MINUTES OF 291ST MEETING OF CENTRAL LICENSING BOARD HELD ON 30th MAY, 2023

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291st meeting of the Central Licensing Board (CLB) was held on 30th May, 2023 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Dr. Akhtar Abbas Khan, Director (Licensing), Drug Regulatory Authority of Pakistan, Islamabad Chaired the meeting. Following members attended the meeting: -

S.No	Name & Designation	Status
1.	Mrs. Ume Laila Additional. Director, Drug Regulatory Authority of Pakistan, Islamabad.	Secretary/ Member
2.	Mr. Azher Jamal Saleemi, Chief Drugs Controller, Government of Punjab, Lahore	Member
3.	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Baluchistan, Quetta	Member
4.	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Government of Khyber Pakhtunkhwa.	Member
5.	Mr. Ghulam Ali Lakho, Chief Inspector of Drugs , Government of Sindh, Karachi	Member
6.	Mr. Ajmal Sohail, Director, Division of Quality Assurance and Lab Testing, Drug Regulatory Authority of Pakistan, Islamabad	Member
7.	Mr. Abid Ali, Deputy Draftsman, Ministry of Law & Justice Division, Islamabad	Member

Mrs. Ume Laila Additional Director / Secretary Licensing Board presented the agenda before the Board. Mr. Mubashir Iqbal Deputy Director (Lic), Ms. Zunaira Faryad, AD (Lic) and Mr. Yaqoob Kakar, Assistant Director (Lic), Mr. Hasan Afzaal and Umer Latif DD QA assisted the Secretary Central Licensing Board in presenting the agenda. The Board deliberated and decided the following case on priority as per orders from the Honorable Islamabad High Court.

Item-I **CONFIRMATION OF THE MINUTES OF 290th MEETING**

290th meeting of the Central Licensing Board (CLB) was held on 28th April, 2023 in the Committee Room, DRAP, Islamabad. Accordingly, draft minutes of 290th meeting of Central Licensing Board were circulated among members through WhatsApp and email for perusal and comments (if any). All members consented the draft minutes through WhatsApp/email and after approval of Chairman CLB, fair minutes were circulated among relevant Divisions / Sections

for implementation / compliance of decisions. Moreover, it was decided that CLB meetings would be scheduled at least every 2 months or as needed.

Presentation: **WHO GLOBAL BENCHMARKING OF NATIONAL REGULATORY SYSTEM OF PAKISTAN.**

WHO Regulatory System Strengthening team conducted Benchmarking of National Regulatory System of Pakistan from 03-12 May, 2023. WHO mission comprises 14 Auditors from WHO HQ Geneva, EMRO office, Cairo and Country office as well as experts from leading NRAs having ML-3 participated in the Benchmarking against WHO computerized Global Benchmarking Tool. WHO Auditors visited DRAP, Central Drug Laboratory Karachi and Directorate of Drugs Control Punjab, for interviewing the regulatory work force of Pakistan. Dr. Alirerza Khadim, WHO Team Lead, applauded the progress made by the DRAP and affiliated organizations in recent years. WHO team provided its recommendations for further strengthening of regulatory system and agreed on roadmap for future collaboration.

Licensing is one of the module of GBT. Two auditors audited the Licensing functions of the DRAP on GBT tool. Licensing Division has prepared a presentation for worthy members of the Central Licensing Board. The objective of the presentation is to request the Board to devise a mechanism for information sharing and timeframe to improve coordination / communication among DRAP and provinces.

Discussion and Decision:

The Board appreciates the efforts of the DRAP and Licensing divisions in successfully completing the WHO benchmarking process. The board further discussed that all stakeholders should be actively involved in achieving WLA status through the implementation of Quality Management Systems (QMS). To ensure that the licensing division is receiving the necessary information as per Institutional Development Plans from provincial drug control units, it was decided that CDIs/members shall initiate the process of establishing QMS in their respective departments.

A. DRUG LICENSING DIVISION

Item-II **GRANT OF NEW DRUG MANUFACTURING LICENSE.**

The respective panel of experts for grant of Drug Manufacturing License has forwarded following cases. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection /	Ranking/ Evaluation	Inspection Panel Members
1	M/s Air Pharmaceuticals (Pvt) Ltd, Plot No.74-75-A, Small Industrial Estate, Kasur.	16-05-2023	Good	1. Mr. Muhammad Shamoon Chaudhary, Expert Member. 2. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Mr. Nafees Ur Rehman, Assistant Director (I&E), DRAP, Lahore.

Recommendations of the panel: -

Based on the areas inspected, technical staff met, discussion held during inspection, the documents reviewed and considering the findings of the inspection, the panel **recommends** the grant of Drug Manufacturing License (By way of formulation) to M/s Air Pharmaceuticals (Pvt) Ltd, Plot No.74-75-A, Small Industrial Estate, Kasur, for **Syrup Section (General) only**.

It is pertinent to mention here that a notice has been received from **Assistant Registrar (Writ), Islamabad High Court, Islamabad that W.P 824/2023** has been filed by Abdul Ghaffar S/o Muhammad Yousaf Vs FOP etc. He pleaded that DRAP may be directed to cancel the approval/license issued in favor of M/s Air Pharmaceuticals (Pvt.) Ltd., Kasur as the proposed pharmaceutical unit is only at the distance of 50feet from the building of waste management Disposal where the waste of hospitals of Punjab is being disposed of and the proposed site is also surrounded by brick kilns, the smoke of which is harmful for human life.
The case was fixed on 17-05-2023in the Islamabad High Court but was not listed.

Decision of the Central Licensing Board in 291st meeting:

The Board considered the facts and deferred the grant of Drug Manufacturing License by way of Formulation in the name of M/s Air Pharmaceuticals (Pvt) Ltd, Plot No.74-75-A, Small Industrial Estate, Kasur for taking legal opinion from Mr Abid Ali, member CLB.

2	M/s PharmArt Laboratory, Plot No.G-56, Phase II, S.I.T.E., Super Highway, Karachi	19-05-2023	Good	1. Additional Director (E&M), DRAP, Karachi. 2. Mr. Ghulam Ali Lakho, CDI, Karachi. 3. Mr. Muhammad Yaqoob Kakar, Assistant Director, DRAP, Islamabad.

Recommendations of the panel: -

As per instructions contained in DRAP, Islamabad Letter No.F.2-13/2021-Lic Dated: 30th March, 2023, a detailed inspection of M/s PharmArt Laboratory, Plot No.G-56, Phase II, S.I.T.E., Super Highway, Karachi was carried out on 19th May, 2023. During opening meeting their Organogram, JDs, SMF, approved design, HVAC provision and design, medical reports of employees, SOPs were discussed at length and found an adequate retrieval and an appropriate maintenance of key documents. The firm is found built as per approved. Total 33 AHUs are provided in production areas for better compliance & to control the hazards of contamination. All Equipment's noted adequately installed. Lab equipment's were seen calibrated and with proper log books. Quality manuals, IQ, QQ &PQ documents were also in place. Firm has HPLC & FTIR for testing its QC lab.

Keeping in view the above stated facts the panel unanimously recommends the grant of Drug Manufacturing License (By way of formulation) for following sections;
(1) Tablet (General) (2) Capsule (General) (3) Syrup/Suspension (General) (4) Sachet (General) (5) Tablet (Cephalosporin) (6) Capsule (Cephalosporin) (7) Dry Powder Suspension (Cephalosporin) (8) Sterile Dry Powder Injection (Cephalosporin) (9) Sachet (Cephalosporin)

Decision of the Central Licensing Board in 291st meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s PharmArt Laboratory, Plot No. G-56, Phase II, S.I.T.E., Super Highway, Karachi on the recommendations of the panel of experts for the following sections subject to verification of necessary testing equipment.

(1) Tablet (General)
(2) Capsule (General)
(3) Syrup/Suspension (General)
(4) Sachet (General)
(5) Tablet (Cephalosporin)
(6) Capsule (Cephalosporin)
(7) Dry Powder Suspension (Cephalosporin)
(8) Sterile Dry Powder Injection (Cephalosporin) (9) Sachet (Cephalosporin)

Item- II: **GRANT OF ADDITIONAL SECTIONS/ REVISION/AMENDMENTS ETC.**

<table>
<tr><th>S #</th><th>Name of the firm</th><th>Date of Inspection /</th><th>Ranking/ Evaluation</th><th>Inspection Panel Members</th></tr>
<tr><td>1</td><td>M/s. Pharmagen Ltd, Kot Nabi Bukhsh Wala, 34-Km Ferozepur Road, Lahore.

DML No.000325 (Semi-Basic).

<u>APIs (03)</u>.

i. Montelukast Sodium
ii. Sitagliptin Phosphate
iii. Valsartan</td><td>21-03-2023
&

22-058-2023</td><td>Good</td><td>1. Muhammad Shamoon Ch. Expert Member
2. Majida Mujahid, Additional Director, DRAP, Lahore.
3. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore.
4. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore</td></tr>
<tr><td></td><td colspan="4">Recommendations of the panel: -

The panel of inspectors recommends for the renewal of drug manufacturing license and the grant of the products Montelukast Sodium, Sitagliptin Phosphate and Valsartan (subject to development and performance of nitrosamines (NDMA and NDEA etc) impurities testing in valsartan API) under DNL No.000352 in favor of M/s Pharmagen Ltd, 34-Km, Ferozepur Road, Lahore to manufacture Active Pharmaceutical Products by way of semi-basic manufacturing as per above mentioned list.

<u>Decision of the Central Licensing Board in 291st meeting:</u>

The Board considered and approved the grant of following additional API and Manufacturing Flow Chart in the name of M/s. Pharmagen Ltd, Kot Nabi Bukhsh Wala, 34-Km Ferozepur Road, Lahore under DML No. 000325 (Semi-Basic Manufacture) on the recommendations of the panel of experts' subject to confirmation from the firm regarding pharmacopeia.

<u>API (03)</u>

i. Montelukast Sodium
ii. Sitagliptin Phosphate.

The Board further decided to refer back "Valsartan" to the Panel of inspectors for their clear recommendation.</td></tr>
<tr><td>2</td><td>M/s. Abbot Laboratories (Pakistan) Limited, Plot</td><td>23-05-2023</td><td>Good</td><td>1. Additional Director, DRAP, Karachi.
2. FID, DRAP, Karachi.</td></tr>
</table>

	No.13, Sector 20, Korangi Industrial Area, Karachi. **DML No.** 000004 (Formulation) **<u>Facility (01)</u>:** i. Finished Good Warehouse for New Proposed Cold Room			3. Deputy Director, DRAP, Karachi.

Recommendations of the panel: -

Based on the people met, areas visited and commitment of the Firm's management for continuous improvement of personnel, processes and facilities, the panel is of the view to recommend:

- Grant of Amendments in Facilities under Drug Manufacturing License (By way of Formulation) No.000004 to the firm M/s. Abbot Laboratories (Pakistan) Limited, Plot No.13, Sector 20, Korangi Industrial Area, Karachi holding Drug Whole Sale License no.048/2023dated 18/01/2023 (copy enclosed) for following section:

<u>Decision of the Central Licensing Board in 291st meeting:</u>

The Board considered and approved the grant of following additional facility in the name of M/s. Abbot Laboratories (Pakistan) Limited, Plot No.13, Sector 20, Korangi Industrial Area, Karachi under DML No. 000004 (Formulation) on the recommendations of the panel of experts for following facility.

i. Finished Good Warehouse for New Proposed Cold Room

Item-IV: **GRANT OF RENEWAL / REGULARIZATION OF LOP OF DRUG MANUFACTURING LICENSES.**

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses and regularization. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s Medisure Laboratories Pakistan (Pvt) Ltd., A-115, S.I.T.E., Super Highway, Karachi. DML No.000503 (Formulation) **Period:** Commencing on 06-10-2022& ending on 05-10-2027.	18-05-2023	Good	1. Chief Drug Inspector, Sindh. 2. Area FID, DRAP, Karachi. 3. Assistant Director, DRAP, Karachi.

Recommendations of the panel:

As per instructions contained in DRAP, Islamabad Letter No.F.2-2/2001-Lic (Vol-III) Dated: 12thMay, 2023, a detailed inspection of Medisure Laboratories Pakistan (Pvt) Ltd. situated at A-115, S.I.T.E., Super Highway, Karachi was carried out on 18th May, 2023. During opening meeting their Organogram, JDs, SMF, approved design, HVAC provision and design, an APQR of frequently manufactured product, Self- audit report, medical reports of employees, training records and several working SOPs were discussed at length and found an adequate level of compliance and an appropriate maintenance of necessary documents. The firm is found built as per approved design and necessary changes as per current design are satisfactorily carried out. AHUs are provided as required in production areas for better compliance & to control the hazards of contamination. Equipment's were adequately validated. Lab equipment's were seen calibrated and with proper log books. Quality manuals, IP testing records and line clearance documents were also in place.

Keeping in view the above stated facts and based on the attitude of the management towards continuous improvements, the panel unanimously recommends the grant of renewal of their DML No.000503 (By way of formulation) for next five years for the following sections;

S.#	Sections	S.#	Sections

1.	Tablet (General)	2.	Capsule (General)
3.	Dry Powder Suspension (General)	4.	Sterile Dry Powder Injectable/General, Sterile Liquid Injectable (Ampoule & Vial)/Sterile Ophthalmic Ear and Nasal Drops
5.	Oral Liquid (General)	6.	Cream/Ointment
7.	Sachet (General)	8.	Cephalosporin (Dry Powder Suspension and Capsule)
9.	External Preparations Powder (General)	**********	

Decision of the Central Licensing Board in 291st meeting

The Board considered and approved the grant of renewal of DML No. 000503 by way of Formulation in the name of M/s Medisure Laboratories Pakistan (Pvt) Ltd., A-115, S.I.T.E., Super Highway, Karachi on the recommendations of the panel of experts for the period Commencing on 06-10-2022& ending on 05-10-2027 for the following sections subject to verification of necessary testing equipment.

S.#	Sections	S.#	Sections
1.	Tablet (General)	2.	Capsule (General)
3.	Dry Powder Suspension (General)	4.	Sterile DryPowder Injectable/General, Sterile Liquid Injectable (Ampoule & Vial)/Sterile Ophthalmic Ear and Nasal Drops
5.	Oral Liquid (General)	6.	Cream/Ointment
7.	Sachet (General)	8.	Cephalosporin (Dry Powder Suspension and Capsule)
9.	External Preparations Powder (General)	**********	

2.	M/s Caliph Pharmaceuticals (Pvt) Ltd, Plot No. 17, Special Industrial Zone (EPZ), Risalpur.	**13-03-2023**	**Good**	1. Prof. Dr. Jamshed, Expert Member, Peshawar. 2. Faisal Shahzad, Area Federal Inspector of Drugs, DRAP, Peshawar.

	DML No.000748 (Formulation). Period: Commencing on 13-08-22 ending on 12-08-2027.			3. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.

Recommendation:

Based on documentation reviewed, technical / management people met, materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, allied facilities and commitment of the firm to upgrade their facility in accordance with latest requirements laid down by DRAP, the panel is of the view that the firm is operating at good level of GMP compliance and unanimously **recommends** grant of renewal of Drug Manufacturing License to the firm with effect from 13-08-2023 in accordance with DRAP Islamabad letter No.3-6/2005-Lic (Vol-I) dated 06-03-2023 for following six sections:-

1. Tablet Section (General).
2. Dry Powder Suspension Section (General).
3. Capsule Section (General).
4. Liquid Syrup Section (General).
5. Cream / Ointment Lotion Section (General).
6. Sachet Section (General).

Decision of the Central Licensing Board in 291st meeting:

The Board considered and approved the grant of renewal of DML No. 000503 by way of Formulation in the name of M/s Caliph Pharmaceuticals (Pvt) Ltd, Plot No. 17, Special Industrial Zone (EPZ), Risalpur on the recommendations of the panel of experts for the period Commencing on 13-08-22 ending on 12-08-2027 for the following sections subject to verification of necessary testing equipment.

1. Tablet Section (General).
2. Dry Powder Suspension Section (General).
3. Capsule Section (General).
4. Liquid Syrup Section (General).
5. Cream / Ointment Lotion Section (General).
6. Sachet Section (General).

3	M/s. Pharmagen Ltd, Kot Nabi Bukhsh Wala, 34-Km Ferozepur Road, Lahore. DML No.000325 (Semi-Basic). Period: Commencing on 25.10.2020 & ending on 24.10.2025.	21-03-2023 & 22-058-2023	**Good**	1. Muhammad Shamoon Ch. Expert Member 2. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 4. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore

Recommendations of the panel: -

The panel of inspectors recommends for the **renewal of drug manufacturing license** and the grant of the products Montelukast Sodium, Sitagliptin Phosphate and Valsartan (subject to development and performance of nitrosamines (NDMA and NDEA etc) impurities testing in valsartan API) under DNL No.000352 in favour of M/s Pharmagen Ltd, 34-Km, Ferozepur Road, Lahore to manufacture Active Pharmaceutical Products by way of semi-basic manufacturing as per above mentioned list.

Decision of the Central Licensing Board in 291st meeting

The Board considered and approved the grant of renewal of DML No. 000352 by way of Formulation in the name of M/s. Pharmagen Ltd, Kot Nabi Bukhsh Wala, 34-Km Ferozepur Road, Lahore on the recommendations of the panel of experts for the period Commencing on 25.10.2020 & ending on 24.10.2025 for the following APIs subject to verification of necessary testing equipment.

SR#	APIs
1.	Hydroxy Chloroquine Sulphate (USP/BP/EP).
2.	Chloroquine Phosphate (USP/BP/EP)
3.	Moxifloxacin (USP/BP/EP)
4.	Empagliflozin (In House Specs).
5.	Dapagliflozine (In House Specs).
6.	Remedisivir (In House Specs).
7.	Favipiravir (In House Specs)
8.	Dexlansoperazole Pellets (Manufacture Specs).
9.	Amoxycillin Trihydrate
10.	Ampicillin Trihydrate
11.	Cephalexin Hydrate
12.	Cefaclor

		13.	Cefadroxil	
		14.	Ledipasvir	
		15.	Daclatasvir Dihydrochloride	
		16.	Velpatasvir	
		17.	Vildagliptin	
		18.	Cloxacillin Sodium	
		19.	Ampicillin Anhydrous	
		20.	Cephalexin hydrate	
		21.	Cephradine	
		22.	Cephradine L- Arginine	
		23.	Cefotaxime Sodium	
		24.	Ceftrioxone Sodium	
		25.	Cephalexine Sodium	
		26.	Cefazoline Sodium	
		27.	Cefoperazone Sodium	
		28.	Ceftazidime Pentahydrate	
		29.	Cefuroxime Sodium	
		30.	Cefixime	
		31.	Cefuroxime Axetil	

		32.	Flucoxacillin Sodium	
		33.	Ciprofloxacin Hydrochloride	
		34.	Moxifloxacin Hydrochloride	
		35.	Pefloxacin Mesilate	
		36.	Levofloxacin	
		37.	Azithromycin	
		38.	Clarithromycin	
		39.	Sulamethoxazole	
		40.	Omeprazole	
		41.	Sulamethoxazole Magnesium Trihydrate	
		42.	Paracetamol	
		43.	Pyrazinamide	
		44.	Naproxen Sodium	
		45.	Ibuprofen	
		46.	Simvastatin	
		47.	Atorvastatin Calcium Trihydrate	
		48.	Amlodipine Besylate	
		49.	Montelukast Sodium	
		50.	Mefenamic Acid	

		51.	Dexamethasone Sodium Phosphate		
		52.	Dexamethasone Acetate		
		53.	Betamethasone Sodium Phosphate		
		54.	Betamethasone Valerate		
		55.	Betamethasone Dipropionate		
		56.	Sofosbuvir		
4.	M/s Polyfine Chempharma, 51-Hayatabad Industrial Estate, Peshawar. DML No.000216 (Formulation). Period: Commencing on 14-03-21 ending on 13-03-2026.	**29-03-2023 & 26-05-2023**	**Good**	1. Faisal Shahzad, Additional Director, DRAP, Peshawar. 2. Mr. Atiq Ul Bari, FID, DRAP, Peshawar. 3. Mr. Abdullah, Assistant Director, DRAP, Islamabad.	

Recommendation:

Based on the areas inspected, the people met, documentation reviewed, the intension towards further improvements and corrective and preventive action taken, the firm is considered to be operating at good level of compliance with cGMP guide lines as per drug act, 1976 and rules framed thereunder.
Keeping in view the above, the panel unanimously recommended the grant of renewal of DML by way of formulation to M/s Polyfine Chempharma, 51-Hayatabad Industrial Estate, Peshawar. The panel also recommended the grant of following additional section to the Firm.

i. Eye Ointment (General).
ii. The firm submitted that the additional section Dry Powder for injection (Carbapenem) is not ready for inspection and they will intimate DRAP again when the section is ready for inspection.

Decision of the Central Licensing Board in 291st meeting

The Board considered and approved the grant of renewal of DML No. 000216 by way of Formulation in the name of M/s Polyline Chempharma, 51-Hayatabad Industrial Estate, Peshawar on the recommendations of the panel of experts for the period Commencing on 14-03-21 ending on 13-03-2026 for following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-

	I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 and subject to verification of necessary testing equipment. ; 1. Tablet (General), 2. Capsule (General), 3. Sachet (General), 4. Tablet (penicillin) 5. Oral Dry Powder (Penicillin) 6. Capsule (Penicillin), 7. Table (Psychotropic), 8. Capsule (Cephalosporin) 9. Dry Powder for injection (Cephalosporin) 10. Oral Dry Powder for suspension (Cephalosporin) 11. Liquid Injectable ampoule (General) 12. Oral Liquid (General), 13. Dry Powder for suspension (General), 14. Eye Drop (General) 15. Warehouse (RMS, FGS, PMS) 16. Quality Control Laboratory, The Board also considered and approved the grant of following additional section in the name of M/s Polyfine Chempharma, 51-Hayatabad Industrial Estate, Peshawar under DML No. 000216 (Formulation) on the recommendations of the panel of experts i. Eye Ointment (General).			
5.	M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore. DML No.000493 (Formulation). Period: Commencing on 27-02-2022 ending on 26-02-2027.	**02-02-2023**	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab. 2. Dr. Syed Zia Husnain, FID, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	Panel inspected the unit and has evaluated the various documents in connection with production, Quality Control and Quality Assurance. Various technical aspects were also discussed with firm management at length. Based on the physical inspection of the unit, evaluation of the documents and discussion with the technical staff, Panel has recommended the facility for renewal of Drug Manufacturing License of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga Off Raiwind Road, Lahore w.e.f. 27-02-2022 for following eight section:- 1. Liquid Repacking. 2. External Preparation/ 3. Oral Liquid Section (General). 4. Tablet Section (General). 5. Oral Dry Powder Section (General). 6. Capsule Section (General). 7. Sachet Section (General).			

	8. Cream / Ointment Section (General). **Decision of the Central Licensing Board in 291st meeting** The Board considered and approved the grant of renewal of DML No. 000493 by way of Formulation in the name M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore on the recommendations of the panel of experts for the period Commencing on 14-03-21 ending on 13-03-2026 for following sections: 1. Liquid Repacking. 2. External Preparation/ 3. Oral Liquid Section (General). 4. Tablet Section (General). 5. Oral Dry Powder Section (General). 6. Capsule Section (General). 7. Sachet Section (General). 8. Cream / Ointment Section (General).

Item-III: **MISC. CASES**

Case No-1 **CHANGE OF MANAGEMENT OF M/S AHSONS DRUG COMPANY SINDH**

As per available record M/s. Ahsons Drug Company, T/1, SITE, Tando Adam Sindh is a licensed pharmaceutical manufacturer holding the Drug Manufacturing License No. 000138 by way of formulation. As per available record of the firm the below mentioned details of the management are tabulated;

Sr. No.	Date of received application	Management as per Application	Proposed New Management
1	28th November, 1993	1. Mr. Abdul Razzaque 2. Mr. Abdul Hameed 3. Mrs. Zaenab Begum 4. Dr. Abdul Saleem, F.R.C.S	XXXXXXXX
2	21st November, 1995.	1. Mr. Abdul Razzaque 2. Mr. Abdul Hameed 3. Mrs. Zaenab Begum 4. Dr. Abdul Saleem, F.R.C.S	XXXXXXXX
3	08th December, 1997	1. Mr. Abdul Razzaque 2. Mr. Abdul Hameed 3. Mrs. Zaenab Begum	

		4. Dr. Abdul Saleem, F.R.C.S	XXXXXXXX
4	04th December, 1999	1. Mr. Abdul Razzaque 2. Mr. Abdul Hameed **3. Mrs. Zaenab Begum** 4. Dr. Abdul Saleem, F.R.C.S	1. Mr. Abdul Razzaque 2. Mr. Abdul Hameed **3. Mr. Abdul Wahab** 4. Dr. Abdul Saleem, F.R.C.S
5	30th November, 2004	1. Mr. Abdul Razzaque 2. Mr. Abdul Hameed 3. **Mr. Abdul Wahab** 4. Dr. Abdul Saleem, F.R.C.S	XXXXXXXX
6	letter No.F.2-14/95-Lic(Vol-I) dated 22nd November, 2008.	1. Mr. Abdul Razzaque 2. Mr. Abdul Hameed 3. Mr. Abdul Wahab 4. Dr. Abdul Saleem, F.R.C.S	XXXXXXXX
7	21st November, 2014	1. Mr. Abdul Razzaque 2. Mr. Abdul Hameed 3. Mr. Abdul Wahab 4. Dr. Abdul Saleem, F.R.C.S	1. Mr. Abdul Hameed 2. **Mr. Abdul Sattar** 3. Dr. Abdul Saleem, F.R.C.S 4. **Mr. Abdul Qadir** 5. **Mrs. Shakoran Begum**
8	30th November, 2019	1. **Mr. Abdul Hameed** 2. Mr. Abdul Sattar 3. Dr. Abdul Saleem, F.R.C.S 4. Mr. Abdul Qadir 5. **Mrs. Shakoran Begum**	1. **Mr. Abdul Wahab** 2. Mr. Abdul Sattar 3. **Dr. Abdul Saleem, F.R.C.S** 4. Mr. Abdul Qadir

2. The firm applied for the change in management that was considered by the CLB in its 284th meeting and issued vide letter No. F.2-14/95-Lic(Vol-I) dated 12th January, 2022. The approved management is as follows:

Current Management Form-1A	**New Management (Year 2021)**
i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1.	i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1.
ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5.	ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5.
iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1.	iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1.

iv. Mr. Abdul Saleem S/o Abdul Hakeem CNIC No. 44206-0143901-1. v. Mst. Shakooran Begum Wd/o Late Abdul Hakeem	

3. Later on the represntations/requests were received from Mr. Abdul Saleem (previous partner of the firm), Ms. Khairunsia, Mst. Kulsoom D/o Late Abdul Hakeem, District Sanghar and legal heirs of Mst Zaineb claiming that that their mother was also a share holder of the firm and they have requested to suspend the DML of the firm and **add their names in the license of M/s Ahsons DC, Tando Adam Sindh.** The requests were considered by the CLB in its 285th meeting and the Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000138 by way of formulation of M/s. Ahsons Drug Company, T/1, SITE, Tando Adam Sindh may not be suspended or cancelled by Central Licensing Board.

In the light of decision of the Board, show cause notice dated 11th May 2022 was issued to the firm.

4. In the meanwhile application for cancellation of DML of the Ahsons Drug Company was received from Mr. Mubashir Hassan S/o Mushtaq Hussain special power of attorney of original partner Mr. Abdul Saleem S/o Abdul Hakeem wherein it was requested to cancel the DML of Ahsons DC Tehsil Tando Adam District Sanghar Sindh in the interest of Justice. Also request to investigate the matter and refer the case to relevant agency for further action as per criminal laws. Otherwise we have no other option to knock the door of the relevant court of law.Any other relief which deems fit and proper may also be granted".

The matter was considered by the CLB in its 289th meeting held on 23rd January, 2023 the Board decided to verify the partnership deed and Form-E from the Registrar of firm and decided to defer the matter till verification".

5. In the meanwhile Mr. Abdul Saleem Ansari filed a writ petition W.P.362/2023 Misc . Other (SB) Titled Mas Agson Drug Co. Vs CEO DRAP etc. wherein the Honourable Mr. Justice Babar Sattar, Islamabad High Court, Islamabad passed an order received vide Letter No. 4054/Writ dated 07-Feb-2023 from Assistant Registrar (Writ) that;

"3. *Let the office send a copy of this petition alongwith annexures to respondent No.1, who will treat it as part of the representations dated 03.02.2022 and 16.11.2022 pending before him. Respondent No.1 will issue notices to respondent No. 5,6 and 7 and decide the representations after affording the petitioner as well as respondents No.5, 6 and 7 an opportunity to be heard in accordance with law within a period of sixty days.*

4. The instant writ petition stands ***disposed of*** *in the above terms*."

6. The Registrar of Firms Hyderabad through letter No. RF/HYD/10080/2023/404 dated 17th May, 2023 confirmed the below mentioned management of the firm since 08/09/1973;

S. No	Name of Partners	Shares
1	Mr. Abdul Razaque S/o Abdul Hakeem	35%
2	Mr. Abdul Hameed S/o Abdul Hakeem	35%
3	Mr. Abdul Saleem S/o Abdul Hakeem	10%
4	Mst:Zainab W/O Abdul Hakeem	20%

7. In compliance to the Honorable Islamabad High Court orders the notices for personal hearing were issued to the following persons:

i. Mr. Abdul Wahab
ii. Mr. Abdul Sattar
iii. Mr. Abdul Qadir
iv. Mr. Abdul Saleem
v. Ms. Khairunisa
vi. Ms. Kulsoom
vii. Ms. Badar un nisa
viii. Ms. Zahida Khatoon
ix. Ms. Bilquees Khalid

PROCEEDINGS OF THE 291ST MEETING:

Mr. Shaukat Ali Joiya, Advocate High Court along with Mr. Mubashir Hassan (Attorney for Mr. Abdul Saleem S/o Abdul Hakeem) appeared before the Board and presented the legal facts regarding below mentioned legal heirs of the deceased Mrs. Zainab Begum and Mr. Abdul Saleem one of the members of the management as per the Registrar of Firms office and requested that the names of the legal heirs should be included in the management of the firm.

i. Ms. Khairunisa
ii. Ms. Kulsoom
iii. Ms. Badar un nisa
iv. Ms. Zahida Khatoon
v. Ms. Bilquees Khalid

Mr. Muhammad Raza Qureshi along with Mr. Abdul Wahab on behalf of the Ahsons Drug Company appeared before the Board and defended their stance that the matter for legal heirs is still under appeal in the court of law and that the Registrar of firms is not changing the management

of the firm as per their requests and amended partnership deed between current management and Mr. Abdul Saleem. They requested to continue with the current management of the firm.

Decision of the Central Licensing Board:

The Board after hearing the representatives and thorough discussion on the matter decided as follows:

The Drug Manufacturing License No 000138 by way of formulation of M/s Ahsons Drug T/1, SITE, Tando Adam Sindh in terms of Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provisions of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 by concealment of facts and submission of unauthentic titled documents without making entries in the titled documents by the Registrar of firms in terms of Partnership Act, 1932 hereby suspended till the production of original / certified copy of management of the firm issued by the Registrar of Firms. Further, manufacturing/production activities of the firm are stopped subject to provision of certified true copies of the titled document(s).

Case No. 2 **GRANT OF DRUG MANUFACTURING LICENSE TO M/S BLISS INDUSTRIES (PVT) LTD., KARACHI.**

Following case regarding grant of Drug Manufacturing License was placed before 289th meeting of Central Licensing Board and is reproduced as under;

1	M/s Bliss Industries (Pvt) Ltd., Plot No.G-A-52-A6, National Industrial Park, Karachi.	**05-01-2023**	**Good**	1. Mr. Ghulam Ali Lakho, Senior DI Karachi. 2. Dr. Najam Us Saqib, Additional Director (Licensing), DRAP, Islamabad. 3. Ms. Sanam Kausar, AD, DRAP, Karachi.
	Recommendations of the panel: M/s Bliss Industries (Pvt) Ltd, Plot No. G-A-52-A6, National Industrial Park, Karachi was inspected in connection with the grant of DML (Formulation) as per DRAP letter F.2-2/2022-Lic dated 1st November 2022. Following are observations: During the inspection, panel observed that the firm has constructed as per approved layout plan approved by the DRAP authorities.			

	Firm was observed well maintained in general. Necessary Production and quality control machinery/equipment was seen installed and well maintained as required for manufacturing and test/analysis of the pharmaceutical products. HVAC seen installed and operational. Adequate technical personnel also seen available on site that were observed well conservant with the GMP requirements. "Based on the people met, documents reviewed and considering the finding of the physical inspection, panel recommends the grant of Drug Manufacturing License (Formulation) for the following sections:

S.No.	Name of Section	S.No.	Name of Section
01	Tablet (General)	02	Capsule (General)
03	Oral Liquid Section (General)		

Decision of the Central Licensing Board in 289th meeting

The Board observed that the firm already holds a license at M/s Bliss Industries (Pvt) Ltd. 255/2 Shah Nawaz Bhutto Road Karachi DML No. 000086 (Formulation) in a residential area. The board decided to get the latest status of the court case filed by the firm and place before the CLB in its next meeting.

Accordingly, a letter was issued on 03-03-2023 to Additional Director (E&M), DRAP, Karachi to provide the latest status of the court case filed by the said firm.

Now, Mr. M. Suhail Zafar Bhatti, Advocate vide his letter No. SZB-MS/856 dated 10-04-2023 (**Annex-I**) addressed to the Section Officer – SOL-I, Ministry of Law, Justice & Human Rights Division, Pakistan Secretariat, Government of Pakistan, Islamabad has forwarded updated status of the case.

The firm has been called for personal hearing. The firm through legal representative Mr. Muhammad Rafique Bhatti, Advocate High Court vide letter reference No. Suit No. 423 of 2015/MRB dated 27-05-2023 has submitted the following reply;

"Honorable Secretary,

I have been honour to write this letter with reference to your letter No.F.2-2/22-Lic sated 26th May, 2023, regarding personal hearing.

It is very kind to be stated that due to my Client's health problem, he is unable to travel from Karachi to Islamabad and to attend the respective meetingbefore the Central Licensing Board held on 30th May, 2023 which is pure bonafideon the part of my Clientand not deliberate. It is stated that in your letter under reply that you have stated to explain the company's position on the subject case. Nevertheless, under mentioned verdicts are in explanation of the position of my Client, as under:-

Following is/are position on the case :

1. New factory was established as New premises, at G-A-52, A/6, NIP., Karachi.

2. Inspection has been done by DRAP team, in the month of January, 2023.
3. Grant of License is under process for its approval.
4. The company is aiting for issueance of License and transfer of existing product, so operations can be smoothly transferred to new factory.
5. Furthermore , company is wlling to withdraw the Suite No. 423/2015 from the Court of Law, if it gets the License and product transfer approval from the DRAP, in order to make smooth operational transfer without any delay in providing quality products to the people of Pakistan.

These are submissions in this regard and it is requested to please go through this letter and to please grant the License to the Bliss Industry and I undertake that after issuance of License in favour of my Client. I will withdraw the matter from the court of Law and obliged.

Thanking you in anticipation,

Muhammad Rafique Bhatti,
Advocate High Court."

Proceedings & Decision of the Central Licensing Board in 291st meeting:

No one on behalf of the firm appeared in person. However, Mr Khalid Ashraf CEO of the firm through telephone confirmed to the Board that if the Board grant them license at new premises they shall withdraw the matter from court of law. The CEO did not clarify whether they shall withdraw DML from old premised or not. The Board after perusal of record and facts decided to deferred the case till decision by the Court.

Case No.3. **NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976**

The Budget & Accounts Division, DRAP, Islamabad have forwarded list of Licensees who did not deposit CRF under subject rule quoted as under:

> *"(14) The Licensee shall by the 30th June and the 31st December each year, whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

Directorate General Audit (Federal Audit) (OS-02 FY 2020-21 has observed) that there were 645 registered Pharmaceutical companies (Licensees) and the management did not collect receipts on account of CRF from 211 companies during 2020-21 & 2020-22. Audit is of the view that non-recovery of receipts deprived the DRAP from its due receipts and recommends fixing of responsibility for non-recovery besides recovery of the receipts at the earliest. The detail of the firms is as under: -

Sr.	DML No.	Name of Pharmaceutical Unit
1	000022	M/s Reckitt Benckiser Pakistan Ltd.
2	000048	M/s Karachi Chemical Industries (Pvt) Ltd.
3	000053	M/s Risma Laboratories
4	000071	M/s Epla Laboratories (Pvt) Ltd.
5	000075	M/s Orta Laboratories (Pvt) Ltd.
6	000084	M/s Lahore Pharma
7	000086	M/s Bliss Industries (Pvt) Ltd.
8	000092	M/s National Institute of Health ChakShahzad Islamabad.
9	000094	M/s Dosaco Laboratories
10	000126	M/s ISIS Pharmaceutical & Chemical Works
11	000131	M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd.
12	000132	M/s Kohs Pharmaceuticals (Pvt) Ltd.
13	000136	M/s Hilton Pharma (Pvt) Ltd.
14	000138	M/s Ahson Drug Co.
15	000146	M/s Ideal Pharma Industries
16	000148	M/s Marvi Pharmaceuticals
17	000156	M/s Oval Pharmaceuticals
18	000168	M/s Gaba Pharmaceutical Laboratories
19	000182	M/s PharmaWise Labs (Pvt) Ltd
20	000183	M/s Micko Industrial Chemical Company (Pvt) Ltd.
21	000207	M/s Sapient Pharma
22	000222	M/s Ali Industries
23	000244	M/s IPP (Pvt) Ltd.
24	000245	M/s Elko Organization (Pvt) Ltd.
25	000255	M/s Pharmacare Laboratories (Pvt) Ltd.
26	000259	M/s Siza International (Pvt) Ltd.
27	000269	M/s Medi Vet (Pvt) Ltd.
28	000280	M/s Pliva Pakistan (Pvt) Ltd.
29	000282	M/s Gelcaps (Pakistan) Ltd.
30	000284	M/s Getz Pharma (Pvt) Ltd.
31	000290	M/s Syntex Pharmaceuticals
32	000295	M/s Pacific Pharma
33	000303	M/s Healer Laboratories (Pvt) Ltd.

34	000307	M/s Vetcon Pharmaceuticals (Pvt) Ltd.
35	000315	M/s Hizat Pharmaceutical Industry
36	000317	M/s Imco Pharmaceutical Labs (Pvt) Ltd.
37	000334	M/s Bio Fine Pharmaceuticals (Pvt) Ltd.
38	000338	M/s A.Z. Pharmaceutical Co Ltd.
39	000339	M/s English Pharmaceutical Industries
40	000354	M/s Faisal Pharmaceutical Industries
41	000356	M/s Uni-Tech Pharmaceuticals (Pvt) Ltd.
42	000358	M/s Zaynoon Pharmaceuticals (Pvt) Ltd.
43	000370	M/s IPP
44	000371	M/s Yousuf Ali Shah chemical Industries (Pvt) Ltd.
45	000373	M/s Alpha Chemicals (Pvt) Ltd.
46	000380	Shazeb Pharmaceutical Industries Ltd.
47	000389	M/s Ferroza International Pharmaceuticals (Pvt) Ltd.
48	000396	M/s M.S. Enterprises Ltd.
49	000404	M/s LeamaChemi Pharma (Pvt) Ltd.
50	000406	M/s Amrose Pharmaceuticals
51	000412	M/s Unipharma (Pvt) Ltd.
52	000413	M/s Famous Pharmaceutical
53	000421	M/s Nexus Pharma (Pvt) Ltd.
54	000423	M/s Alza Pharmaceuticals
55	000428	M/s Flow Pharma (Pvt) Ltd.
56	000433	M/s Ahad International Pharmaceutical Limited
57	000436	M/s Shafi Textile Corporation
58	000437	M/s Raazee Therapeutics (Pvt) Ltd.
59	000441	M/s Alina Combine Pharmaceuticals (Pvt) Ltd.
60	000443	M/s Humayun International Pharma (Pvt) Ltd.
61	000444	M/s Mass Pharma (Pvt) Ltd.
62	000446	M/s Delta Pharma (Pvt) Ltd.
63	000448	M/s Genera Pharmaceuticals
64	000451	M/s Caylex Pharmaceuticals (Pvt) Ltd.
65	000453	M/s Alpine Pharma (Pvt) Ltd.
66	000459	M/s P.D.H Pharmaceuticals (Pvt) Ltd.
67	000465	M/s Wellcare Pharmaceuticals
68	000468	M/s Mediways International
69	000469	M/s Perfect Pharma (Pvt) Ltd.
70	000472	M/s Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd.
71	000473	M/s Shifa Laboratories (Pvt) Ltd.
72	000475	M/s Mediceena Pharma (Pvt) Ltd.
73	000478	M/s Moreno Iglisias Research Laboratories (Pvt) Ltd.
74	000487	M/s Invotek Pharmaceuticals

75	000495	M/s MBL Pharma
76	000505	M/s Jafson Pharmaceuticals (Pvt) Ltd.
77	000506	M/s Regent Laboratories
78	000508	M/s Elvin Pharmaceuticals (Pvt) Ltd.
79	000518	M/s Gray's Pharmaceuticals
80	000519	M/s Medi-Excel Pharmaceuticals
81	000522	M/s Alson Pharmaceutical
82	000523	M/s Hygeia Pharmaceuticals
83	000525	M/s NoaHemis Pharmaceuticals
84	000529	M/s Trison Research Laboratories (Pvt) Ltd.
85	000538	M/s Webros Pharmaceuticals
86	000541	M/s Novins International (Pvt) Ltd.
87	000545	M/s Universal Pharmaceuticals (Pvt) Ltd.
88	000554	M/s Farmaceutics International
89	000555	M/s Aneeb Pharmaceuticals (Pvt) Ltd.
90	000568	M/s Lowitt Pharma (Pvt) Ltd.
91	000570	M/s Zinta Pharmaceuticals Industry
92	000573	M/s Pak Risen Pharmaceuticals
93	000575	M/s Synchro Pharmaceuticals
94	000581	M/s Hansel Pharmaceuticals (Pvt) Ltd.
95	000582	M/s International Pharma Labs
96	000586	Searle IV Solutions (Pvt) Ltd.
97	000593	M/s Miracle Pharmaceuticals (Pvt) Ltd.
98	000596	M/s Cherished Pharmaceuticals (Pvt) Ltd.
99	000607	M/s Envoy Pharmaceuticals (Pvt) Ltd.
100	000610	M/s Wnsfield Pharmaceuticals
101	000612	M/s Heal Pharmaceuticals (Pvt) Ltd.
102	000615	M/s Medimarker's Pharmaceuticals (Pvt) Ltd.
103	000631	M/s Westmount Pharmaceuticals Industry
104	000632	M/s Legacy Pharmaceuticals (Pvt) Ltd.
105	000634	M/s Harrison Pharmaceuticals
106	000637	M/s SAAAF Pharmaceutical Industries
107	000638	M/s Amson Vaccines & Pharma (Pvt) Ltd.
108	000648	M/s Aptcure (Pvt) Ltd.
109	000652	M/s Noble Pharma
110	000653	M/s WellbornePharmachem and Biologicals
111	000659	M/s Breeze Pharma (Pvt) Ltd.
112	000660	M/s Aventek Pharmaceuticals
113	000665	M/s 3S Pharmaceuticals (Pvt) Ltd.
114	000670	M/s Linear Pharma
115	000678	M/s Berlex Lab. International

116	000680	M/s Grand Pharma (Pvt) Ltd.
117	000682	M/s ARP (Pvt) Ltd.
118	000690	M/s Med Asia Pharmaceutical (Pvt) Ltd.
119	000699	M/s Medwell Pharmaceuticals
120	000700	M/s Baxter Pharmaceuticals
121	000706	M/s Frontier Pharmaceutical (Pvt) Ltd.
122	000708	M/s Armoz Pharma (Pvt) Ltd.
123	000709	M/s Crespak Medical Industries
124	000710	M/s Medicare Disposable Industries
125	000711	M/s Siam Pharmaceuticals
126	000712	M/s Sunrise Pharma (PVt) Ltd.
127	000716	M/s National Institute of Health
128	000720	M/s Warafana Pharmaceuticals
129	000721	M/s Winilton Pharmaceuticals (Pvt) Ltd.
130	000723	M/s City Pharmaceutical Laboratories
131	000730	M/s Pakistan Institute of Nuclear Sciences & Technology
132	000732	M/s Fizi Pharmaceutical & Chemical Laboratories,
133	000740	M/s Unisa Pharmaceutical Industries Ltd.
134	000749	M/s Medella Pharmaceuticals (Pvt) Ltd.
135	000753	M/s Rukha Pharmaceutical Laboratories (Pvt) Ltd.
136	000754	M/s Espoir Pharmaceuticals
137	000757	M/s Reign Pharmaceuticals
138	000760	M/s Fredmann Pharmaceuticals (Pvt) Ltd.
139	000761	M/s Pharma Health Pakistan (Pvt) Ltd.
140	000762	M/s Simz Pharmaceuticals (Pvt) Ltd.
141	000770	M/s B.J Pharmaceuticals
142	000771	M/s Novae Pharmaceuticals
143	000772	M/s Metro Pharmaceuticals
144	000786	M/s Avant Pharmaceutical (Pvt) Ltd.
145	000791	M/s Agror Pharma (Pvt) Ltd.
146	000795	M/s Herbion Pakistan (Pvt) Ltd.
147	000802	M/s Aurik Pharmaceuticals
148	000814	M/s PCP Laboratories
149	000816	M/s Ice Berg Pharmaceuticals (Pvt) Ltd.
150	000817	M/s Gallop Water Sciences
151	000819	M/s Revive Pharmakon
152	000821	M/s Ras Pharmaceuticals (Pvt) Ltd.
153	000823	M/s Jenner Pharmaceuticals (Pvt) Ltd.
154	000832	M/s Zoic International
155	000836	M/s Vantage Pharmaceutical
156	000846	M/s Arreta Pharmaceuticals (Pvt) Ltd.

157	000850	M/s Divine Pharmaceuticals
158	000857	M/s Perk Pharma (Pvt) Ltd.
159	000869	M/s N.S Pharma
160	000876	M/s Multi Caps
161	000877	M/s Neutro Pharma (Pvt) Ltd.
162	000879	M/s Effort Pharmaceuticals (Pvt) Ltd
163	000881	M/s Liven Pharmaceuticals (Pvt) Ltd
164	000885	M/s Islam Pharmaceuticals
165	000887	M/s Aptly Pharmaceuticals
166	000888	M/s Trillium Pharmaceuticals (Pvt) Ltd
167	000890	M/s Zamko Pharmaceuticals (Pvt) Ltd.,
168	000893	M/s Vetec Laboratories
169	000894	M/s Avensis Pharmaceuticals,
170	000896	M/s Greater Pharma
171	000897	M/s Cure Laboratories (Pvt) Ltd
172	000898	M/s Novex Pharma
173	000901	M/s Carryfor Pharmaceuticals (Pvt) Ltd
174	000902	M/s Pacific Pharmaceuticals Ltd,
175	000903	M/s K.M. Int (Pvt) Ltd.,
176	000904	M/s Shine Laboratories,
177	000906	M/S KBR Pharmaceuticals,
178	000910	M/s Bio-Next Pharmaceuticals (Pvt) Ltd,
179	000912	M/s D. Haans Pharma (Pvt) Ltd,
180	000913	M/s Enzon Pharma Lab (Pvt) Ltd,
181	000915	M/s Dow University of Health Science,
182	000917	M/s Health Capsule Pakistan (Pvt) Ltd,
183	000918	M/s Alpenglow Pharmaceuticals (Pvt) Ltd,
184	000919	M/s Winsbrains Research Laboratories
185	000921	M/s Haarlods Pharmaceuticals (Pvt) Ltd.,
186	000922	M/s Unichem Pharmaceuticals Pakistan (Pvt) Ltd.,
187	000923	M/s. Eterna Pharma (Pvt) Ltd
188	000924	M/s. Fortune Pharmaceuticals,
189	000925	M/s Carer Pharmaceuticals Industries,
190	000926	M/s Krypton Pharma (Pvt) Ltd
191	000928	M/s Lakhani Pharma (Pvt) Ltd,
192	000929	M/s Neo Tech Pharmaceuticals (Pvt) Ltd.,
193	000930	M/s Bioskils Pharmaceuticals,
194	000931	M/s Kayans Pharmaceuticals Industries,
195	000932	M/s Acumen Healthcare (Pvt) Ltd,
196	000933	M/s Getz Pharma (Pvt) Ltd,
197	000934	M/s Biorise Pharmaceuticals,

198	000935	M/s Mili Vet Pharmaceuticals (Pvt) Ltd,
199	000936	M/s Fleming Pharmaceutical,
200	000937	M/s Herbion Pakistan (Pvt) Ltd.,
201	000939	M/s Pinnacle Biotech (Pvt) Ltd.,
202	000940	M/s Vetrox Pharmaceuticals,
203	000941	M/s Swera Pharmaceuticals,
204	000942	M/s World Biz Pharmaceuticals Company (Pvt) Ltd,
205	000943	M/s Akhsah Pharmaceuticals (Pvt) Ltd,
206	000944	M/s Qadir Pharmaceuticals,
207	000945	M/s Pasteur & Fleming Pharma,
208	000946	M/s JHK Pharma (Pvt) Ltd,
209	000947	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd.
210	000948	M/s AGM Pharmaceuticals,
211	000949	M/s Medhouse Pharmaceuticals (Pvt.) Ltd
212	000950	M/s Livewell Capsules (Pvt.) Ltd,
213	000951	M/s Wallace Pharma Evolutions,
onward 000951 (if any)		

The Rule 12 of the LR&A Rules 1976 states that

12. Cancellation or suspension of licenses: (1) If licensee does not comply with any of theconditions of a licence or violates any of the provisions of the Ordinance or the rules, or fails todeposit the requisite amount of the Central Research Fund due from him, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such periodas it thinks fit, either wholly or in respect of some of the drugs to which it relates.

Decision by the Central Licensing Board in 291st meeting:

The Board advised the Licensing Division to get updated list of the defaulters from Budget & Accounts division. The Board considered the case and decided to issue show cause notice to all firms who have not submitted CRF until 31 Dec 2022 under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug Manufacturing License may not be suspended till settlement of Central Research Fund.

Case No.4. **ISSUANCE OF DUPLICATE COPY OF DRUG MANUFACTURING LICENSE TO M/S DON VALLEY PHARMACEUTICALS (PVT) LTD, 31-KM MAIN FEROZEPUR ROAD, LAHORE.**

The Central Licensing Board in its 275th meeting held on 25th June, 2020 approved the grant of renewal of DML No. 000395 (Formulation) of M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km Main Ferozepur Road, Lahore and License was issued on 29th June, 2020. Now, the firm has submitted an application for issuance of duplicate copy of Drug Manufacturing License. stating that their previous DML is lost. Licensing Division has issued duplicate copy of Form-2 on the request of the firm.

Decision by the Central Licensing Board in 291st meeting:

The Board considered and endorsed the proceedings of Licensing Division.

Case No.5. APPROVAL OF LAYOUT PLAN OF PSYCHOTROPIC SECTION (OSD).

M/s Atco Laboratories Ltd., Karachi has applied for approval of layout plan for Tablet (Psychotropic) Section. The proposed layout plan was discussed in 57th meeting of Layout plan committee and decided as under;

> *"The Committee discussed the proposed layout plan with technical team of the firm lead by Head of Quality Operations and decided as under:*
>
> *The Committee observed that the Area requirement for psychotropic section is not complete as per LRA Rules 1976 as there is requirement of 900 Sq. Ft for Tablet manufacturing area while the firm representative has submitted that their registered tablet don't require coating. The committee decided to refer the case to the CLB for policy decision in the matter."*

As per Rule 16 (b) ScheduleB-I (C)

"Equipment for the manufacture of Pills and Compressed Tablets including Hypodermic Tablets. For efficient operation, the tablet production department shall be divided into the following three distinct and separate sections situated in different rooms,
(i) Granulating Section;
(ii) Tableting Section;
(iii) Coating Section.
The following equipment is required in each of the three sections :-

1. Granulating Section: (1) Disintegrator, where applicable.
(2) Power Mixer or granulation mixer with stainless steel cabinet
(3} Granular
(4) Oven thermostatically controlled.

2. Tableting Section:
(1) Tablet machine, single punch or rotary.
(2) Pill machine, where applicable.
(3) Punch and dyes storages cabinet.

The Tableting Section shall be free from dust and floating particles. For this purpose, it is desirable that each tablet machine is connected either to an exhaust system or isolated into cubicles.

3. Coating Section:
(1) Jacketed kettle, or equivalent steam, gas or dect£1cally heated for preparing solution.
(2) Coating pan.
(3) Polishing pan, where applicable,
{4) Heater and exhaust system, where applicable.

The coating section shall be made dust-free and suitable exhaust provided to remove excess powder and the fumes resulting from solvent evaporation.

A total area of not less than 900 square feet for the three Sections is required for basic installations.

The manufacture of Hypodermic Tablets shall be conducted under aseptic conditions in a separate air-conditioned room, the walls of which shall be smooth and washable. The granulation, tableting and packing shall be done in this room."

Decision by the Central Licensing Board in 291st meeting:

The Board discussed that it is not purview of the CLB to relax any requirements of the L, R&A Rules 1976. The request of M/s Atco Laboratories Ltd., Karachi to grant permission to establish Psychotropic tablet section (not fulfilling the area requirement of 900 sq.ft) was not acceded to.

Case No.6. CORRECTION IN MINUTES OF 286th MEETING.

Following case was placed and decided by the CLB in its 286th meeting:

1	M/s Nawan Laboratories (Pvt) Ltd, 136, Sector 15, Korangi Industrial rea, Karachi. DML No.000442 (Formulation)	**31-03-2022**	**Good**	1) Prof. Abdullah Dayo, Expert Member 2) Federal Inspector of Drugs, DRAP, Karachi.

Period: Commencing on 28-06-2021 & Ending 27-06-2026			3) Mr. Krishan Das, Assistant Director, DRAP, Karachi

Recommendations of panel:

"Based on the stated facts and keeping in view the attitude of the of the management towards continuous improvements the panel unanimously recommends the grant of renewal of DML 000442(Formulation) for the next five years for following sections:

S#	Name of Section (s)	S#	Name of Section (s)
1	Tablet (General)	2	Capsule (General)
3	Dry Powder Suspension (Cephalosporin)	4	Sachet (General)
5	Oral Liquid (General)	6	Capsule (Cephalosporin)
7	Dry Powder Suspension (Cephalosporin)	8	Sterile Dry Powder Injection (Cephalosporin)
9	Sterile Liquid Injection (Cephalosporin)Vet	10	Dry Powder Injection (Penicillin) Vet
11	Sterile Liquid Injection (Penicillin) Vet	12	Dry Powder Sachet (Penicillin) Vet
13	Liquid Injection (Vet)	14	Oral Liquid Syrup sachet (Vet)
15	Dry Powder Sachet (Vet)	16	Tablet Bolus (Vet)

Decision of the Central Licensing Board in 286th meeting:

The Board considered and approved the grant of renewal of DML No. 000442 by way of Formulation in the name of M/s Nawan Laboratories (Pvt) Ltd, 136, Sector 15, Korangi Industrial rea, Karachi**,** on the recommendations of the panel of experts for the period Commencing on 28-06-2021 & Ending 27-06-2026for the following section: -

S#	Name of Section (s)	S#	Name of Section (s)
1	Tablet (General)	2	Capsule (General)
3	Dry Powder Suspension (Cephalosporin)	4	Sachet (General)
5	Oral Liquid (General)	6	Capsule (Cephalosporin)
7	Dry Powder Suspension (Cephalosporin)	8	Sterile Dry Powder Injection (Cephalosporin)
9	Sterile Liquid Injection (Cephalosporin)Vet	10	Dry Powder Injection (Penicillin) Vet
11	Sterile Liquid Injection (Penicillin) Vet	12	Dry Powder Sachet (Penicillin) Vet
13	Liquid Injection (Vet)	14	Oral Liquid Syrup sachet (Vet)
15	Dry Powder Sachet (Vet)	16	Tablet Bolus (Vet)

Following typographic mistakes were erroneously made in the decision of Central Licensing Board;

i. In serial number '**3**' the section written "Dry Powder Suspension (**Cephalosporin**)" instead of "Dry Powder Suspension (**General**)".
ii. In serial number **'14'** the section written "Oral Liquid Syrup **Sachet** (Vet)" instead of "Oral Liquid Syrup (Vet)". The extra word **"Sachet"** mentioned by mistake.

The firm has requested to issue a corrigendum letter for above typographic mistakes.

Decision by the Central Licensing Board in 291st meeting:

The Board considered and after deliberation, approved the correction in the minutes of the 286th meeting subject to verification from record.

Case No.7. COMMUNICATION OF DECISION OF CENTRAL LICENSING BOARD UNDER RULE 8 (12) OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.

As per Rule 8 (10) empowers the Central Licensing Board to authorize the Chairperson or any of its members for performing any specific functions of the Board including the disposal of day-to-day business of the Board through Secretary of the Central Licensing Board or any authorized officer. According to, following proposal and are made for the consideration of the Central Licensing Board.

As per Rule 8 (12) the Chairperson and the Secretary shall sign the manufacturing license certificate. The Secretary or any authorized officer shall conduct other correspondence on behalf of Central Licensing Board.

As per current practice of the Division of Licensing the decisions of the CLB are communicated by the Secretary, CLB. In order to expedite the execution / communication of the decisions of the CLB minutes the agenda point is placed before the CLB that in addition to the Secretary, any authorized officer by the Chairman CLB shall also convey the decisions of the meeting of CLB.

Decision by the Central Licensing Board in 291st meeting:

The Board after deliberation decided that any officer authorized by the Chairman CLB shall make other correspondence on behalf of Central Licensing Board.

Case No.8. **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000231 (FORMULATION) OFHIMONT PHARMACEUTICALS (PVT.) LTD, 17-KM, FEROZEPUR ROAD, LAHORE**

M/s. Himont Pharmaceuticals (Pvt.)	**24-03-2022 &**	**Good**	1. Dr. Ikram Ul Haq, Member, Central Licensing Board

Ltd, 17-km, Ferozepur Road, Lahore DML No.000231 (Formulation) Period: Commencing on 27-09-2020 ending on 26-09-2025	**07-04-2022**		2. Ms. Aisha Irfan, FID, DRAP, Lahore, 3. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation etc. the panel **recommends** the renewal of Drug Manufacturing License, to M/s. Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore by way of formulation to the following sections only:

1. Tablet (General) Section.
2. Tablet (Psychotropic) Section.
3. Capsule (General) Section.
4. Dry Powder Suspension
5. Sachet (General) Section.
6. Oral Liquid (General) Section.
7. Liquid injectable (SVP) (General) Section.
8. Capsule (Cephalosporin) Section
9. Dry Powder Suspension (Cephalosporin) Section.
10. Dry Powder Injectable (Cephalosporin) Section.

The panel observed that the firm has not made changes/regularization as per new approved layout plan and informed that it would take 2-3 years' time period, to implement new layout plan, hence the renewal of DML is recommended as per old layout plan respectively.

Decision of the Central Licensing Board in 287th meeting:

The Board considered the case and decided to defer the case till next Board meeting. The Board also decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000231 by

way of Formulation of M/s. Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore may not be suspended or cancelled by the Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause Notice was issued to M/s Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore on 24th August, 2022.

The firm has replied that they have applied for renewal of DML and regularization of sections vide letter dated 17th September, 2020. Meanwhile, the management decided to upgrade the facility and submitted revised layout plan but after the pandemic, the economy and business were so badly affected and they could not go for the project. Due to this reason, the management requested the panel to renew their DML on the basis of previously approved layout plan.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Maqsood Ahmed Technical Director of the firm appeared before the Board. They contended that the regularization and extension of sections will take 2-3 years. The Board while considering the facts on record and after thread bare deliberation decided to defer the renewal application of DML. The firm shall first withdraw the LOP approved on 28th November 2018 (F.1-14/84-Licensing-Vol-6) because they have not made any development/changes for regularization. The firm shall apply for the regularization of existing lay out plan.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

Decision of the Board was conveyed to the firm through letter dated 28th November, 2022. M/s Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore then filed application on 6th December, 2022 for regularization of existing facility and withdrawal of already approved layout plan dated 28th November, 2018. The firm got their existing layout plan regularized on 5th April, 2023.

Proceedings and Decision by the Central Licensing Board in 291st meeting:

The Board observed that the firm has got approval of layout plan of existing facility that requires verification. The Board considering the facts on the record and after thread bare deliberation decided that Chairman CLB shall constitute a panel for inspection of the firm.

Case No-9. **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000259 OF M/S SIZA INTERNATIONAL (PVT) LTD, 18-KM, MAIN FEROZEPUR ROAD, LAHORE.**

M/s Siza International (Pvt) Ltd, 18-KM, Main Ferozepur Road, Lahore had applied for renewal of DML No. 000259 by way of formulation for the period of 26-10-2019 to 25-10-2024. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13th October, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form 1A along with enclosure / annexure / flags.
ii. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
iii. Attested CNIC's copies of all Directors.
iv. Latest Certified true copy of Form-29 (Attestation by SECP).
v. Detail of premises including layout plan.
vi. Proof of licensed sections from CLB.
vii. Approval letter of Production / QC Incharge in case of change than submit required documents as per check list.
viii. Up-to-date nothing due certificate regarding CRF from STO.
All documents should be duly attested.

The firm did not submit their reply in response to this Division's letter dated 23th October, 2021. The application is found still deficient and Final reminder was issued to the firm on 4th February, 2022 with following shortcomings: -

i. Form 1A along with enclosure / annexure / flags.
ii. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
iii. Attested CNIC's copies of all Directors.
iv. Latest Certified true copy of Form-29 (Attestation by SECP).
v. Detail of premises including layout plan.
vi. Proof of licensed sections from CLB.
vii. Approval letter of Production / QC Incharge in case of change than submit required documents as per check list.
viii. Up-to-date nothing due certificate regarding CRF from STO.
All documents should be duly attested.

Firm did not submit their reply till to date and application of Renewal of Drug Manufacturing License is still deficient.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12, Rule 16and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000259 by way of formulation of M/s Siza International (Pvt) Ltd, 18-KM, Main Ferozepur Road, Lahore, may not be suspended or cancelled

by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

Show Cause Letter was issued to the firm dated 26th May, 2022. In compliance to Show Cause Notice, the firm has replied and submitted the required documents.

But in the Form-29, submitted by the firm, in the Stamp of SECP, these words are mentioned that **"this office accepts no responsibility as to the correctness of the details given in the document"**

Proceedings and Decision by the Central Licensing Board in 290th meeting:

Application of the firm for renewal of DML is still deficient of Certified true copy of Form-29 issued by SECP. The Board considering the facts on record decided to offer final opportunity to the firm under Section 41 of Drugs Act, 1976 read with Rule 12 of Drugs (Licensing, Registering & Advertising) rules, 1976.

Accordingly, a letter for personal hearing was issued to the firm on 22-05-2023.

Proceedings and Decision by the Central Licensing Board in 291st meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of Show Cause Notice for the further period issued in the name M/s Siza International (Pvt.) Ltd, 18-KM, Main Ferozepur Road, Lahore

Case No.10. ESTABLISHMENT OF SITE VERIFICATION FOR DURG MANUFACTURING LICENSE.

It is submitted for information that as per the Drugs (Licensing, Registering & Advertising) Rules-1967 i.e., Rule-16(a) and Schedule-B-I, etc. site for establishment is approved by Central Licensing Board, accordingly.

For the application of site approval following documents are required to be submitted with the application for approval, as per the approved SOP.

Following listed documents/information's required for processing the request/application

i). Proper application on covering letter on letter head.

ii). Copy of Challan of fee i.e. Rs.75,00/- for site verification deposited under for verification of site for establishment of Pharmaceutical Manufacturing Unit.

iii). Disclosure of status of firm: proprietorship, partnership, public limited or private limited etc.

iv). Copy of Partnership deed duly executed in the court of competent jurisdiction/registrar of the firms in case of partnership.

v). Copy (s) of CNIC of Chief Executive Officer / Managing Director /Directors/ Partners.

vi). Copy of Certificate of Registration with Registrar of Firms in case of a registered firm.

vii). Complete documents of proposed land / plot (purchase document of land/plot, allotment letter, transfer letter/ possession letter, Fard, copy of site map or Aks Shajrah etc.)

viii). In case if firm is Private Limited, the Certificate of Incorporation with SECP, Memorandum and Article of Association, Form-A, Form-21 and Form-29 duly attested by SECP should also be furnished.

ix). All documents submitted should be duly attested by Notary Public /SECP/Registrar of firms, office as the case may be.

As per DRAP Act, 2022, Drug Act 1976, Licensing, Registering & Advertising Rule, 1976 and approved SOP there is no provision for rented sites. it is not clearly mentioned in the Rules/SOP or guidelines about the duration of the lease or rent agreement. However as per practice minimum lease or rent agreement for two tenures i.e., 10 years is accepted.

Proceedings and Decision by the Central Licensing Board in 291st meeting:

For the purpose of site verification, the Board considered the facts on record and decided to require a minimum lease period / rent agreement of 25 years for the establishment of pharmaceutical plants.

QUALITY ASSURANCE CASES
(GMP NON-COMPLIANCE)

Case No. I: - M/S. NOVARTANA PHARMACEUTICALS, SUNDAR INDUSTRIAL ESTATE LAHORE.

BACKGROUND

QA received letter No. 473/2023-DRAP(L-II) dated 30.01.2023 from the Additional Director DRAP, Lahore. Enclosed is the inspection report of the firm M/s. Novartana Pharmaceuticals, Plot No. 87-B, Sundar Estate Lahore conducted by following panel on 21.12.2022 in response to QA letter dated 06.12.2022.

i. Dr. Syed Zia Husnain, FID, DRAP, Lahore
ii. Hafiz Sanaullah Babar, AD, DRAP, Lahore
iii. Mr. Daniyal Ellahi Cheema, Area PID, Punjab.

The panel during inspection noticed following observations which need urgent attention and rectifications: -

Premises entrance

i. The doors of the premises were open and there were no wind curtains installed. The glass panel on the sides of the door were also shattered.
ii. All the entries including the emergency exit were open and were without wind curtains therefore, the production facility was exposed to the outside atmosphere.
iii. Cartons of glass vials and packing material were present in the corridors rather than in the packaging material store.
iv. HVAC was turned off.

Stores (Raw material store and Packing material store)

i. Un-labelled and without QC clearance raw materials were present in large quantities in the raw material store. The firm did not had a proper receiving or quarantine area.
ii. Packing material including glass ampoules and infusion bottles were placed on the same store along with APIs and excipients and there was no segregation provided for any of the materials mentioned.
iii. Dispensing hood was out of order and the management of firm had stored infusion caps in the dispensing hood. The dispensing was being done on a weighing scale present in the raw material store. (
iv. Tramadol API 1 Kg and Escitalopram API 1.5kg were present in the raw material store without obtaining ADC clearance from DRAP Lahore. On enquiry the management told that tramadol API was cleared from DRAP office Lahore however they did not produce any document at the time of inspection to verify their claim. Escitalopram API was kept for trial purpose as per statement of firm management during inspection. The above mentioned materials (APIs) were seized by the area Provincial Inspector of Drugs on Form-5 of the Provincial Government (Copy of Form-5 attached).

v. The API of product in question i.e. Linzolid was also checked by the panel. Firm provided ADC clearance of 25 Kgs of Linezolid from DRAP Lahore office however, firm had 17kgs out of 25kgs present in their store at the time of inspection. Management of firm claimed that they had only made 03 batches of Linzonov injection however on scrutiny of record it was suspected that firm had made more than 03 batches of product Linzonov infusion of which the BMRs were not present at the time of inspection. On enquiry, the management of firm replied that they had made 02 or 03 more batches of product Linzonov infusion but could not show the record of those batches during visit of the panel.

vi. There were un-identifiable and un-labelled cartons having packing materials and glass vials along with un-labelled bags suspected to contain active pharmaceutical ingredients were present in the packaging material store. The unlabeled bags and cartons were seized by the area Provincial Drug Inspector.

Finished goods store

i. There was no quarantine area and recalled/returned stocks area present in the store.

ii. Samples of product Linzonov Infusion were taken from the retained sample store for the purpose of test/analysis by the Provincial Drug Inspector.

iii. Syrup Section

iv. Doors of the syrup section were damaged, HVAC was not working and the pressure gauges were out of order.

v. The paint on the walls was flaking and the epoxy flooring was damaged that exposed the floor beneath.

vi. Packing material for Linzonov Infusion was stored in the quarantine are of the syrup section.

vii. Firm staff was washing glass infusion bottles in the syrup section. Broken glass shards were scattered all over the bottle washing machine and the floor of syrup section.

Injectable Section

i. Doors of the injectable section were damaged and HVAC was turned off. The pressure gauges were out of order

ii. The buffers were not maintained i.e. the buffer doors were open while sterile filling was being done in the filling section. There was no interlocking of buffers present.

iii. Lights were out of order, paint on the walls was flaking, floor epoxy was damaged reveling the floor below and there was liquid spillage on the floor in the corridors and filling area of sterile section.

iv. Sterile filling was being conducted in an un-controlled area and through an open stainless steel container and the material present in the container (claimed to be paracetamol IV solution) was being filled in the glass

infusion bottles via PVC pipes while the hopper of the filling machine had tools placed in it.

v. The packaging area of injectable section also had empty glass vials and infusion bottles and there was no staff present in that section.

Tablet section

i. HVAC was turned off. The pressure gauges were out of order.
ii. Panels of ceiling were missing and there was fungal growth on walls, ceiling and floor of the tablet section
iii. There was liquid spillage on the floor as well
iv. There were only ribbon mixer and cone mixer present in the section, no tablet manufacturing machinery was present in the section.

Quality Control

i. Quality control procedures required to be up-graded. Microbiology Laboratory was also required further up-gradations.

Quality Assurance

i. Quality assurance needs to be up-graded and special focus required to be given as presently quality assurance was not properly managed. More staff required to be recruited along with proper training. Timely calibration and process validation was also advised.

Documentation

i. BMRs missing. Firm was conducting manufacturing operations without keeping record of production as already mentioned in point 09.
ii. BMRs needs to be up-graded. Reconciliation mechanism required to be established for each API, excipient and quality control regents.
iii. Log books required to be maintained for each operation and equipment.

ACTION TAKEN BY QA&LT

Show cause notice was issued to the firm on 13.02.2023 and reminder was issued on 22.03.2023.

REPLY OF THE FIRM

The firm submitted reply vide letter No. Nil dated 30.03.2023 bearing subject **"Reply to Show Cause Notice".** Wherein, the firm has informed that the production activities at the facility were ceased since 21.12.2023. They have informed further that the premises have been de-sealed on the orders of the Drug Court Lahore. The firm has provided un-official copy of the decision which states that ***"D.I is further directed to inspect the premises after de-sealing and if finds any violation, he (D.I) will be at liberty to proceed in accordance with law."***

EVALUATION OF THE REPONSE

The firm has not addressed point/para wise response to the above noted observations, hence the response cannot be evaluated. CAPA submitted by the firm is not satisfactory.

RECOMMENDATION FROM QA&LT

In view of the scenario detailed above and the fact that the instant inspection was conducted in response to the **Cluster of serious adverse events with Inj Linzonov 600 mg (Linezolid) Batch No. LN003**, and the initial investigation report; the QA&LT Division recommends that,

under rule **12 of the Drugs (Licensing Registering and Advertising) Rules 1976; the proceeding for Cancellation or Suspension of Licenses may be initiated under 12 (1)** *If licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, …, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates*. **Through formal procedure under rule 12 (2)** *The Central Licensing Board shall, before cancelling or suspending a license under sub-rule (1), provide an opportunity of being heard to the licensee. Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 28.04.2023.*

PROCEEDING 290TH MEETING OF CLB: -

The case was presented before the Board, the Board was apprised that firm was issued with show cause notice and to appear before the Board for personal hearing, however, no representative of the firm appeared before the Board. During the detailed deliberation on the case it was discussed that, in light of the decision of Central Licensing Board in its' 278th meeting regarding the delegation it's powers pertaining GMP issues to the Director of QA&LT for timely disposal of matters. The Director QA&LT shall constitute a panel of experts to verify the claim of the firm and the Division may place the outcomes of the inspection before the CLB for assisting the Board in deciding the fate firm.

DECISION OF 290TH MEETING OF CLB: -

Since no representative of the firm appeared before the Board for personal hearing therefore, the Board decided to offer final opportunity of being heard in person to the firm prior to taking any decision for violation of conditions of DML and non-compliance of GMP. The case was deferred till next meeting.

PROCEEDING 291ST MEETING OF CLB: -

Col.(R) Saqib Hayat, CEO M/s Novartana Pharmaceutical, Lahore appeared before the CLB in the 291st meeting in response to QA&LT Letter No. No.F.8-3/2023-QA (M-291-CLB) dated 29.05.2023, for personal hearing. The representatives of the firm stated firm's point of view in the case and submitted that they have now rectified all the shortcomings pointed out during the inspection and requested for verification of compliance.

DECISION OF 291ST MEETING OF CLB: -

The Board after hearing the stance of the firm and thorough deliberation on the facts of the matter; concluded that: -

i. *The production activities of the firm M/s Novartana Pharmaceutical, Lahore shall remain suspended.*
ii. *The panel of experts constituted vide QA&LT Letter No. F. 4-01/2023-QA shall submit the report to Division of QA&LT within 15 days and the Division shall process the GMP related matter for resumption of production activities or otherwise.*
iii. *The Division of QA&LT shall apprise the board on the proceedings thereof in the forthcoming meeting of CLB.*

Case No. II: - <u>M/S. PAK RISEN PHARMACEUTICAL, PLOT NO. 3, BLOCK B, PHASE I-II, INDUSTRIAL ESTATE HATTAR.</u>

<u>BACKGROUND</u>

The inspection report of the firm M/s. Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar, was received at the Division of QA&LT. The inspection was conducted on 05th & 06th August, 2021 by Mr. Faisal Shahzad, FID-I, DRAP, Peshawar. The FID mentioned in his report that prior to this inspection, FID visited the premises of the firm on 05.03.2021 wherein the firm informed that their facility is under maintenance and inspection was postponed on the request of the firm. Later on the firm informed vide their letters dated 06.04.2021 and 28.05.2021 that they have done all maintenance work, resumed production and are ready for inspection. Surprise inspection of the firm was done in order to evaluate adherence of the firm towards cGMP compliance under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976. As per report dated 5th and 6th August, 2021, the FID noticed following observations: -

<u>Change Rooms: -</u>

i. Air curtains installed at the entrance of change rooms are poorly maintained and found rusty / dusty, having number of open cracks in wall at installation points.
ii. Change room for male staff was found maintained with proper step over bench. However, minor maintenance w.r.t. paint job was advised.
iii. Female change room was found not maintained. No insect killer was installed. Change room was found dirty.
iv. SOPs for changeover were not found observed in the female change room.
v. Change room provided for female staff needs improvement w.r.t. hygienic conditions, placement of street shoes/ clothes/ bags etc., in proper cabinets.
vi. Training for change over to avoid any risk of contamination to production areas may be arranged periodically for workers.

<u>Storage Areas: -</u>

i. The firm has provided receiving bay for the incoming raw/ packing materials. However, receiving bay was found poorly maintained. No cleaning equipment was found for dusting / cleaning of incoming materials.
ii. No quarantine area was found / marked in ware house.
iii. No sampling booth facility is available.
iv. Rejection / Recall area is being used as quarantine area.
v. In the raw material approved area temperature / humidity needs to be properly maintained with supporting data / record.

vi. In the dispensing area, dispensing booth is not provided with proper air supply. The same dispensing booth is used for sampling of raw materials. Tools for raw material dispensing also need to be properly labelled after cleaning.

vii. The firm has small finished goods store. No product was found available in the finished goods store. The QCM of the firm informed that all the batches are dispatched as soon as released from their department and no stocks are usually available in the finished goods store.

viii. Empty Ampoules and vials storage area;

1. This area is located at the other end of the building in front of ancillary area i.e., WCs (not properly maintained) provided by the firm for the workers. In front of these WCs, an opening through a narrow, dark gallery leads directly to vials / ampoules storage area without any door.
2. All the vials / ampoules were found without any QC release labels.
3. Storage conditions were found un-hygienic with placement of stocks on dirty floor. Walls, ceiling were also found dirty.
4. Drainage and un-plugged sewerage holes were observed at several places.
5. The firm has provided pass through window from this un-maintained / unhygienic, ampoules / vials store which opens in the De-Cartoning / washing area of injectable section of the firm.

Production areas: -

Liquid Ampoules / Infusion Section: -

i. Vial washing area as reported above is connected with the vials / ampoules store by a pass through SS window. The taps and water sink provided for vial / ampoules washing was observed rusty and not properly maintained.

ii. Similarly, ampoules / small / large vial washing area is provided by a SS overhead hood without any filters while background air quality, though provided through a small HEPA filter, do not seems qualified for class C nor any evidence is produced by the firm for area qualification for injectable vial/ ampoule washing.

iii. Drainage / sewerage system in the area was observed un-hygienic status, filled with mud / broken glass / contaminants and un-fixed slabs over drainage line.

iv. HVAC system of the area is without any proper qualification as the firm did not provided any documentary evidence.

v. Distill water loop system was not satisfactory as the water loop system required for injectable section.

vi. Vials / Ampoules sterilizers were also not properly maintained with tilted, rusty panels/ brackets inside.

vii. No qualification of blowers is done for hot air or their cleaning/ maintenance or air quality inside the heat chambers of sterilizers.

viii. Liquid ampoules/ large vials manufacturing area as well as filling/ sealing area needs maintenance w.r.t. walls, flooring, ceiling, air inlet and outlet grills, epoxy paint, cleaning of machines/ equipment etc.,

ix. Optical checking area as well as packing area also need proper maintenance of walls, floor, and ceiling.

x. In process storage area was not clearly marked. It was informed that all the finished products are stored in finished goods area and as soon as released from QC, it is shifted to sale points.

xi. A spare ampoule filling machine (rusted) is also placed in area which was advised to be removed immediately.

xii. Overall HVAC system of the area is not as per GMP requirements w.r.t. air quality, area segregations w.r.t. air quality, lacking proper doors as required in injectable area, air locks, pressure differentials monitoring and need overall improvement in accordance with GMP guidelines.

Dry Powder Vial Injection: -

i. The vial washing area and sterilization area have same observations as mentioned for liquid injectable since common areas are being used for said purpose. Further, Ceph area requires dedicated facilities and the firm has informed that they are in process of revising their lay out plan. However, the observations of vial washing as well as vial sterilization are same for Ceph vials, as reported above.

ii. Vials after sterilization are opened in vial filling area. The firm was unable to explain how the sterile vials are transported to vial filling station under controlled environment to keep them sterile, since the products are not terminally sterilized manufactured in this section. Area background was informed as Class C (though no validation data available with the firm) while filling operations is under laminar Class A. Laminar curtains (flexible plastic) also not properly mounted not properly cleaned.

iii. The panels of the manual filling machine were observed rusty and sticky powder was observed due to scotch tapings done around the machine panels.

iv. Backside of filling machine was also found not properly maintained and not cleaned.

v. Area not maintained w.r.t. walls, flooring and ceiling. Crack/ peel of plaster was observed at the laminar hood mounting.

vi. Vial sealing machine is also an old rusty equipment not maintained properly.

vii. Overall HVAC system of the area is not as per GMP requirements w.r.t. air quality, area segregations w.r.t. air quality, lacking proper doors as required

in injectable area, air locks, pressure differentials monitoring and need overall improvement in accordance with GMP guidelines.

Quality Control: -

i. The firm management has procured Liquid Particle Counter in the year 2020 but it was never functional.
ii. Similarly, Total Organic Carbon analyzer was also procured by the firm Management in 2020 but it was never functional.
iii. Testing methods are still on UV based as provided HPLC by the management is not with required columns and columns oven. HPLC is also not 21CFR compliant.
iv. FTIR is planned to be procured by the firm Management for License Renewal preparation.
v. Latest Pharmacopeias are also not provided.
vi. Reference standards were never procured; it was advised to procure RSs stepwise from independent source.
vii. Stability studies are being performed but without following a proper stability protocol, the studies are not acceptable. Further, no power backup exists for QC equipment or stability chambers.
viii. No records exist for testing of primary packing materials like glass vials or rubber stoppers.
ix. Microbiology Lab also needs to be upgraded w.r.t. infrastructure, design, facilities, equipment and air system. Testing of all HVAC air systems w.r.t. particulate matter/ microbiological testing must be in line with GMP guidelines.

Quality Assurance: -

i. The department nor any personnel exists for Quality Assurance. The firm has informed that they are in process of hiring of well qualified QA manager.

Personnel: -

i. Hired staff for production but the production Manager was found absent on both occasions of inspection. Further, no leave record of qualified production Manager was available or provided by the firm. One production pharmacist with 2-years' experience is hired by the firm who assisted during the inspection of production areas.
ii. Mr. Jehangir Alam is performing duties as QCM. One microbiologist is hired for microbiology lab.
iii. No technical person hired for QA department.
iv. One non-technical female staff is hired as store In-charge.
v. No training record was available for the technical staff/ workers.

Allied facilities: -

i. The firm has not provided satisfactory loop distill water system along with proper monitoring as required for injectable areas as well as liquid injection manufacturing.

ii. Ancillary areas are also not up to the mark.

Conclusion

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

ACTION TAKEN BY QA&LT

Keeping in view the observations noticed and conclusion of report by the FID, **Show Cause Notice / Order of Suspension of Production Activities in all Sections** was issued to the firm M/s. Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar vide No. F.4-2/2006-QA (Vol-I) dated 23.08.2021.

REPLY OF THE FIRM

In response to this office show cause notice, the firm replied vide letter No. PAK/HTTR/021-1 dated 09.09.2021. The response of firm reproduced below;

"It is humbly stated that we have received show cause notice No. f 4-2/2006-QA (Vol-I) on 30th of August 2021. We have deeply gone through the notice and would like to explain our position to the honorable DRAP in followings: -

During FID visit the firm was already out of production from 2nd August, 2021. FID has visited and witnessed by himself and checked all areas and records there was no production at all.

Lots of things caught rough and unfinished properly because our layout Plan has been submitted for regularization and already discussed in Licensing department and approval is about to be issued within few days as told by the concern department from DRAP.

So, a lot of civil works need to be done that's why we had left our routine (03 months interval) scheduled maintenance/refurnish work and because of unsatisfactory conditions we opted the stoppage of production.

At the time of inspection only Q.C Staff was present in entire unit because of installation and calibration team of Q.C Equipment had to visit at that very day and Rest of that staff was on leave just because there was a stoppage period of the production.

Moreover, Raw Material store Finished Goods store areas are as per DRAP recommendations as previous DML inspection panel approved and suggested this.

Still we are going to do a huge civil work for Layout Plan regularization we need a lot of amendments and rearrangements of our unit flow.

We have noticed and accepted the honorable FID's suggestion and recommendation with open heart and we will follow them and will amend. And we would like to inform you that we have already done most of the work in connection to FID's recommendations before writing this show cause reply i.e.

1	*In Change Rooms New Roof Sealing has been done in both Male and Female & SOPs affixed.*	✓
2	*HVAC system has been qualified through DOP test and as recommended air supply has been increased by addition supply duct as*	✓

	to comply with standards.	
3	*In QC HPLC has been updated (21 CFR compliances) latest Pharmacopeias and Working Standards have been purchased. TOC and Liquid particle counter repaired.*	✓
4	*In R.M store Dispensing both has been supplied with filtered Air.*	✓
5	*S. Steel items have been republished & repaired.*	✓

Rest of the points / works will automatically be rectified when we will do civil works/constructions for Layout plan regularization.

Dear Sir,

We request the honorable DRAP not to take any strict action give us a chance and time as we are in process for regularization of our unit's layout and for that we will have to refurnish, reconstruct and will reinstall most of the sections path ways and their entrance and associated related areas again.

So, ultimately the firm will come with new and improved look as per GMP and Drug Rule (Schedule B-11)"

CORRESPONDENCE BY QA&LT & ITS REPONSE

The firm was asked vide this office letter No. 4-2/2006-QA(Vol-I) dated 21.09.2021 to submit all supporting documents as evidence for the Corrective and Preventive Action (CAPA) plan to this office. The reply of the firm is still awaited.

The firm submitted a detailed reply vide letter No. PRP/DRAP/2021 dated 01.10.2021 wherein they have stated that they are working on rectifying deficiencies pointed out by the FID. Furthermore, they have stated that rectification of most of the observations is associated with civil work. The civil work is associated with regularization of LOP, for which, they have applied.

The matter was placed before the Central Licensing Board in its 283rd meeting.

PROCEEDINGS OF 283RD MEETING OF CENTRAL LICENSING BOARD;

Mr. Shoaib Khan, Admin Manager of M/s Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar appeared before the board and stated that management could not appear before the board due to death of their son. Mr. Shoaib Khan stated that they will construct their facility as per regularized lay out plan within time period of 1 month.

DECISION OF 283RD MEETING OF CENTRAL LICENSING BOARD;

The board after considering the statement of firm's representative and deliberating on the matter and decided as under;

i. The production of the firm M/s Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar shall remain suspended.
ii. Following panel of experts shall inspect the firm M/s Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate Hattar;
    a. Prof. Dr. Jamshaid Ali Khan, Expert Member.
    b. Area FID DRAP Peshawar.
    c. Area Assistant Director DRAP Peshawar.

iii. The Additional Director QA&LT shall pass orders on the recommendations of panel inspection report and present case in subsequent meeting of CLB for ratification.

PANEL INSPECTION REPORT

The panel inspection report was received at the QA&LT Division vide Letter No.11-53/2005-Pak Risen-DRAP 332 dated 27th March, 2023 from Mr. Faisal Shehzad received in this office on 05.04.2023; Titled " Decision of Central Licensing Board in its 283rd meeting; Pak-Risen Pharmaceuticals", the inspection was conducted on 26.01.2023 by panel of experts nominated by the CLB. The panel has made following observations: -

Change Rooms

The firm improved its change rooms with reference to paint and air curtains however, overall change over process, control of contamination, uniform/shoes changeover has not been properly organized/ defined nor the SOPs prepared to clearly mention the steps to proceed in change rooms to avoid contamination. Uniform change areas, pest control system and dust control procedures were found not adequate.

Storage areas

Storage area for primary packing material is observed as devoid of any receiving bay or cleaning e.g. for incoming materials. No quarantine/sampling area is designated. No temperature humidity monitoring system. Obnoxious smell due to old, closed, moist, small cubicle type building without any air circulation system was noted. No substantial improvement was observed as already reported in inspection dated 05th-06th August, 2021.

Production Areas (Liquid Ampoules/ infusion section)

The firm has improved area limited to paint/epoxy flooring and similar civil work, however, technical observations mentioned under the inspection report dated 05th-06th August, 2021 are not addressed in letter and spirit nor any documentary evidence has been generated for any review.

Dry Powder Vial Injection

The firm has improved area limited to paint/epoxy flooring and similar civil work, however, technical observations mentioned under the inspection report dated 05th-06th August, 2021 were not addressed in letter and spirit nor any documentary evidence has been generated for any review.

Quality Control

Technical observations mentioned under the inspection report dated 05th-06th August, 2021 were not addressed in letter and spirit nor any documentary evidence has been generated for any review.

Quality Assurance

Technical observations mentioned under the inspection report dated 05th-06th August, 2021 were not addressed in letter and spirit nor any documentary evidence has been generated for any review.

Allied Facilities

Technical observations mentioned under the inspection report dated 05th-06th August, 2021 were not addressed in letter and spirit nor any documentary evidence has been generated for any review.

The panel has concluded ***"Keeping in view the above mentioned observations, the panel is of the opinion that the firm has not followed corrective and preventive actions in true letter and spirit for injectable dosage form and matter is accordingly reported to QA&LT Division for further necessary action."***

RECOMMENDATION FROM QA&LT

In view of the scenario detailed above and the fact that the instant inspection was conducted in response to the decision of the CLB from its 283rd meeting, since the firm had claimed to have made rectifications and ample time for the same was given to the firm; the QA&LT Division recommends that, under rule **12 of the Drugs (Licensing Registering and Advertising) Rules 1976; the proceeding for Cancellation or Suspension of Licenses may be initiated under 12 (1)** *If licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, …, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates*. **Through formal procedure under rule 12 (2)** *The Central Licensing Board shall, before cancelling or suspending a license under sub-rule (1), provide an opportunity of being heard to the licensee. Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 28.04.2023.*

PROCEDING 290TH MEETING OF CLB: -

The case was presented before the Board, the Board was apprised that firm was issued with show cause notice and to appear before the Board for personal hearing, however, no representative of the firm appeared before the Board.

DECISION OF 290TH MEETING OF CLB: -

Since no representative of the firm appeared before the Board for personal hearing therefore, the Board decided to offer final opportunity of being heard in person to the firm prior to taking any decision for violation of conditions of DML and non-compliance of GMP. The case was deferred till next meeting.

PROCEEDING 291ST MEETING OF CLB: -

Mr. Sabir Khan, CEO M/s Pak-Risen Pharmaceutical and Dr. Sheryar Nazir MD, M/s Pak-Risen Pharmaceutical, Hattar appeared before the CLB in the 291st meeting in response to QA&LT Letter No. No.F.8-3/2023-QA (M-291-CLB) dated 29.05.2023, for personal hearing. The representatives of the firm narrated that now they have made extensive improvements and requested for inspection to verify the improvements.

DECISION OF 291ST MEETING OF CLB: -

The Board after hearing the stance of the firm and thorough deliberation on the facts of the matter; concluded that: -

i. *The production activities of the firm M/s Pak-Risen Pharmaceutical Hattar, shall remain suspended.*

ii. *A panel of experts shall be constituted including the Chief Inspector of Drugs Khyber-Pakhtunkhwa Mr. Younis Khattak, Area Federal Inspector of Drugs and One Auditor from GMP Audit pool, DRAP, which shall be mandated to verify the rectification status of the previous observations and evaluate overall compliance of the firm with respect to conditions of DML and GMP.*

iii. *The Division of QA&LT shall apprise the board on the proceedings thereof in the forthcoming meeting of CLB.*

Case No. III: <u>COMPLAINT OF COS-CH COUGH SYRUP (PRODUCT ENLISTMENT NO. 0265680138, BATCH NO. H5046) MANUFACTURED BY M/S CIBEX PVT LTD PLOT NO. F-405 SITE KARACHI</u>.

A complaint dated 3rd February 2023 was received from a patient regarding manufacture & sale of spurious cough syrup namely **"COS-CH"** manufactured by M/s Cibex (Pvt) Ltd, F-405, SITE Area, Karachi.

M/s. Cibex (Pvt) Ltd, located at **F-405, SITE Area, Karachi** is enlisted as manufacturer of **Liquid (Solution, Syrup, Suspension, Drop), Tablet, Capsule, Sachet, Cream** vide **Enl. No.00265** by the Authority (approved in 12th Meeting of EEC and as approved vide File No.1-17/2015-DDC)				
Meeting Number	Product Enlistment Number	Approved Brand Name, Dosage Form, Formulation	Recommended Use	Pack Size
68th Meeting	265680138	COS-CH COUGH WITH HONEY SYRUP Each 5ml contains: Levomenthol …….6.25mg Honey…….300mg	Supplement for relief from cough	120ml

2. Following panel is constituted to conduct a PSI regarding complaint and submission of comprehensive report: -

1. Additional Director (E&M), DRAP, Karachi.

2. Area Federal Inspector of Drugs, DRAP, Karachi.

3. Inspection report of M/s. Cibex (Pvt) Ltd, located at F-405, site area, Karachi, Mr.Abdul Rasool Sheikh along with Dr.Shoiab Ahmed visited the premises on 23rd February 2023 to verify the authentication of the complaint.

- Mr. Ameen Nota, CEO of the firm,
- Miss Wajeeha Mateen Production Manager
- Mr. Adeel Manager Supply Chain and other technical person from respective departments assisted during the course of inspection.

Followings are the outcome of the inspection by the panel.

i. As per the details provided and the same was verified from the management of the firm that firm is possessing Manufacturing Enlistment No.00265 under H&OTC Rules and also possessing necessary Form-7 for COS-CH syrup E.No.0265680138.
ii. The firm also possessing DML No.000784 (By way of formulation) at the same premises for some general sections like tablets, Capsules, Liquid Syrup at ground floor, whereas H&OTC Nutraceutical separate facilities are kept as first floor for tablets, capsules and liquid syrups.
iii. During the detail inspection of the entire facilities it was dawned upon that the firm is manufacturing their all H&OTC products in their liquid Pharma section which was verified from respective log books. H&OTC facilities were seen un-operational at the time of inspection. From dispensing to packing all production activities for Nutraceutical products are carried out in their Pharma sections (records pertaining to these activities were taken into custody and copies are enclosed for your kind perusal).
iv. As evident from machine log books prior to COS-CH syrup various Pharma products like Famotidine, Ibuprofen and Paracetamol were manufactured inside the Pharma liquid section and on the same machines which might have caused cross-contamination into the H&OTC product, hence sample of the same batch was taken on form-3 for further confirmation of these impurities into the product form 4 enclosed.
v. The samples were sent to CDL for further testing and confirmation.
vi. The records taken further potentiated that the nothing was tested on semi-finished and finished goods like potency of active, identification & most critical the microbial bio-burden of the syrup and that may have caused the syrup hazardous and ineffectiveness.
vii. The management further provided a statement whereby confirming that their H&OTC products were being manufactured in their Pharma liquid sections.
viii. Keeping in view of the above stated observations it was concluded that besides provisions of H&OTC Enlistments & respective sections the firm had not to manufacture those products in their Pharma section and could tantamount to an offence of manufacturing an un-registered product with the most possibilities of cross-contamination hence their both the liquid sections (Neutra & Pharma) were ordered to be locked-sealed on form-1 under section 18(1) h of the Drugs Act 1976.

4. **Recommendation of the Panel**

It is recommended by the panel that their DML and HOTC License may kindly be suspended for certain period after due deliberations at the boards concerned in the larger public interest.

5. It is stated that as per Rule 8 (16) of Drugs (Licensing, Registration & Advertising) Rules 1976, the Central Licensing Board shall cancel or suspend the manufacturing license or withdraw permission of any particular section or a firm after giving personal hearing or show cause notice to the concerned firm.

6. In light of above case is placed before the Board in light of recommendations of the panel, please.

Decision of 290th CLB: The Board decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000451 by way of formulation (DML No.000784) of M **/s.** Cibex (Pvt) Ltd, located at F-405, SITE Area, Karachi, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

PROCEEDING 291ST MEETING OF CLB: As per the decision of 290th meeting of CLB**,** Representative of the firm M/s. Cibex (Pvt) Ltd, located at F-405, SITE Area, Karachi was issued Show Cause/ Personal Hearing letter dated 24th May 2023. In compliance to decision of 273rd meeting of CLB, firm's representative i.e. Mr. Haroon Dugal (Legal Advisor) and Mr. Ameen Nota (CEO) appeared before the Board and presented their stance. The representatives of the firm admitted the findings of the inspection and submitted that they received huge order from the market therefore, they committed this mistake.

DECISION OF 291ST MEETING OF CLB: -

The Board after considering the statement of firm's representative and through deliberation on the matter, ***decided to cancel the Drug Manufacturing License of the firm bearing No. 000784 up to the extent of "Oral Liquid Section"*** under Section 41 of the Drugs Act, 1976 read with DRAP Act, 2012 and Rule 12 of the Drugs (L, R&A) Rules, 1976, for non-compliance of Rule 16 and 19 of the Drugs (L,R&A) Rules, 1976, from the date of issuance of decision of the 291st meeting of CLB. The Board further decided to forward the reference to H&OTC Division to take up the matter of manufacturing of H&OTC products in the Pharmaceutical section in the light of inspection report.

Case No. IV: SHOW CAUSE NOTICE / STOP PRODUCTION OF M/S ROTEX PHARMA, PLOT # 206, 207, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD.

The inspection of M/s Rotex Pharma, Plot # 206 & 207, Industrial Triangle Kahuta Road, Islamabad was carried out from 20.02.2023 to 22.02. 2023, by the following inspectors of Drug Regulatory Authority of Pakistan: -

i. Dr. Mahvash Ansari, Deputy Director DRAP, Islamabad. **(Lead Auditor)**
ii. Dr. Uzma Barkat, Deputy Director DRAP, Islamabad. **(Auditor)**
iii. Dr. Affan Ali, Deputy Director DRAP, Islamabad. **(Auditor)**

2. The panel has reported various observations of critical nature, furthermore the panel has concluded the report as:

"The inspection was conducted for the purpose of benchmarking. The unit is a shared facility currently manufacturing Cephalosporin, Carbapenem, Steroidal, and Oncology products along

with General products. Hence inspection was planned considering the sensitivity of products being handled and criticality of the operations being carried out in the facility focusing on Oncology & Cephalosporin section along with General section, in order to assess the control measures established to assure sterile manufacturing and to avoid Contamination and Cross-contamination. ***Based on the findings of the inspection, review of documents and records, systems, utilities, physical inspection of areas in the manufacturing facility mentioned above, and interview of personnel, it is concluded that the firm is not operating at an acceptable level of cGMP compliance"***

3. Therefore, keeping in view the public interest and to safe guard the public health at large the competent authority i.e. Director QA&LT (as authorized by Central Licensing Board (CLB) in its 273rd meeting) has decided to stop production of your firm in all manufacturing sections with immediate effect.

4. The firm was issued Show Cause notice/ Personal Hearing on 28th April 2023. A letter No. Ref: HDLC/ROTEX/DRAP/631 dated 2nd May 2023 from Haroon Dugal Law Chambers stated the said inspection was alleged and flawed. Our Client has approached the Court of Learned Senior Civil Judge, Islamabad through a Civil Suit titled as M/s Rotex Pharma (Pvt) Limited Vs. Drug Regulatory Authority Pakistan and others (Civil Suit) questioning the legitimacy and constitutionality of the said investigation

5. Consequently, a reminder letter dated 25th May 2023 was issued for personal hearing to be held on 30th May 2023.

PROCEEDING 291ST MEETING OF CLB: Representative of the M/s Rotex Pharma, Plot # 206 & 207, Industrial Triangle Kahuta Road, Islamabad was issued Show Cause/ Personal Hearing letter dated 28th April 2023.

In compliance to letter dated 28th April 2023, firm's representative i.e. Mr. Haroon Dugal (Legal Advisor), Mr. Umar (CEO), Mrs. Mauvra Khawaja appeared before the Board and presented their stance, in which they submitted that they intend to challenge the inspection report. The firm requested to grant them an adjournment for enabling them to avail the statutory remedy against the inspection under the GMP Inspection Committee (Appeal) Regulations, 2017(S.R.O.1012(I)/2017

DECISION OF 291ST MEETING OF CLB: -

The Board after considering the statement of firm's representative and deliberation on the matter decided to accede the firm's request and adjourned the matter till the decision of GMP inspection committee as per S.R.O.1012(I)/2017.

Case No. V: SHOW CAUSE NOTICE / STOP PRODUCTION OF M/S CARAWAY PHARMACEUTICALS, PLOT NO 12, STREET NO. N-3, RCCI INDUSTRIAL ESTATE, RAWAT, ISLAMABAD

The inspection of your firm i.e. M/s. Caraway Pharmaceuticals (Pvt.) Ltd. Plot No. 12, Street No. N-3, RCCI Industrial Estate, Rawat, Islamabad, Pakistan was carried out from 31.10.2022 to 03.11. 2022, by the following inspectors of Drug Regulatory Authority of Pakistan: -

i. Mr. Hasan Afzaal, Deputy Director, **(Lead Auditor)**
ii. Mr. Adnan Shahid Ullah, Deputy Director, **(Auditor)**
iii. Mr. Adil Saeed, Deputy Director, **(Auditor)**

2. The panel has reported various observations of critical nature, furthermore the panel has concluded the report as:

"It has been unanimously concluded by the panel that as the nature of the deficiencies is critical in most cases, hence the firm is operating at a high-risk status certain points require urgent attention."

3. Keeping in view the public interest and to safe guard the public health at large the competent authority i.e. Director QA&LT (as authorized by Central Licensing Board (CLB) in its 273rd meeting) has decided to stop production of your firm in all manufacturing sections with immediate effect. You are therefore, directed to stop manufacturing of drugs in all sections with immediate effect.

4. **Reply of the Firm: -**

The firm submitted a letter S No. 15929 dated 16th May 2023, stating that we had raised an internal CAPA on which we started working since November 2022. The firm further said that all critical and major points have been addressed. They also submitted CAPA.

PROCEEDING 291ST MEETING OF CLB: The matter was discussed in the Board. The QA&LT Division apprised the Board that firm has submitted the reply to show cause notice and accordingly CAPA has also been submitted by the firm. CAPA was evaluated in the division and the Director QA&LT has constituted a panel of inspectors for verification of CAPA as per delegation of powers. Inspectin for verification of CAPA is yet to be conducted.

DECISION OF 291ST MEETING OF CLB: -

The Board after deliberation in matter decided that QA&LT will conduct the inspection as per constituted panel and apprise the Board after the follow-up activities and regulatory decision in the said matter.