
- ii. Ms. Asma Akram D/O Muhammad Akram

*Of M/S Asma Doll, H. no. 4 Al Baghdad villas Housing scheme Hasilpur Baghdad-Ul-Jaded Bahawalpur*

1. Manufacturing/repacking of drugs/therapeutic goods/medicated cosmetics without license
2. Not registered (unregistered) drugs/therapeutic goods/medicated cosmetics
3. Misbranded drugs/therapeutic goods/medicated cosmetics

*Personal Hearing Notice was issued to the accused persons on 19-01-2024*

**PQCB 32<sup>nd</sup> committee meeting held on 25-01-2024:**

*The subject case was considered by the Committee of Provincial Quality Control Board in its 32<sup>nd</sup> meeting held on 25-01-2024 under the chairmanship of Director General, Drugs Control*

(Convener), Primary and Secondary Healthcare Department, Punjab. Secretary DQCB Bahawalpur Mr. Jahangir Khan attended the meeting in person and Drug Inspector Bahawalpur City Mr. Adnan Akram appeared before the Committee along with all original record. Both accused persons Ms. Asma Akram & Mr. Asif Akram along with Counsel Mr. Azeem Ashraf Cheema Advocate of M/S Asma Doll H. No. 4 Al Baghdad Villas Housing scheme Hasilpur Baghdad Ul Jaded Bahawalpur appeared before the Committee to plead the case.

The Accused person Ms Asma Akram D/O Muhammad Akram apprised the Committee that she is a social media activist and running a beauty Saloon by name of M/S Asma Doll Beauty Bar since last 7 years and all beauty products which are being used are purchased from third party manufacturer through online purchase.

She also apprised the committee that purchase from that party was stopped after Drugs Inspector took samples of different products from her premises in presence of her Brother M. Asif S/O Muhammad Akram on 25-07-2023.

The counsel apprised the Committee and admitted that his client purchases the manufactured goods/cosmetics in large quantity/container and then repack in small jars/bottles/containers and labelled with the Asma Doll Products. The counsel also submitted two (02) different bills in favor of their argument but Committee didn't agree with them as these bills are not proof of said products.

Mr. Adnan Akram, Current Drug Inspector Bahawalpur City apprised the Committee that on first raid eight (08) different products sample were taken and the raiding inspector (Mr. Ali Raza, the then Drugs Inspector Bahawalpur city) also observed that accused persons were manufacturing/repacking the cosmetic products and also took pictorial evidence of all such activity on the time of raid and 4 out of 8 samples were declared to contain the suspected Allopathic ingredient by the Drugs Testing Laboratory (DTL) Bahawalpur. After receiving of DTL reports, I, Mr. Adnan Akram Drugs Inspector Bahawalpur city visited the M/S Asma Doll H.No. 4 Al-Baghdad Villas Housing society Bahawalpur and seized 20 different products/articles/Therapeutic goods on Form 5 and also visited M/S Asma Doll Beauty Bar near Habib Bank Chowk Model Town-A Bahawalpur.

The Committee after careful perusal of case record, statement by the accused persons and stance of area Drug Inspector, unanimously decided to grant the **Permission for Registration of FIR** being the cognizable offence under Schedule II of DRAP Act, 2012 and rules framed thereunder, against the below-mentioned accused persons:

- i. Mr. Asif Akram S/O Muhammad Akram
- ii. Ms. Asma Akram D/O Muhammad Akram

Of M/S Asma Doll H. No. 4 Al Baghdad villas Housing scheme Hasilpur Baghdad-Ul-Jaded Bahawalpur

1. Manufacturing/repacking of drugs/therapeutic goods/medicated cosmetics without license
2. Not registered (unregistered) drugs/therapeutic goods/medicated cosmetics
3. Misbranded drugs/therapeutic goods/medicated cosmetics

The Committee directed the Area Drugs Inspector to launch the complaint against the above-mentioned accused person in concerned Police station at earliest.

v. On the directions of Committee of Provincial Quality Control Board in 32<sup>nd</sup> Committee Meeting dated 25-01-2024, Drug Inspector registered FIR No. 317/24 dated 25-02-2024 .

vi. Investigating Officer submitted complete challan to concerned drug inspector.

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. **Manufacturing/ Repacking/ Selling of drugs/ therapeutic goods/ medicated cosmetics without license**
- b. **Manufacturing/ Repacking/ Selling of Not registered (Unregistered) drugs/ therapeutic goods/ medicated cosmetics**
- c. **Manufacturing/ Repacking/ Selling of Misbranded drugs/ therapeutic goods/ medicated cosmetics**

3. Show-cause notice issued to accused person(s) dated 03-02-2025

Sr.	Summary of the case	
1.	Date of sampling	25-07-2023
2.	Sent to DTL	26-07-2023
3.	Date of receipt in DTL	27-07-2023
4.	Issuance of DTL Report	22-09-2023
5.	Time Extension	N/A
6.	Retesting Request	N/A
7.	Fate of retesting request	N/A
8.	Investigation Report of DI	05-11-2024
9.	Permission of SCN	287 <sup>th</sup> meeting dated 08-01-2025
10.	SC Notice Issued	03-02-2025
11.	Reply of the firm	Not received
12.	History (3 years)	4 cases of the firm (Subject cases)

Personal hearing notice issued to accused person(s)

Case is placed before the Board for decision.

**PROCEEDINGS & DECISION BY THE BOARD:**



Case No. 3

PQCB/SM-19-09/2023

Lyallpur Town, District Faisalabad

ATTENDANCE

<b>Secretary DQCB</b>  <b>Drug Inspector</b>	<p><b><u>Accused Persons involved in subject case</u></b></p> <ol style="list-style-type: none"><li>1. M/s A&amp;K Pharmaceuticals, situated at 94-A, Small Industrial Estate, Sargodha Road, Faisalabad-Pakistan through its CEO/ Managing Director, Muhammad Mohsin Akhtar s/o Akhtar Ali</li><li>2. Muhammad Mohsin Akhtar s/o Akhtar Ali      CEO/ Managing Director</li><li>3. Shahbaz Ali s/o Muhammad Javed Iqbal      Production Manager</li><li>4. Aqsa Hussain w/o Umair Hussain      Quality Control Manager</li><li>5. Pervaiz Anwar s/o Ch. Muhammad Sharif      Plant Incharge</li></ol> <p>of M/s A&amp;K Pharmaceuticals, situated at 94-A, Small Industrial Estate, Sargodha Road, Faisalabad-Pakistan.</p>
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**BRIEF FACTS OF THE CASE**

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

- i. He along with witnesses, on 27-07-2023, inspected the premises of M/s A&K Pharmaceuticals, situated at 94-A, Small Industrial Estate, Sargodha Road, Faisalabad-Pakistan, recovered & seized eighteen (18) different types of articles/drug samples on Form-5. A room with unregistered/unlisted therapeutic goods (without Form-6 & 7) was locked & sealed under contraventions of the Drugs Act 1976 (as amended) / DRAP Act 2012 and Rules framed there under:

Sr. No.	Name of drug	Batch No.	Manufactured by	Quantity	Reason of seizure
1	Exitone Oral Powder 1000gms	EX-00206	M/s A&K Pharmaceuticals	(04) 1000gms	Expired since 02-2023 (Finished Good Store)
2	Lineosole Water Soluble Powder 1000gms	LIN-00192	-do-	(02) 1000gms	Expired since 01-2023 (Finished Good Store)
3	Clozenew Plus Douch 100ml	CLO-064	-do-	(12) 100ml	Expired since June- 2023 (Separate Room)
4	The solution/ liquid app. 500ml sealed in a plastic bottle bearing no label & unit carton	Nil	-do-	(17) 500ml	Misbranded (May be expired liquid and used for repacking)

5	Unit carton of Inj. Genin 100ml	GN-2001	M/s A&K Pharmaceuticals	20	Expired since 02-2022 (From Packing Store)
6.	Label of Inj. Genin	GN-2201	-do-	App. 500	Mfg: 04-22 Expiry: 03-24 (Packing/ Printing Material store)
7.	Yellow color Powder said tube Chlortetracycline HCl packed in polythene transparent bag kept inside round small drum with cap (Brown Color) Identification Tag was removed with sharp instrument			App. 3Kg	Mfg Date: Miss Expiry: Nil Mfg Name: Nill etc.  (Misbranded Powder) Back side label removed which showed may be used for repacking (Misbranded)
8.	Levoxazole Oral Susp.100ml	Nil	-do-	(22) 100ml	
9.	Adek Forte Liquid 1000ml	022	-do-	(10) 1000ml	Un-registered Therapeutic Goods without Form-6 & 7
10.	Jetesole Liquid 1000ml	JS-024	-do-	(10) 1000ml	-do-
11.	Gumbozole Liquid 1000ml	GZ-016	-do-	(10) 1000ml	-do-
12.	Nova AK Torte 500ml	028	-do-	(12) 500ml	-do-
13.	Mentolex Liquid 1000ml	MX-023	-do-	(12) 1000ml	-do-
14.	Jetesole Plus 1000ml	JP-029	-do-	(12) 1000ml	Un-registered Therapeutic Goods without Form No. 6 & 7
15.	Aveta-C 100% 1kg	220630	-do-	(10) 1 kg	-do-
16.	Raw Material Tylosin	L-201203003	Ningxia Taiyiun	34 kg	Expired Dec-19, 2022

	(Pharmagrade)		BioTech.com China	
17.	Oxacare 1000ml Oral Susp, Batch No. OXC-00171, Marisil 1000ml Liquid Batch No. 079, Levoxazole 100ml Batch No. Nil and Misbranded 100ml Bottles kept in labelling sections. Recovered three bottles of each remaining present there.			
18.	White color powder enclosed in a blue polythene bag having no identity.		3 kg	Misbranded Powder

**Raw Material Store:** Vitamins are not stored at registered/ required temperature. Here materials are stored with no partition/ segregation of proper labelling, however, Antibiotic raw material like tetracycline is placed/ store adjusting on same pellet with excipient and vitamin like Vit-C etc. Moreover, KOH is stored with Albendazole. No calibrated pouch was kept there. No liquid raw material store hence the liquid like PG, Methanol etc. placed outside the unit in open air in front of dedusting passage. **Finished Goods Store:** Above mentioned expired drugs have been recovered from Finished Goods Store temperature was not maintained (29.6°C). Finished Goods were stored in front of QC Lab and approximately all the corridors on the floor without pallets attached with walls. **Powder Filling:** Bags were kept there without label. P-Trap and Boards of electric and supply lines were outside wire which were source of dust, contamination. **Liquid Filling Door:** No identification tags on Tanks & machinery. No BMR present there. Temperature is 29°C. **Inject-able Section:** Filled injection vials without labels are placed in injectable Corridor at 1<sup>st</sup> floor. **Packing Room Inject-able:** Flies are flying / seen inside the inj. Packing Room. Packing of different products is being carried out at same place. Different areas of inject-able sections are being painted/ white washed without displaying the tag “under renovation”. There is no signboard of above said unit for identification placed/ displayed outside.

- i. The drug inspector Lyallpur Town, District Faisalabad also took three different types of samples on Form No 04 dated 27-07-2023 and sent to Drugs Testing Laboratory Faisalabad for the purpose of test/analysis. These samples declared of standard qualities from Drugs Testing Laboratory Faisalabad.
- ii. Case was considered in 269<sup>th</sup> meeting dated 03-10-2023 and Board, after due deliberation and discussion at length unanimously decided to grant permission for registration of FIR On the direction of Provincial Quality Control Board. Drug Inspector registered FIR No. 1552/23 dated 18-10-2023 against you.

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)/ Schedule II of The DRAP Act 2012 and Rules framed there under by the way of: -:

1. **Violation of DRAP Act 2012 Schedule-II, Drugs Act 1976, cGMP**
2. **Expired Drugs**
3. **Misbranded Drugs**
4. **Unregistered Therapeutic Goods (Form-7)**
5. **Manufacturing without Enlistment Form No. 6**
6. **Manufacturing/ stocking/ selling without product enlistment Form No. 7**
7. **Expired Raw Material**
8. **Expired Packing Material**
9. **Without Signboard Building**
10. **Dirty, Dusty Conditions**

Drug Inspector also requested the Board to grant **extension in sealing period** and **custody of seized drugs/items**.

3. Show-cause notice(s) issued to accused person(s) dated 22-10-2024
4. Personal hearing notice(s) issued to accused person(s) dated 22-10-2024
5. Case is placed before the Board for decision.

**Summary:**

**Inspection Date:** 27-07-2023

**PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD:**

5. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **269<sup>th</sup> meeting** held on **03-10-2023** under the Chairmanship of Secretary, Primary & Secondary Healthcare Department Punjab. Ms. Rubina Akhtar, District Faisalabad attended the meeting online via zoom link and Mr. Saqib Javaid Bhatti, Drug Inspector Lyallpur Town, District Faisalabad was present along with the original case record. Among the nominated accused persons, Shahbaz Ali (Production Incharge) and Pervaiz Anwer (Plant Manager) of M/s A&K Pharmaceuticals, situated at 94-A, Small Industrial Estate, Sargodha Road, Faisalabad-Pakistan appeared before the Board and pleaded their case upon following grounds:

- They are a licensed manufacturer of allopathic drugs since 2004, with more than 100 products registered and the map for their Nutraceutical unit has been approved from the DRAP.
- Only trial batches of the Nutraceutical products were being manufactured at the time of inspection by the drug inspector.
- They have placed the recovered expired API/ Excipients in a separate room in the manufacturing premises.

6. The Drug Inspector, Lyallpur Town, District Faisalabad briefed case to the Board regarding details of his inspection of M/s A&K Pharmaceuticals, situated at 94-A, Small Industrial Estate, Sargodha Road, Faisalabad-Pakistan that firm failed to provide valid Drug Manufacturing License and any plan for Nutraceutical Unit approved from DRAP. The firm also failed to provide any proof of registration of the nutraceutical products being manufactured in the same premises and further no sale/ purchase record was provided by the firm at the time of inspection. The drug inspector Lyallpur Town, Faisalabad also presented the pictorial evidence of huge quantities of illegally manufactured therapeutic goods such as Multivitamin Solution named Jetesole 1000ml, Nova AK Forte 500ml, Adek Forte Liquid 1000ml, all manufactured by M/s A&K Pharmaceuticals.

7. The Board after careful perusal of the case record, statements of the accused of the firm present and stance of the drug inspector observed that:

- Firm failed to provide valid Drug Manufacturing License for pharmaceutical products, any approved plan for Nutraceutical Unit, approval from DRAP to manufacture trial batches of nutraceutical products and proof of registration of recovered therapeutic goods from their premises.
- Firm was utilizing the same premises as that for the pharmaceutical products to manufacture those trial batches of nutraceutical products.
- Firm was unable to exhibit Enlistment Form No. 6 & 7 despite repeated enquiries by the Board.
- Some of the articles/ drugs were expired since long and the firm was unable to provide any satisfactory



11. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 286th meeting held on 30.10.2024 under the Chairmanship of Special Secretary (operations), Primary & Secondary Healthcare Department, Punjab/ Vice-Chairman, PQCB. Ms. Rubina Akhtar , Secretary DQCB, Faisalabad attended the meeting via zoom link and Mr. M. Saqlain, Drug Inspector, Lyallpur Town, District Faisalabad was present along with original case record. Pervaiz Anwar (nominated as Plant In charge) and in attendance GM among the nominated accused person on behalf of M/s A&K Pharmaceuticals, situated at 94-A, Small Industrial Estate, Sargodha Road, Faisalabad-Pakistan appeared before the Board. The firm submitted request for adjournment.

The Board after discussion unanimously decided to adjourn the case in best interest of justice and further decided to provide another/ final chance of personal hearing to accused persons.

Personal hearing notice(s) issued to accused person(s) dated 14-02-2025 and Case is placed before the Board for decision.

**PROCEEDINGS AND DECISION BY THE BOARD:**

Case No. 4

**PQCB/R-505/2022**

**Lahore General Hospital, Lahore**

**ATTENDANCE**

<b>Secretary DQCB</b>  <b>Drug Inspector</b>	<p><b><u>Accused Persons involved in subject case</u></b></p> <p>1. <b>M/s PharmaWise Labs (Pvt.) Ltd. formerly Fakma Pharma (Pvt.) Ltd., 25-M Q.A. Industrial Estate, Lahore-Pakistan</b> through its Chief Executive Officer (CEO), Ch. Nadir Khan.</p> <p>2. Ch. Nadir Khan                      Chief Executive Officer (CEO)</p> <p>3. Saba Adnan                              Production Incharge</p> <p>4. Abida Abbas                              Quality Control Incharge/Warrantor</p> <p><b>of M/s PharmaWise Labs (Pvt.) Ltd. formerly Fakma Pharma (Pvt.) Ltd., 25-M Q.A. Industrial Estate, Lahore-Pakistan.</b></p>
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**BRIEF FACTS OF THE CASE**

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

- i. She, on 17-08-2022, inspected the premises of Main Medicine Store of Lahore General Hospital, District Lahore, took following drug sample on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory Lahore vide memorandum no. 136798 dated 17-08-2022.
- ii. The 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
Capsule. WISPRAZOL [Omeprazole 20mg]  <b>Mfg Date:</b>  July 2022  <b>Expiry Date:</b>  July 2025	032	M/s PharmaWise Labs Pvt. Ltd. formerly Fakma Pharma Pvt. Ltd., 25-M Q.A. Industrial Estate, Lahore- Pakistan.	01- 177002454/DTL  dated  15-10-2022	<p><b>Analysis with specifications applied: USP 2021</b></p> <p><b><u>PHYSICAL CHARACTERISTICS:</u></b> White coloured spherical pellets enclosed in hard gelatin purple cap and off-white body in blister packing of seven units.</p> <p><b><u>IDENTIFICATION:</u></b> The retention time of the major peak in the sample chromatogram corresponds to the retention time of the major peak in standard chromatogram. (OMEPRAZOLE IDENTIFIED).</p> <p><b><u>ASSAY OF OMEPRAZOLE:</u></b></p> <p>Stated:            20 mg/ caps</p> <p>Determined:    20.84 mg/ caps</p> <p>Percentage:    104.19%</p> <p>Limit:            90.0% – 110.0 % of the labelled amount</p>



Board. The Secretary PQCB apprised that Drug Testing Laboratory report conveyed by the Provincial inspector of Drugs to manufacturer vide letter No. DI/674/LGH Dated 03-11-2022 received by Institutional Manager of firm Habib-Ullah on 04-11-2022 and Manufacturer requested for retesting vide letter no Nil dated 12-11-2022 on unusual conditions.

3. The office of the Provincial Quality Control Board asked the firm, to adduce evidence in controversion of Govt. Analyst Test Report vide letter No. PQCB/P-879-10/2022 dated 23.11.2022 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) but the firm did not adduce evidence. While, the firm submitted the reply vide letter no. nil dated 12.12.2022 and requested that:

*“to constitute a committee under Rule 5(2) of Punjab Drug Rules 2007, in whose presence our exactly the same above drug Wisprazol Capsules are tested by the same Govt. Analyst who tested it previously and reported it to be of Substandard Quality, indeed in the presence of our analyst.”*

4. The matter was discussed in detail by the Board. The Board after due deliberation and discussion unanimously decided that if the firm adduced the evidence u/s 22 (4) of the Drugs Act, 1976 (as amended) then the subject request for retesting shall be **Allowed**. Otherwise, the subject request for retesting **Turned Down** as there is no such provision in the Drugs Act 1976 (as amended)/DRAP Act, 2012 and rules framed there under to retest the sample from the same Provincial Drug Testing Laboratory.

**In response to PQCB Orders regarding retest request, M/s PharmaWise submitted a copy of letter dated 30-03-2023 in the office of the PQCB in which firm withdrew its retesting letter dated 12-11-2022**

*Under the heading of DISSOLUTION TEST (BUFFER STAGE), USP 2021 has given TEST-1 and TES-2. Under the heading of LABELLING, the same USP has advised that the respective manufacturer of Capsule Omeprazole for Buffer Stage testing if employs TEST-2, he shall declare the same on label of the container of his same product i.e. Capsule Omeprazole, failing which the Regulatory shall employ TEST-1. **Keeping in view the SANCTITY of the above advice / direction/ guidance of the USP, we M/S PharmaWise Labs., who employs the above test-2, has DEFAULTED as neither NDIVIDUAL BLISTER of 07 Capsules of our above drug nor its 154's Capsules carton bear printed on them the expression "FOR BUFFER STAGE DISSOLUTION TEST PLEASE FOLLOW USP TEST-1."***

*In view of the humble submissions made as above it is requested to ask the learned Mst. Sidra Saghir, The Govt. Analyst to conduct Buffer Stage Dissolution Test-2 on our above drug. Capsule Wisprazol by employing USP DISSOLUTION TEST-2, by taking the sample from the balance quantity lying in safe custody with DTL, Lahore. Alternately sample of our above same drug be again sent to DTL by Madam Sehrish Iqbal, The Drug Inspector, Lahore General Hospital, Lahore for saving the patient from non-availability of the above drug, in the hospital.*

*In the meantime, we withdraw our letter dated 12-11-2022 addressed to Madam Sehrish Iqbal, Drug Inspector Lahore General Hospital, Lahore, copy of which was also sent to Mr. Muhammad Shafeeq Rana, The then Secretary PQCB, Punjab, Lahore. The above default on our part and the INCONVENIENCE caused is deeply regretted, as TO ERR IS PRECISLY HUMAN AND NOT TO RECTIFY IS EVIL.*

6. 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**

7. Show-cause notice(s) issued to accused person(s) dated 31.08.2023.

**Firm replied to the show cause notice vide letter dated 19-09-2023**

Kindly refer to the subject Show Cause Notice, delivered to us by postal authorities on 13-09-2023. In this behalf we state:

Whatever has been conveyed to us through the above Show CAUSE NOTICE, kindly appreciate that presently all that is PREMATURE and uncalled for as explained below:

1. Herewith we enclose photocopy of our duly receipted letter dated 03-04-2023 addressed to Madam Farzana Andleeb, The Director Drug Testing Laboratory, Lahore. Copy of the same was also duly delivered to your good office on 03-04-2023.
2. Herewith we enclose photocopy of our duly receipted letter dated 03-04-2023 addressed to Madam Serish Iqbal, Drug Inspector, Lahore General Hospital, Lahore. Copy of same along with its enclosures was also delivered to your good office.
3. In both our above letters we respectfully intimated that for carrying out **BUFFER STAGE DISSOLUTION TEST, TEST-2, given in USP-21 was to be employed**, in the case of our above drug Capsule Wisprazol by Govt. Analyst. We therefore in both our above letters requested your honor to request the concerned Govt. Analyst to please carryout "BUFFER STAGE DISSOLUTION TEST-2" on our above drug and accordingly issue Test Analysis Report in Form-7.
4. Kindly peruse that in the above-mentioned SHOW CAUSE NOTICE there is **no mention of any of our above letters** dated 03-04-2023 and thus it seems that your office inadvertently missed to entertain our, by all means, valid request.
5. It is relevant to record that all over the country, at present, there are **ten manufacturers of Capsules Omeprazole** the samples of which are tested / analyzed by each of Drug Testing Laboratory of Punjab. In each case the above Buffer Stage Dissolution Test-2, given in USP21 is performed.
6. With the permission of the learned BOARD, it is also relevant to record that for manufacturing **OMEPRAZOLE CAPSULES, OMPRAZOLE PALLETS of required strength are procured from market**. At present there is only one manufacturer M/S Vision Pharmaceuticals (Pvt) Limited, 22-23 Industrial Triangle Kahuta Road, Islamabad, who advice the manufacturer to carry out the above Test-2, on the pallets supplied by them.
7. **We have no hesitation in accepting our inadvertent negligence that prior to January 2023. we did not know that USP directs to print on the packing material of Capsule Omeprazole. "THE PRODUCT MEETS THE USP DISSOLUTION TEST-2"**, which vide our above letter dated 03-04-2023, we intimated to all the concerned including the worthy PQCB, your office that since January 2023 we started printing the same on the Aluminum Foil of blister of our drug Capsule Wisprazol (Omeprazole 20-mgs).
8. It is also pertinent to record over-here that due to our above omission **huge quantity** of 3-Lacs (300,000) Wisprazol Capsule (Omeprazole Capsule 20-mgs), worth Rs. 462,000/- are lying stuck up in the drug store of Lahore General Hospital, Lahore.

In view of the humble submission made as above it is requested to favour so that our above drug Capsule Omeprazole is **retested for Buffer Stage testing** according to USP Dissolution Test-2 by taking the sample from the remainder quantity lying in DTL Lahore or by directing the Madam Sehrish Iqbal, Drug Inspector, LGH, Lahore to **again send the sample** with the above note on Form-6.

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

**CURRENT PROCEEDINGS AND DECISION BY THE BOARD:**

10. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **275<sup>th</sup> (Special) meeting** held on **31-01-2024** under the Chairmanship of Special Secretary, Primary & Secondary Healthcare Department Punjab/ Vice-Chairperson PQCB. Mr. Hassan Saeed, Secretary DQCB District Lahore and Ms. Sadia Rana, Drug Inspector Lahore General Hospital, District Lahore was present along with the original case record. Among the nominated accused persons, Ch. Nadir Khan (Chief Executive Officer) of M/s PharmaWise Labs

Pvt. Ltd. formerly Fakma Pharma Pvt. Ltd., 25-M Q.A. Industrial Estate, Lahore-Pakistan appeared before the Board and submitted that the nominated Production & Quality Control Incharges have left the firm, so he is representing them too. Firm's representative stated that the DTL has not applied Dissolution Test-2 while testing their subject drug sample, as the firm is procuring Omeprazole Pallets of required strength from M/s Vision Pharmaceuticals (Pvt) Limited who also advises manufacturer to apply Dissolution Test-2. He further admitted that they were unaware of the requirement laid down by USP to mention on the label if dissolution testing is being carried out in accordance with Dissolution Test 2. Firm's CEO reiterated firm's request for testing their subject product while applying dissolution test-2 and requested the Board for a lenient view while presenting the updated label of the subject drug sample by mentioning "Dissolution Test-2" on the label. He assured the Board their product is now being marketed with this corrected label.

11. The Board after careful perusal of the case record and scrutiny of DTL report observed that the Capsule. Wisprazol [Omeprazole 20mg] Batch No. 032 has been declared substandard by the Drugs Testing Laboratory, Lahore on the basis of non-compliance of dissolution test as the sample failed to comply the release limit at S1 stage, as percentage release of all six units was determined to be below Q-25% (50%) when tested as per USP specifications. The Board observed that the testing of the subject drug sample was carried out by applying Dissolution Test-1 in accordance with the USP Specifications, whereas, nowhere on the label of the subject sample the manufacturer has mentioned regarding the application of firm's claimed Dissolution Test-2 which, as per USP Specifications has to be mentioned on the label otherwise.

12. The Board further observed that the firm has now taken the remedial measures in the label of Capsule Wisprazol by mentioning "Dissolution Test-2" on it. The label of sample in question is not having the type of Dissolution test. Hence, the Board, after due deliberation and detailed discussion decided to **pend the case** of M/s PharmaWise Labs Pvt. Ltd. formerly Fakma Pharma Pvt. Ltd., 25-M Q.A. Industrial Estate, Lahore-Pakistan and recommended to **send the sample** of drug Capsule Wisprazol to the Pakistan Drug Testing and Research Centre ( **PDT&RC**), Lahore for Dissolution Testing on USP Test-2, on expenditure of the firm. The PDT&RC will submit the test/ analysis report to the firm and to the office of the Secretary PQCB which will be then placed before the Board for decision of the case.

13. The sample was submitted to Pakistan Drug Testing and Research Centre (PDT&RC), Lahore for Dissolution Testing on USP Test-2, from where the sample was declared **Standard** as detailed below:

Name of drug	Batch No.	Name of manufacturer	Test Report No. & Date	NIH Test Report Results												
Cap Wisprazol	032	M/S PharmaWise Labs Pvt. Ltd. formerly Fakma Pharma Pvt. Ltd., 25-M Q.A. Industrial Estate, Lahore-Pakistan	PDTRC/TR-Pharma/061/2024 dated 26.12.2024	<p><b>Method/ Specs Applied:</b> USP</p> <p><b>Detail of Test/ Analysis and Result:</b></p> <table border="1"> <tr> <td><b>Dissolution Test 2 Buffer Stage</b></td> <td><b>Determined</b></td> <td>92.489%</td> <td><b>Limit</b></td> <td>NLT</td> <td>75%</td> </tr> <tr> <td><b>Dissolution Test 2 Acid Stage</b></td> <td><b>Determined</b></td> <td>11.505%</td> <td><b>Limit</b></td> <td>NMT</td> <td>15%</td> </tr> </table> <p><b>Result:</b> The Sample is of <b>Standard Quality</b> on the basis of Test Performed.</p>	<b>Dissolution Test 2 Buffer Stage</b>	<b>Determined</b>	92.489%	<b>Limit</b>	NLT	75%	<b>Dissolution Test 2 Acid Stage</b>	<b>Determined</b>	11.505%	<b>Limit</b>	NMT	15%
<b>Dissolution Test 2 Buffer Stage</b>	<b>Determined</b>	92.489%	<b>Limit</b>	NLT	75%											
<b>Dissolution Test 2 Acid Stage</b>	<b>Determined</b>	11.505%	<b>Limit</b>	NMT	15%											

12. Personal hearing notice(s) issued to accused person(s) dated 14.02.2025.

13. Case is placed before the Board for decision.

**Summary:**

**Manufacturing Date:** 07.2022

**Expiry Date:** 07.2025

**Sampling Date (Form 4):** 17.08.2022

**Sent to DTL (Form 6):** 17.08.2022

**Date of receipt in DTL:** 18.08.2022

**DTL Report Date (Form 7):** 15.10.2022

**Time Extension:** Not Time Barred

**1<sup>ST</sup> DI Communication with firm on dated:** 03.11.2022

**Retesting Request of Firm:** 12.11.2022

**Fate of Firm's Retest Request:** The Board after due deliberation and discussion unanimously decided that if the firm adduced the evidence u/s 22 (4) of the Drugs Act, 1976 (as amended) then the subject request for retesting shall be **Allowed**. Otherwise, the subject request for retesting **Turned Down** as there is no such provision in the Drugs Act 1976 (as amended)/DRAP Act, 2012 and rules framed there under to retest the sample from the same Provincial Drug Testing Laboratory. Then the request letter was withdrawn by the firm vide letter dated 30.03.2023.

**Investigation Report Dated:** 18.04.2023

**SCN:** 31.08.2023

**Reply SCN:** 19.09.2023

**History (Last 03 Years): Product: 01 subject reported case, Firm: 04 cases reported including subject case.**

**CURRENT PROCEEDINGS & DECISION BY THE BOARD:**

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Case No. 5

PQCB/R-491/2023

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

**ATTENDANCE:**

Secretary DQCB	<b><u>Accused Persons involved in subject case</u></b>
Drug Inspector	
	1. M/S Medi-Vet (Pvt) Ltd., 17Km Sheikhpura Road, Lahore-Pakistan, through its Director, Razia Khalid
	2. Razia Khalid Director
	3. Shakeel Ahmad Production Manager
	4. Dr. Muzammal Sattar Quality Control Manager
	5. Akif Mehmood Warrantor
	of M/S Medi-Vet (Pvt) Ltd., 17Km Sheikhpura Road, Lahore-Pakistan.

**BREIF FACTS OF THE CASE:**

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

- i. He, on 10-01-2023, inspected the business premises of M/s Hadi Pets & Vets Clinic, Railway Road, Dera Ghazi Khan and took 02 different types of drug samples on Form No.04 for the purpose of test/analysis and sent to Drug Testing Laboratory, Multan.
- ii. The subject drug sample, sent vide memo no. 153908 dated:10-01-2023, 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 Melacam-10 [Each ml contains, Meloxicam B.P...10mg]	22W-01	M/S Medi-Vet (Pvt) Ltd., 17Km Sheikhpura Road, Lahore-Pakistan.	01-105000634 /DTL, Dated 11-03-2023
<b>Mfg. date: 09-2022</b>			
<b>Exp. date: 09-2024</b>			
<b>Reg # 063542</b>			
<b>Specification applied: BP vet 2022</b>			
<b>Description:</b> A light yellow color liquid in a labeled amber glass vial closed with a rubber stopper and seal with aluminum packed in a labeled outer hard carton.			

**Identification** Meloxicam Identified.

**Assay: HPLC**

Meloxicam

Stated: 10.0 mg/ mL

Determined: 9.5 mg/ mL

Percentage: 95.0 %

Limit: 95-105% (Complies)

**Extractable Volume**

Limit: NLT stated (50ml)

Determined: 50.0.0 mL (Complies)

**pH**

Limit: 7.5- 9.1

Determined: 11.16 (Does not Comply)

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

**Result:** The above sample is **Sub-Standard** on the basis of **pH Test**.

- iii. M/s Hadi Pets & Vets Clinic, Railway Road, Dera Ghazi Khan, provided invoice/ warranty No. 0 dated: 25-12-2022 and No. 0 dated: 05-01-2023 issued by M/S New Baloch Medicine & Vet Store, Tounsa Road, Chowk Choraththa, D.G. Khan, as a proof of its purchase.
- iv. Warrantor portion of drug sample was sent to M/S New Baloch Medicine & Vet Store, Tounsa Road, Chowk Choraththa, D.G. Khan.
- v. M/s New Baloch Medicine & Vet Store, Tounsa Road, Chowk Choraththa, D.G. Khan in turn provided invoice/warranty no. MV/D.G.K-123/22082 dated: 29-10-2022 issued by M/S Medi-Vet (Pvt) Ltd., 17Km Sheikhpura Road, Lahore-Pakistan, as a proof of purchase.
- vi. A copy of test/analysis report was sent to M/S Medi-Vet (Pvt) Ltd., 17Km Sheikhpura Road, Lahore-Pakistan, and they were asked to explain their position and provide the requisite information in this regard.
- vii. In Response, the firm challenged the test/analysis report and requested for re-testing of the above-mentioned drug sample from Appellate Laboratory NIH, Islamabad. The retesting request was allowed in 26<sup>th</sup> Committee meeting held on 11-10-2023.
- viii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the sample was declared **Substandard** as detailed below:

Name of drug	Batch No.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Injection Melacam-	22W-01	M/S Medi-Vet (Pvt) Ltd.,	0231-P/2023	<b>Analysis with specifications applied: BP- Vet 2017</b>

10	17Km Sheikhupura Road, Lahore-Pakistan.	dated: 31-10-2023	<p><b>pH</b></p> <p>Determined: 10.4 ±0.06</p> <p>Limit: 7.5- 9.1</p> <p><b>(Does Not Comply with BP- Vet 2017)</b></p> <p><b>Result:</b> The sample is of <b>Substandard</b> quality on the basis of test performed.</p>
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ix. Copy of NIH report was sent to M/S Medi-Vet (Pvt) Ltd., 17Km Sheikhupura Road, Lahore - Pakistan.

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

Names of accused	Offence
<p>1. M/S Medi-Vet (Pvt) Ltd., 17Km Sheikhupura Road, Lahore-Pakistan, through its Director, Razia Khalid</p> <p>2. Razia Khalid Director</p> <p>3. Shakeel Ahmad Production Manager</p> <p>4. Dr. Muzammal Sattar Quality Control Manager</p> <p>5. Akif Mehmood Warrantor</p> <p>of M/S Medi-Vet (Pvt) Ltd., 17Km Sheikhupura Road, Lahore-Pakistan</p>	<p>a. Manufacturing for sale /sale of Substandard drug</p> <p>b. Issuance of false warranty</p>
<p>6. Razia Khalid Director</p> <p>7. Akif Mehmood Warrantor</p> <p>of M/S Medi-Vet (Pvt) Ltd., 17Km Sheikhupura Road, Lahore-Pakistan</p>	<p>In connivance with each other have contravened the provision of section 23 (1)(a)(f) by supplying incorrect and misleading informations and signed the warranty statement of invoice no. MV/D.G.K-123/22082 dated: 29-10-2022 by using the name of a deceased director Saeed Iqbal Sheikh (Late) as warrantor, despite knowing his death.</p>

3. Show-cause Hearing notice issued to accused person(s) dated 27-11-2024

Sr.	Summary of the case
1.	<p>Date of sampling</p> <p>10-01-2023</p>
2.	<p>Sent to DTL</p> <p>10-01-2023</p>

3.	<b>Date of receipt in DTL</b>	13-01-2023
4.	<b>Issuance of DTL Report</b>	11-03-2023
5.	<b>Time Extension</b>	N/A
6.	<b>Retesting Request</b>	yes 31-03-2023
7.	<b>Fate of retesting request</b>	Allowed (Substandard)
8.	<b>Investigation Report of DI</b>	12-07-2024
9.	<b>Permission of SCN</b>	282 <sup>nd</sup> meeting dated 24-07-2024
10.	<b>SC Notice Issued</b>	27-11-2024
11.	<b>Reply of the firm</b>	Not received
12	<b>History (3 years)</b>	Total cases: 04 cases of product: 3

Case is placed before the Board for decision.

**PROCEEDINGS & DECISION BY THE BOARD:**

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