

**MINUTES OF 319th MEETING OF CENTRAL LICENSING BOARD
HELD ON THURSDAY, 7th AUGUST, 2026**

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VENUE: Committee Room of Drug Regulatory Authority of Pakistan, NCLB Building,
Near NIH, Islamabad.

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**Division of Drug Licensing
Drug Regulatory Authority of Pakistan
Islamabad**

319th meeting of the Central Licensing Board (CLB) was held on 7th August 2026 in the Committee Room of NCLB Building, Drug Regulatory Authority of Pakistan, Islamabad under the Chairmanship of Dr. Noor Muhammad Shah, Director (Division of Drug Licensing), Drug Regulatory Authority of Pakistan, Islamabad. Following members attended the meeting: -

S. No	Name & Designation	Status
1.	Ch. Zeeshan Nazir Bajar, Director (QA& LT), Representative of the Division of QA & LT, DRAP Islamabad.	Member
2.	Abid Ali, Additional Draftsman, Representative of M/o Law & Justice, Government of Pakistan, Islamabad.	Member
3.	Dr. Faisal Mehmood, Chief Drugs Controller, Government of Punjab, Lahore	Member
4.	Mr. Ghulam Ali Lakho, Chief Inspector of Drugs, Government of Sindh, Karachi	Member
5.	Mr. Mehtab Afsar, Chief Inspector of Drugs Peshawar, Government of Khyber Pakhtunkhwa. (attended online via Zoom)	Member
6.	Mr. Sarwar Khan Kakar, Chief Inspector of Drugs, Government of Baluchistan, Quetta.	Member
7.	Mr. Abdullah Diyo, Additional Director (Licensing), DRAP	Secretary-cum-Member

The meeting started with the recitation of verses from the Holy Qura'an. The Chairman welcomed the participants. Mr. Abdul Ghaffar, Deputy Director (Lic-II), Mr. Akbar Ali, Deputy Director (Lic-I), Ms. Zunaira Faryad, Deputy Director (Lic-III), Mr. Abdullah Bangash, Deputy Director (Lic-IV) and Ms. Saadia Mehewish Additional Director (QA<) assisted the Secretary of the Board in presenting the agenda.

Item No.I GRANT OF NEW DRUG MANUFACTURING LICENSES.

The **recommendations** of the panel of experts/Inspectors for grant of new Drug Manufacturing License are placed for consideration / Decision of the Board for following cases, please:

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s. Premier Life Pharmaceuticals (Pvt.) Ltd., Plot N. 181/1, Road L-9, Industrial Estate Gadon Swabi. New DML <i>Evaluator: Abdul Ghaffar (DD-Lic)</i>	24-07-2026	Good	1. Faisal Shahzad, Additional Director DRAP, Peshawar. 2. Shahid Nawaz, FID-II, DRAP, Peshawar. 3. Zakir Shah, Chief Drug Inspector, Khyber Pakhtunkhwa, Peshawar.
<u>Recommendations of the panel: -</u> Keeping in view of the above inspection details, the panel unanimously recommends the grant of DML by way of formulation to M/s Premier Life Pharmaceuticals (Pvt.) Ltd., Plot NO. 181/1, Road L-9, Industrial Estate Gadon Swabi for the following sections: i. Oral Liquid Section I (Veterinary) ii. Oral Liquid Section II (Veterinary) iii. Bolus Section (Veterinary) iv. Oral Dry Powder Section (Veterinary) v. Topical Spray (Veterinary) pump type without propellant. Panel also informed that the applicant was not ready for inspection of Liquid Injection (Vial) Veterinary section and they will apply for inspection as and when they will be ready. <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors approved the grant of Drug Manufacturing License – By way of Formulation in the name of M/s Premier Life Pharmaceuticals (Pvt.) Ltd., Plot No.181/1, Road L-9, Industrial Estate, Gadoon Swabi for the following sections: 1. Oral Liquid Section-I (Veterinary) 2. Oral Liquid Section-II (Veterinary) 3. Bolus Section (Veterinary) 4. Oral Dry Powder Section (Veterinary) 5. Topical Spray (Veterinary) (Pump Type without Propellant)				

2.	M/s Himmel Pharmaceuticals (Pvt.) Ltd., Plot No.69, Phase-1A, M-3 Industrial City, Faisalabad. Grant of DML <i>Evaluator: - Akbar Ali (DD-Lic)</i>	31-07-2026	Good	1. Mr. Abdul Rashid Sheikh, Deputy Director, DRAP, Lahore. 2. Mr. Muhammad Umar Latif, Federal Inspector of Dugs, DRAP, Lahore
<u>Recommendations of the panel: -</u> In view of the inspection of the building facility, flow of personnel and materials, and evaluation of equipment installed, technical personnel interviewed, quality management system, quality assurance practices, practices in production and quality control, utilities and documentation reviewed at the time of inspection. The panel is of the opinion to recommend the facility for grant of Drug Manufacturing License (By Way of Formulation) with reference to DRAP, Islamabad letter Tracking ID No. V4T-SMU-PEPT dated, 04-06-2026, to M/s Himmel Pharmaceuticals (Private) Limited for the following sections: i. Tablet Section (General) ii. Capsule Section (General) iii. Oral Liquid Section (General) iv. Warehouse v. Quality Control Laboratory vi. Microbiology Laboratory vii. Research & Development Lab. <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors approved the grant of Drug Manufacturing License – By way of Formulation in the name of M/s Himmel Pharmaceuticals (Pvt.) Ltd., Plot No.69, Phase-IA, M-3 Industrial City, Faisalabad for the following sections: 1. Tablet (General) 2. Capsule (General) 3. Oral Liquid (General) 4. Research & Development Laboratory (For product development)				
3.	M/s Jafson Pharmaceuticals (Pvt.) Ltd., Plot No.65-B, Industrial Estate Hayatabad, Peshawar. Afresh-Grant of DML <i>Evaluator: - Abdul Ghafar (DD-Lic)</i>	23-04-2026 & 02-07-2026	Good	1. Mr. Mehtab Afsar, Chief Inspector of Drugs, Peshawar. 2. Syed Adnan Ali Shah, Deputy Director, DRAP, Peshawar. 3. Mr. Shahid Nawaz, FID, DRAP, Peshawar.

	<u>Recommendations of the panel: -</u> Keeping in view of the above inspection details, the panel unanimously recommends the Re-grant of DML No. 000507 by way of formulation to M/s Jafson Pharmaceuticals (Pvt.) Ltd., Plot No.65-B, Industrial Estate Hayatabad, Peshawar for the following section: i. Liquid Section General ii. Tablet Section General iii. Capsule Section General <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors approved the grant (afresh) of Drug Manufacturing License– By way of Formulation in the name of M/s Jafson Pharmaceuticals (Pvt.) Ltd., Plot No.65-B, Industrial Estate Hayatabad, Peshawar with same DML No. 000507 for the following sections: 1. Liquid Section (General) 2. Tablet Section (General) 3. Capsule Section (General)															
4.	M/s Sami Pharmaceuticals (Pvt) Ltd., F-124, Off Hub River Road, S.I.T.E., Karachi. Grant of DML <i>Evaluator: - Abdullah (DD-Lic)</i>	13-07-2026 & 17-07-2026	Good	1. Dr. Noor Muhammad Shah, Chairman CLB, DRAP, Islamabad. 2. Mr. Abdul Rasool Sheikh, Additional Director, DRAP, Karachi. 3. Mr. Muhammad Tahir Waqas, Area FID, DRAP, Islamabad.												
<u>Recommendations of the panel: -</u> Based on the inspection findings, the inspection panel concludes that the manufacturing facility has been established with an appropriate Pharmaceutical Quality System together with adequate manufacturing, quality control, engineering and support facilities necessary for the proposed manufacturing operations. The overall infrastructure, equipment qualification, validation status, environmental controls, documentation system and quality assurance arrangements provide reasonable assurance that pharmaceutical products can be consistently manufactured and controlled in accordance with established quality standards. The facility was assessed to be capable of operating at a Good level of cGMP compliance. In view of the above and considering the overall Good level of compliance with applicable cGMP requirements, the inspection panel is of the opinion to recommend grant of Drug Manufacturing License (DML) - By Way of Formulation, to M/s SAMI Pharmaceuticals (Pvt.) Ltd., located at F124, Off Hub River Road, S.I.T.E., Karachi, for the following manufacturing sections and dosage forms: <table><tr><th colspan="4">Block A (General / General Antibiotic Section)</th></tr><tr><th>Sr. No.</th><th>Name of Section (s)</th><th>Sr. No.</th><th>Name of Section (s)</th></tr><tr><td>i.</td><td>Dry Powder Suspension (General/General Antibiotic)</td><td>ii.</td><td>Cream/Ointment/Gel (Steroidal)</td></tr></table>					Block A (General / General Antibiotic Section)				Sr. No.	Name of Section (s)	Sr. No.	Name of Section (s)	i.	Dry Powder Suspension (General/General Antibiotic)	ii.	Cream/Ointment/Gel (Steroidal)
Block A (General / General Antibiotic Section)																
Sr. No.	Name of Section (s)	Sr. No.	Name of Section (s)													
i.	Dry Powder Suspension (General/General Antibiotic)	ii.	Cream/Ointment/Gel (Steroidal)													

iii.	Tablet-I (General/General Antibiotic)	iv.	Lotion/Solution (General / Antibiotic)
v.	Capsule (General/General Antibiotic)	vi.	Nasal Preparation Drops/Spray (General/General Antibiotic)
vii.	Sachet (General/General Antibiotic)	viii.	Warehouse
ix.	Cream/Ointment/Gel (General/General Antibiotic)	x.	Research & Development Laboratory
xi.	Quality Control Laboratory	xii.	Tablet-II (General/General Antibiotic)
Block D (Oncology Section)			
Ground Floor			
xiii.	Tablets (Oncology)	xiv.	Capsule (Oncology)
xv.	Warehouse Raw Material / Packaging Material and Finished Goods (Oncology)		
Second Floor			
xvi.	Freeze Dried (Oncology) Section	xvii.	Sterile Dry Powder (Oncology)
xviii.	Liquid (Oncology)	xix.	Research and Development Laboratory
Third Floor			
xx.	Quality Control Laboratory		
Block E			
Ground Floor		First Floor	
xxi.	Warehouse for Raw Material / Packaging Material / Finished Goods (General/General Antibiotic)	xxii.	Warehouse for Raw Material / Packaging Material (General/General Antibiotic)
Second Floor			
xxiii.	Warehouse for Raw Material / Packaging Material (General/General Antibiotic)		

The firm has requested vide application TID 9YH-TBE-T9SN for amendment of the unlicensed manufacturing section title. They state that their LOP already has "Nasal Preparations (Drops/Spray)" sterile section, and the installed equipment has been verified by the inspection panel (inspection dated 13 July 2026) as suitable for manufacturing sterile Eye, Ear, and Nasal Preparations (Drops/Spray). Accordingly, the firm have requested that the approved section title be revised from "Nasal Preparations (Drops/Spray) (General/General Antibiotics)" to "Sterile Eye/Ear/Nasal Preparations (Drops/Spray) (General/General Antibiotics)" to accurately reflect the manufacturing capability of the existing sterile facility.

It is submitted that the approved Layout Plan (LOP) of the section also fulfills the requirements for sterile manufacturing for ophthalmic preparation.

Decision of the Board:

The Board, on the recommendation of the Panel of experts / Inspectors approved the grant of Drug Manufacturing License – By way of Formulation in the name of M/s SAMI Pharmaceuticals (Pvt.) Ltd., F-124, Off Hub River Road, S.I.T.E., Karachi for the following sections:

	S No.		Name of Section		S No.		Name of Section	
	Block A (General/General Antibiotic)							
	i.		Dry Powder Suspension (General/General Antibiotic) - Second Floor		ii.		Lotion/ Solution (General / General Antibiotic)- Second Floor	
	iii.		Tablet-I(General/General Antibiotic) - Second Floor		iv.		Sterile Eye/Ear/Nasal Preparations (Drops/ Spray) (General / General Antibiotic) - Second Floor	
	v.		Cream/ Ointment/Gel (General-General Antibiotic) - Second Floor		vi.		Cream/ Ointment/ Gel (Steroidal) - Second Floor	
	vii.		Tablet-II (General/General Antibiotic) - Third Floor		viii.		Capsule (General/General Antibiotic) - Third Floor	
	ix.		Sachet (General/General Antibiotic)- Third Floor		x.		Research and Development Laboratory - Third Floor (For Product Development)	
	Block D (Oncology Section)							
	xi.		Tablets (Oncology) -Ground Floor		xii.		Capsules (Oncology)-Ground Floor	
	xiii.		Freeze Dried (Oncology) - Second Floor		xiv.		Sterile Dry Powder (Oncology) - Second Floor	
	xv.		Liquid (Oncology)- Second Floor		xvi.		Research and Development Laboratory Second Floor (For Product Development)	
	5.	M/s Kyzer Pharma, Plot No. A-185, Lasbela Industrial Estate Development Authority, Hub Lasbela, Baluchistan. Grant of DML <i>Evaluator: - Abdullah (DD-Lic)</i>		14-07-2026	Good	1. Mr. Sarwar Khan Kakar, Member CLB. 2. Mr. Muhammad Yaqoob, FID, DRAP, Quetta.		
	<u>Recommendations of the panel: -</u> Keeping in view of the above inspection details, the panel unanimously recommends the grant of DML to M/s Kyzer Pharma, Plot No.A-185, Lasbela Industrial Estate Development Authority, Hub Lasbela, Baluchistan, Pakistan for Tablet General and Capsule general sections. <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors approved the grant of Drug Manufacturing License – By way of Formulation in the name of M/s Kyzer Pharma, Plot No.A-185, Lasbela Industrial Estate Development Authority, Hub, Lasbela, Balochistan for the following sections: 1. Tablet (General) 2. Capsule (General)							

6.	M/s Unison Chemical Works, 15 Km, Raiwind Road, Lahore. Grant of DML <i>Evaluator: - Abdullah (DD-Lic)</i>	03-06-2026	Not Recommended	1. Dr. Syed Zia Husnain, Additional Director, DRAP, Lahore. 2. Ms. Maham Misbah, FID Lahore-I. 3. MS. Ufaq Tanveer Butt, Deputy Director, DRAP, Lahore.
<u>Recommendations of the panel: -</u> In view of the inspection of the building, facility, layout, and evaluation of equipment installed, technical personnel interviewed, quality management system, utilities and documentation reviewed at the time of inspection and on the basis of overall risk based approach, the panel is of the opinion to NOT RECOMMEND the grant of Drug Manufacturing License By Way of Semi Basic Manufacturing with reference to DRAP, Islamabad letter Tracking ID A53-DW8-PJN2 dated 12-03-2023 to M/s Unison Chemical Works, Post Office Araian 15 Km, Raiwind Road, Lahore for the following section 1. Bulk Lyophilized Powder The panel of inspectors also does NOT RECOMMEND the grant Enlistment of Active Pharmaceutical Ingredients with reference to DRAP, Islamabad letter Tracking ID: ILS-8TR-3Q2N dated 30-03-2026 and Tracking ID: 2J8-Q7U-XBWJ dated 21-04-2026 to M/s Unison Chemical Works, Post Office Araian 15 Km, Raiwind Road, Lahore. <u>Decision of the Board:</u> Mr. Abu Bakr, Director of the firm, appeared before the Board and requested that some time may be allowed to the firm for rectification of the shortcomings/deficiencies pointed out by the Inspection Panel. The Board considered the request and directed the firm to rectify all the shortcomings/deficiencies pointed out by the Inspection Panel and to inform the Licensing Division for re-inspection upon completion of the required rectifications.				
7.	M/s Bions Pharmaceuticals, Plot No.05 & 25, Street No. W-4 & W-5, Rawat Industrial Estate, Rawat. Grant of DML <i>Evaluator: - Akbar Ali (DD-Lic)</i>	22-07-2026	Good	1. Mrs. Tehreem Sara, Additional Director, DRAP, Islamabad. 2. Mr. Sanauallah Babar, Deputy Director, DRAP, Islamabad.
<u>Recommendations of the panel: -</u> In conclusion, after reviewing the documentation submitted by the firm, inspecting the premises and noting the positive attitude and intent of the management, the panel is of the view that the establishment has requisite human resource, facilities, infrastructure, utilities, machinery, laboratory equipment, documentation, standard operating procedures, and Quality Management System for carrying out the proposed manufacturing activities as prescribed under the Drug Act, 1976, the DRAP Act, 2012, and the rules framed thereunder and therefore, unanimously recommends the grant of				

	Drug Manufacturing License by (way of formulation) to M/s Bions Pharmaceuticals, situated at Plot No.05 & 25, Street No. W-4 & W-5, Rawat Industrial Estate, Rawat, Islamabad for the below mentioned sections along with Quality Control Laboratory and approved stores (Raw material store, Packaging Material store & Finished goods store): i. Oral Powder (General) (Veterinary) ii. Oral Liquid (General) (Veterinary) <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors approved the grant of Drug Manufacturing License – By way of Formulation in the name of M/s Bions Pharmaceuticals, Plot No.05 & 25, Street No.W-4 & W-5, Rawat Industrial Estate, Rawat for the following sections: 1. Oral Powder (General) (Veterinary) 2. Oral Liquid (General) (Veterinary)
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**Item No.II GRANT OF ADDITIONAL SECTIONS / RENEWAL OF DML /
REGULARIZATION / AMENDMENTS IN LOP**

The recommendations of the panel of experts/Inspectors for approval of Additional Section(s) / Renewal of DML / Regularization /Amendments in LOP of drug manufacturing licenses are placed for consideration / Decision of the Board for following cases, please:

S No.	Name of the firm	Date of Inspection	Ranking	Inspection Panel Members
1.	M/s Citi Pharma Ltd., 3-Km, Head Balloki Road, Phool Nagar, Kasur. DML No.000512 (Formulation) <i>Evaluator: - Zunaira Faryad (DD-Lic)</i>	02-06-2026	Good	1. Dr. Syed Zia Husnain, Additional Director, DRAP, Lahore 2. Mr. Muhammad Umar Latif, FID-II, DRAP, Lahore
<u>Recommendations of the panel: -</u> In view of the inspection of the building, facility, layout, and evaluation of equipment installed, technical personal interviewed, quality management system, quality assurance practices, practices in production and quality control, utilities and documentation reviewed at the time of inspection and on the basis of overall risk based approach, the Panel recommended the grant of following areas to M/s Citi Pharma Ltd., 3-Km, Head Balloki Road, Phool Nagar, Kasur. 1. Quality Control (QC) Laboratory Section 2. Microbiology Laboratory Section 3. Research & Development Laboratory Panel is also recommended the regularization of layout of following section to M/s Citi Pharma Ltd., 3-Km, Head Balloki Road, Phool Nagar, Kasur. 1. Oral Dry Powder Suspension Section (General) (Formulation) <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the following additional facilities of M/s Citi Pharma Ltd., 3-Km, Head Balloki Road, Phool Nagar, Kasur under Drug Manufacturing License No. 000512 (By way of Formulation): 1. Quality Control Laboratory 2. Microbiology Laboratory 3. Research & Development Laboratory The Board further approved the regularization of the Layout Plan of following section: 1. Oral Dry Powder Suspension (General)				
2.	M/s Macter International Ltd., Plot No. F-216, S.I.T.E., Karachi. DML No.000141 (Formulation)	22-06-2026	Good	1. Dr. Suraish, Ex-Member Policy Board. 2. Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi.

	<i>Evaluator: - Abdullah (DD-Lic)</i>			3. Mr. Muhammad Tahir Waqas, Area FID, DRAP, Karachi.
	<u>Recommendations of the panel: -</u> Based on the areas inspected, people met, documentation reviewed and the overall level of GMP compliance with respect to the maintenance and operation of equipment, production processes, quality control facilities, and warehouse activities, M/s Macter International Ltd., Karachi has established the proposed Cream/Ointment/Gel-I Section in accordance with the approved layout plan and has demonstrated an acceptable level of compliance with the requirements of Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976. The panel is of the view to recommend the grant of following additional section of M/s Macter International Ltd., located at Plot No.F-216, S.I.T.E., Karachi:- i. Cream/Ointment/Gel(I) – Ground Floor <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the following additional section of M/s Macter International Ltd., Plot No. F-216, S.I.T.E., Karachi under Drug Manufacturing License No. 000141 (By way of Formulation): 1. Cream / Ointment / Gel-I (Ground Floor)			
3.	M/s Tabros Pharma Private Limited., L-20/B, Sector 22, F.B Industrial Area, Karachi DML No.000106 (Formulation) <i>Evaluator: - Abdullah (DD-Lic)</i>	05-08-2026	Good	1. Abdul Rasool Sheikh, Additional Director, DRAP, Karachi. 2. Muhammad Tahir Waqas, Area FID, DRAP, Karachi. 3. Asfandiyar Ajab Khan, Deputy Director, DRAP, Karachi.
	<u>Recommendations of the panel: -</u> In view of the satisfactory observations recorded during the inspection and the overall Good level of compliance with applicable cGMP requirements, the Inspection Panel is of the view to recommend approval for the following revised sections of M/s Tabros Pharma Private Limited, located at L-2-/B, Sector 22, F.B Industrial Area, Karachi: i. Tablet (Steroid)-(Revised) ii. Capsule (General/General Antibiotic)-(Revised) iii. Oral Liquid Syrup (Steroid)-(New) <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the following revised and new sections of M/s Tabros Pharma Private Limited, L-20/B, Sector-22, F.B. Industrial Area, Karachi under Drug Manufacturing License No. 000106 (By way of Formulation): 1. Tablet (Steroid) (Revised) 2. Capsule (General / General Antibiotic) (Revised) 3. Oral Liquid Syrup (Steroid) (New).			

4.	M/s GMP Pharmaceuticals (Pvt) Ltd., 28-Km, Sheikhpura Road, Sheikhpura. DML No.000815 (Formulation) <i>Evaluator: - Zunaira Faryad (DD-Lic)</i>	09-12-2025	Inadequate	1. Dr. Syed Zia Husnain , Additional Director, DRAP , Lahore 2. Mr. Faisal Mahmood, Chief Drugs Controller Punjab, Lahore.
<u>Recommendations of the panel: -</u> In view of the inspection of the building, facility, layout, and evaluation of equipment installed, technical personal interviewed, quality management system, quality assurance practices, practices in production and quality control, utilities and documentation reviewed at the time of inspection and on the basis of overall risk based approach, particularly keeping in view the deficiencies below, non-installation of required equipment at the time of inspection and allegations with regards to spurious drug of the firm which are yet under investigation by Punjab Drug Control, the panel was of the opinion to not-recommend grant of following two additional section to M/s GMP Pharmaceuticals (Pvt) Ltd., 28-Km Sheikhpura Road, Sheikhpura. i. Tablet Section (General) ii. Capsule Section (General)				
Sr.	Deficiencies/Non-Compliance	Classification of deficiency Guidance Document No. QALT/GL/CG/002 Effective date: 30-03-2023	Reference(LRA Rules including schedule B/ Decision of RB vide No.F.313-DRB/2021 (PE&R) dated 29.12.2021/WHO TRS)	
1	Some instruments were not installed at the time of panel inspection such as fluid bed dryer which required for active production	Critical	Other	
2	Transfer windows were not installed to make flow proper without cross contamination	Major	Other	
3	Quality management system and quality risk management SOPs required to be reviewed	Major	Other	
4	CAPA management require a systematic approach to identify and address and non-conformance	Major	Other	
5	There is no API raw material separation tags according to pharmacological class	Minor	Other	
6	More AC's need to be placed in packaging material quarantine	Minor	Other	
<u>Decision of the Board:</u> The Board deliberated the matter and decided to issue show cause notice to M/s GMP Pharmaceuticals (Pvt) Ltd, 28-Km, Sheikhpura Road, Sheikhpura under DML				

	No.000815 (Formulation) for violating rule 16, the conditions of Good Manufacturing Practices (conditions for grant of Drug Manufacturing License) under section 41 of Drug Act 1976 and rule 12 of Drugs (L, R&A) rules 1976. The firm is further directed not to conduct production activities in absence of conformance of good manufacturing practices prescribed under the Drugs Act, 1976.			
5.	M/s Albro Pharmaceuticals (Pvt) Ltd., 340S Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore. DML No.000175 (Formulation). Period: From 14-06-2025 to 13-06-2030 <i>Evaluator: - Zunaira Faryad (DD-Lic)</i>	04-06-2026	Good	1. Dr. Syed Zia Husnain, Additional Director, DRAP, Lahore 2. Ms. Maham Misbah, Federal Inspector of Drugs, DRAP, Lahore
<u>Recommendations of the panel: -</u> In view of the inspection of the building, facility, layout, and evaluation of production flow, equipment installed, technical personal interviewed, quality management system, quality assurance practices, practices in production and quality control, utilities and documentation reviewed at the time of inspection and on the basis of overall risk approach, the panel is of the opinion to recommend the facility for renewal of Drug Manufacturing License 000715 (by way of formulation) with reference to DRAP, Islamabad letter Tracking ID No. ZMH-JSG-6PJE dated 27-04-2026 to M/s. Albro Pharmaceuticals (Pvt). Ltd. Lahore for the following sections. As firm has been established since and subsequently. DML was renewed. Firm is also operational since long hence matter of 2.5 kanal area of premises may be considered by the Central Licensing Board, as per current policy. 1. Tablet Section (General) 2. Capsule Section (General) 3. Oral Liquid (General) <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License No. 000175 (By way of Formulation) of M/s Albro Pharmaceuticals (Pvt.) Ltd., 340-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore for the period of 14-06-2025 to 13-06-2030 for the following sections: 1. Tablet (General) 2. Capsule (General) 3. Oral Liquid (General) The Board further deliberated upon the issue regarding the area of the premises and, considering that the firm has been operating under a valid Drug Manufacturing License for a considerable period, directed that the matter may be dealt with in accordance with the prevailing policy and applicable decisions of high courts etc. Furthermore, the Board decided that, in cases where the codal formalities for renewal of a DML have not yet been completed, the renewed License shall be issued only upon completion of all requisite codal formalities.				

6.	M/s Novamed Pharmaceuticals (Pvt.) Ltd., 28 KM Ferozepur Road, Lahore DML No. 000590 (Formulation). Period: From 08-04-2026 to 07-04-2031 <i>Evaluator: - Zunaira Faryad (DD-Lic)</i>	15-06-2026	Good	1. Dr. Faisal Mehmood, Chief Drug Controller, Punjab. 2. Ms. Maham Misbah, Federal Inspector of Drugs, DRAP, Lahore
<u>Recommendations of the panel: -</u> In view of the inspection of the building, facility, layout, and evaluation of equipment installed, technical personnel interviewed, quality management system, quality assurance practices, practices in production and quality control, utilities and documentation at the of inspection and on the basis of overall risk based approach, the panel is of the opinion to recommend the facility for Renewal of Drug Manufacturing License No. 000590 (By Way of Formulation) with reference to DRAP, Islamabad letter Tracking ID No. 2N7-GEI-GVXQ dated, 15-04-2026 to M/s Novamed Pharmaceuticals Pvt. Ltd. 28 Km , Ferozepur Road, Lahore for the following sections: 1. Capsule Section (General) 2. Cream/Ointment/Gel Section (General) 3. Dry Powder Injection Section (General) 4. Dry Powder Suspension Section (General) 5. Liquid Injectable (Ampoule/Vial) Section (General) (SVP Glass Vials only) 6. Oral Liquid Section (General) 7. Tablet Section (General) 8. Dry Powder Suspension Section (Cephalosporin) 9. Dry Powder Injectable Section (Cephalosporin) 10. Capsule Section (Cephalosporin) <u>Decision of the Board:</u> The Board, on the recommendation of the panel of experts / Inspectors, approved the renewal of Drug Manufacturing License of M/s Novamed Pharmaceuticals (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore for the period of 08-04-2026 to 07-04-2031 (DML No. 000590 – By way of Formulation) for the following sections: 1. Capsule Section (General) 2. Cream/Ointment/Gel Section (General) 3. Dry Powder for Injection Section (General) 4. Dry Powder for Suspension Section (General) 5. Liquid Injectable (Ampoule/Vial) Section (General) (SVP Glass Vials only) 6. Oral Liquid Section (General) 7. Tablet Section (General) 8. Dry Powder Suspension Section (Cephalosporin) 9. Dry Powder Injectable Section (Cephalosporin) 10. Capsule Section (Cephalosporin)				
7.	M/s Obsons Pharmaceuticals, 209-S Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.	06-07-2026	Not Satisfactory	1. Dr. Syed Zia Husnain, Additional Director, DRAP, Lahore

DML No.000416 (Formulation). Period: From 07-08-2025 to 06-08-2030 <i>Evaluator: -Zunaira Faryad (DD-Lic)</i>			2. Ms. Maham Misbah, Area Federal Inspector of Drugs, DRAP, Lahore
<u>Recommendations of the panel: -</u> The panel inspection of M/s Obsons Pharmaceuticals 209-S Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore was conducted on 06-07-2026 in compliance to DRAP Licensing Division Letter NO. 4NJ-XYX-3RPL dated 22-04-2026, to verify the compliance of the firm to GMP. Overall, the premises, building area and flow, personnel, documentation, validations, quality assurance practices, quality management system, quality control practices and utilities of the firm were found to be NOT SATISFACTORY at the time of inspection. Details of observations noted by the panel are listed in the below table. Therefore, the panel has not recommended the renewal of license to M/s Obsons Pharmaceuticals, 209-S Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.			
<u>OBSERVATION & LIST OF DEFICIENCIES</u>			
Sr.	Deficiencies/Non-Compliance		
1.	The flow of production area was inadequate for the operation as the total area was 2.5 kanal, approximately.		
2.	The firm did not have approved layout plan, production in charge was not yet approved from licensing division DRAP, Islamabad.		
3.	Role of Quality Assurance department was not defined or observed during the inspection.		
4.	Sliding doors were installed in the production facility leading to accumulation of dust and power.		
5.	Walls in production areas were not smooth/easy to clean.		
6.	Pressure differentials were not maintained at the time of inspection.		
7.	Solution preparation was being done in the same area in which thiocoata machine was installed.		
8.	Overall flow was criss-cross. Flow of capsule area was not uni-directional. Entry into capsule filling area is through capsule mixing area.		
9.	Due to area congestion, Cone mixer, ribbon mixer, tray dryer, Fluidized bed dryer were installed in one room posing a risk of cross contamination.		
10.	Firm has oral liquid section, However, microbiological laboratory was not developed nor any microbiological was appointed. Even microbial testing of water was not being conducted in-house.		
11.	Processes were not validated, Batches were being released in unvalidated state.		
12.	Logbook of equipment utilization were not maintained.		
13.	Cleaning validation of syrup/Suspension transfer lines were not conducted.		
14.	Procedure for recall was not established in true letter and spirit. Proper root cause analysis was not documented by the firm for the batches recalled by the firm.		
15.	Annual product quality reviews were rudimentary.		

	<u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License of M/s Pharmawise Labs (Pvt.) Ltd., 25-Km, Kot Lakhpat Industrial Estate, Lahore under DML No. 000182 (By way of Formulation) for the period of 20-12-2024 to 19-12-2029 for the following sections: 1. Syrup Section (General) 2. External Applications (Antiseptic Liquids) 3. Cream/Ointment/Gel (General) 4. Sachet ORS (General) 5. Tablet (General) 6. Liquid Repacking Section 7. Tablet (General/Antibiotic) 8. Oral Dry Powder (General/Antibiotic) 9. Tablet (Steroid) 10. Capsule (General)			
9.	M/s Ambrosia Pharmaceuticals, Plot No.18, Street No.9, National Industrial Zone, Rawat. DML No.000561 (Formulation). <i>Evaluator: - Akbar Ali (DD-Lic)</i>	29-06-2026	Good	1. Ms. Tehreem Sara, Area FID, DRAP, Islamabad.
	<u>Recommendations of the panel: -</u> In view of the satisfactory compliance achieved against the observations raised during the previous inspection and the substantial improvements made in the manufacturing facility, utilities, validation, documentation and quality systems, the renewal and inclusion of the Cream & Ointment Section (General & Steroidal) in the Drug Manufacturing License (DML-000561) of M/s Ambrosia Pharmaceuticals, Plot No.18, Street No.9, National Industrial Zone, Rawat, Islamabad is recommended for the consideration of the Central Licensing Board (CLB) <u>Decision of the Board:</u> The Board was appraised that DML of the firm was renewed in 309th meeting of CLB except Cream/Ointment section. Area FID was directed to conduct reinspection of this section, therefore upon the re-inspection /CAPA verification, the Board, on the recommendation of the Area FID, approved the renewal and regularization of Drug Manufacturing License of M/s Ambrosia Pharmaceuticals, Plot No.18, Street No.9, National Industrial Zone, Rawat under DML No. 000561 (By way of Formulation) following section: 1. Cream & Ointment Section (General & Steroidal)			
10.	M/s Filix Pharmaceuticals (Pvt) Ltd., Plot No.4-A, Main Road, RCCI Industrial Estate, Rawat. DML No. 000779 (Formulation). Period: From 30-08-2023 to 29-08-2028	18-03-2026	Good	1. Mr. Mubashir Iqbal, Deputy Director, DRAP, Islamabad. 2. Mr. Fahad Nadeem, Deputy Director, DRAP, Islamabad. 3. Mr. Zia Ullah, DD/FID-I, DRAP, Islamabad.

	<i>Evaluator: - Akbar Ali (DD-Lic)</i>			
	<u>Recommendations of the panel: -</u> Based upon the findings of inspection, the documentation and available record reviewed, the premises inspected, the manufacturing, warehousing and quality control facilities provided, quality assurance system in place, qualified personnel, utilities installed, environmental control and monitoring system employed, noting the positive attitude and intent of the firm's management in rectifying the deficiencies, the panel is of the view that the facility is operating at an acceptable level of cGMP compliance and fulfils the requirements for the renewal of Drug Manufacturing License and grant of additional section, as prescribed under the Drug Act, 1976, the DRAP act, 2012 and the rules framed thereunder, and therefore unanimously recommend the renewal of Drug Manufacturing License for the following sections. Tablet Section (General) Capsule Section (General) Capsule Section (Cephalosporin) Dry Powder for Suspension Section (Cephalosporin) Moreover, the panel also recommends the grant of following additional section to Filix Pharmaceuticals (Pvt) Ltd., Plot No.4-A, Main Road, RCCI Industrial Estate, Rawat. Cream/Ointment Section (General) (The nomenclature of the section may be considered in light of Licensing Division Letter No.F.1-66/2011-Lic dated 22nd February, 2018 for layout approval, wherein the section mentioned as 1. Gel Section 2. Cream/Ointment & Lotion Section General) <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License of M/s Filix Pharmaceuticals (Pvt.) Ltd., Plot No.4-A, Main Road, RCCI Industrial Estate, Rawat for the period 30-08-2023 to 29-08-2028 under DML No. 000779 (By way of Formulation) for the following sections: Tablet (General) Capsule (General) Capsule (Cephalosporin) Dry Powder for Suspension (Cephalosporin) Cream/Ointment Section (General) (Additional Section)			
11.	M/s Cure Laboratories (Pvt.) Ltd., Plot No.11 & 12, Street NS-2, RCCI, Islamabad. DML No. 000897 (Formulation). Period: From 05-03-2024 to 04-03-2029 <i>Evaluator: - Akbar Ali (DD-Lic)</i>	04-05-2026	Good	- Mr. Mubashir Iqbal, Deputy Director, DRAP, Islamabad. - Mr. Fahad Nadeem, Deputy Director, DRAP, Islamabad. - Mr. Zia Ullah, DD/FID-I, DRAP, Islamabad.
	<u>Recommendations of the panel: -</u>			

	In compliance to Licensing Division Letter Tracking IDSs:JZB-S1B-8JJJ, W2d-VAP-M6RQ dated 11th February, 2026, the constituted panel on 04-05-2026 conducted inspection of the firm M/s Cure Laboratories (Pvt.) Ltd., Plot No.11 & 12, Street NS-2, RCCI, Islamabad for the grant of renewal of DML No.000897 (Formulation) and grant of additional section. During inspection, the facility adequacy with respect to premises and plant was thoroughly assessed for the pharmaceutical products manufactured by the firm. Based in inspection findings, the documentation reviewed, the manufacturing and quality control facilities provided, quality management system in place, installed utilities, technical personnel employed, firm's track record/commitment for continual improvement and the details mentioned in observation section, the panel, unanimously recommend the grant of renewal of Drug Manufacturing License No.000897 (Formulation) and grant of additional Dry Powder for Suspension (General) Section. <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License of M/s Cure Laboratories (Pvt.) Ltd., Plot No.11 & 12, Street NS-2, RCCI Industrial Estate, Islamabad for the period 05-03-2024 to 04-03-2029 under Drug Manufacturing License No. 000897 (By way of Formulation) for following sections: 1. Tablet (General) 2. Capsule (General) 3. Capsule (Cephalosporin) 4. Dry Powder for Injection (Vial) (Cephalosporin) 5. Dry Powder for Suspension (Cephalosporin) The Board further approved the grant of the following additional section: 1. Dry Powder for Suspension Section (General)			
12.	M/s Rogen Pharmaceuticals, Plot No.30, S-4, National Industrial Zone, Rawat. DML No.000692 (Formulation). Period: From 18.07.2025 to 17.07.2030 <i>Evaluator: - Akbar Ali (DD-Lic)</i>	08-04-2026	Good	1. Mr. Khalid Mahmood, Deputy Director, DRAP, Islamabad. 2. Dr. Muhammad Ahsan Hafiz, Deputy Director, DRAP, Islamabad. 3. Hafiz Muhammad Umair, Deputy Director, DRAP, Islamabad.
<u>Recommendations of the panel: -</u> Keeping in view the fact that the firm is involved only in manufacture of solid dosage forms and is production limited batches of the registered products, and based on the review of documents and records, assessment of systems and utilities, the inspection panel is of the view to recommend the renewal of Drug Manufacturing License of M/s Rogen				

	Pharmaceuticals, Plot No.30, S-4, National Industrial Zone, Rawat, Islamabad for following sections: - Tablet (General) - Capsule (General) 1 - Capsule (General) 2 - Sachet General - Semi-Solid (Cream/Ointment) General - Topical Lotion & Gel (General) <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License of M/s Rogen Pharmaceuticals, Plot No.30, Sector S-4, National Industrial Zone, Rawat for the period 18-07-2025 to 17-07-2030 under Drug Manufacturing License No. 000692 (By way of Formulation) for the following sections: - Tablet (General) - Capsule (General)-I - Capsule (General)-II - Sachet (General) - Semi-Solid (Cream/Ointment) (General) - Topical Lotion & Gel (General)			
13.	M/s Haleon Pakistan Limited, Petaro Road, Jamshoro, Sindh. DML No.000010 (Formulation). Period: From 31.03.2025 to 30.03.2030 <i>Evaluator: - Abdullah (DD-Lic)</i>	04-07-2026	Good	- Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. - Dr Awais Ahmed, Deputy Director/Area FID, DRAP, Karachi. - Prof. Dr. Muhammad Ali Ghoto, Dean Faculty of Pharmacy, University of Sindh, Jamshoro, Hyderabad.
<u>Recommendations of the panel: -</u> Keeping in view the above mentioned observations, the facility was considered as suitable for the intended manufacturing activities under the approved scope of the Drug Manufacturing License and Panel unanimously recommended the “Grant of following Revised Sections to M/s Haleon Pakistan Limited, Petaro Road, Jamshoro, Sindh, Pakistan (ML # 000010) by way of formulation”. - Tablet (General) – I (Human) (Revised) - Tablet (General) – II (Human) (Revised) - Tablet (General) – III (Human) (Revised) - Tablet (General) – IV (Human) (Revised) - Tablet (General) – V (Human) (New) - Liquid – General (Human) (Revised) - Quality Control Laboratory (Revised) - Warehouse (Revised) Furthermore, The firm is advised to submit differential fees (if any) for grant of Ointment/Creams/Gel (General) as a new section of “Ointment/Creams/Gel (General)-II”.				

	<u>Decision of the Board:</u> The Board considered the case and, in view of the outstanding observations and the Corrective and Preventive Actions (CAPAs) submitted by M/s Haleon Pakistan Limited, deferred the grant of the additional/revised sections. The Board directed the firm to complete all the committed CAPAs and inform the same panel along with Chief Inspector of Drugs, Sindh for verification.																											
14.	M/s Fortune Pharma (Pvt) Ltd., Plot No. K/201, S.I.T.E., Superhighway Phase II, Karachi. DML No.000924 (Formulation). Period: From 22.02.2026 to 21.02.2031 <i>Evaluator: - Abdullah (DD-Lic)</i>	16-07-2026	Good	1. Mr. Ghulam Ali Lakho, Chief Inspector of Drugs, Sindh. 2. Dr. Shoaib Ahmed, Additional Director (QMS), DRAP, Karachi. 3. Mr. Muhammad Tahir Waqas, FID-I, DRAP, Karachi.																								
<u>Recommendations of the panel: -</u> Keeping in view the above, and based on the inspection of the premises, interaction with the personnel concerned, review of the relevant documents, and the managements commitment to maintaining and continually improving its Pharmaceutical Quality System (PQS), the inspection panel is of the view to recommend the renewal of Drug Manufacturing License (DML) No.000924 for formulation operations in the following sections in favour of M/s Fortune Pharma (Pvt) Ltd., Plot No. K/201, S.I.T.E., Superhighway Phase II, Karachi. Furthermore, based on the available manufacturing facilities, installed production capacity, and the firm’s demonstrated capability to comply with applicable the inspection panel also recommends the grant of approval for the utilization of manufacturing capacity for contract manufacturing.																												
<table><tr><th colspan="4">Section(s) / Area Name</th></tr><tr><td>1.</td><td>Capsule (General)</td><td>2.</td><td>Sachet Powder (General)</td></tr><tr><td>3.</td><td>Tablet (General)</td><td>4.</td><td>Liquid Injection Vials (General)</td></tr><tr><td>5.</td><td>Liquid Syrup (General)</td><td>6.</td><td>Cream/Ointment (General)</td></tr><tr><td>7.</td><td>Sterile Liquid Injection Ampoule SVP (General)</td><td>8.</td><td>Tablet (Psychotropic)</td></tr><tr><td>9.</td><td>Capsule (Psychotropic)</td><td>10.</td><td>Sterile Liquid Ampoule (Psychotropic)</td></tr></table>					Section(s) / Area Name				1.	Capsule (General)	2.	Sachet Powder (General)	3.	Tablet (General)	4.	Liquid Injection Vials (General)	5.	Liquid Syrup (General)	6.	Cream/Ointment (General)	7.	Sterile Liquid Injection Ampoule SVP (General)	8.	Tablet (Psychotropic)	9.	Capsule (Psychotropic)	10.	Sterile Liquid Ampoule (Psychotropic)
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<u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License of M/s Fortune Pharma (Pvt.) Ltd., Plot No. K-201, S.I.T.E. Superhighway Phase-II, Karachi for the period 22-02-2026 to 21-02-2031 under Drug Manufacturing License No. 000924 (By way of Formulation) for the following sections: 1. Capsule (General) 2. Sachet Powder (General)																												

	3. Tablet (General) 4. Liquid Injection Vials (General) 5. Liquid Syrup (General) 6. Cream/Ointment (General) 7. Sterile Liquid Injection Ampoule SVP (General) 8. Tablet (Psychotropic)* 9. Capsule (Psychotropic)* 10. Sterile Liquid Ampoule (Psychotropic)* <i>*Subject to submission of NOC from the Ministry of Interior and Narcotics Control in the light of Ministry of Interior and Narcotics Control letter No.5-8/2012-Policy-I dated 06-11-2020 and Division of Controlled Drugs, DRAP letter No.5-4/2020-CD dated 10-11-2020.</i>																																			
15.	M/s Geofman Pharmaceuticals, Plot No.23/107, Sector-20, Korangi Industrial Area, Karachi. DML No.000090 (Formulation). Period: From 06.03.2026 to 05.03.2031 Evaluator: - Abdullah (DD-Lic)	23-07-2026	Good	1. Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Mr. Muhammad Tahir Waqas, FID-I, DRAP, Karachi. 3. Mr. Asfandiyar Ajab Khan, Deputy Director, DRAP, Karachi.																																
Recommendations of the panel: - Keeping in view of above, based on the premises inspected, people met, documentation reviewed and commitment of the management towards maintaining and continuously improving its pharmaceutical quality system, the panel is of the view to recommend the grant of renewal of Drug Manufacturing License (DML) No.000090 – By way of Formulation for the following sections to M/s Geofman Pharmaceuticals, Plot No.23/107, Sector-20, Korangi Industrial Area, Karachi for the following sections. <table><tr><th>Sr. No.</th><th>NAME OF SECTIONS DETAILS</th></tr><tr><td>1.</td><td>Tablet (General)</td></tr><tr><td>2.</td><td>Capsule (General)</td></tr><tr><td>3.</td><td>Liquid Syrup (General)</td></tr><tr><td>4.</td><td>Liquid Injectable SVP (General-I)</td></tr><tr><td>5.</td><td>Sterile Liquid Infusion LVP/SVP (General) – Revised & Regularized)</td></tr><tr><td>6.</td><td>Nasal Drop Section</td></tr><tr><td>7.</td><td>Tablet (General Antibiotic)</td></tr><tr><td>8.</td><td>Capsule (General Antibiotic)</td></tr><tr><td>9.</td><td>Dry Suspension (Cephalosporin)</td></tr><tr><td>10.</td><td>Capsule (Cephalosporin)</td></tr><tr><td>11.</td><td>Sachet (Cephalosporin)</td></tr><tr><td>12.</td><td>Dry Powder Injectable SVP (Cephalosporin)</td></tr><tr><td>13.</td><td>Liquid Injectable SVP (General-II)</td></tr><tr><td>14.</td><td>Capsule Pellet Filling (General)</td></tr><tr><td>15.</td><td>Liquid Injectable SVP (Hormone)</td></tr></table>					Sr. No.	NAME OF SECTIONS DETAILS	1.	Tablet (General)	2.	Capsule (General)	3.	Liquid Syrup (General)	4.	Liquid Injectable SVP (General-I)	5.	Sterile Liquid Infusion LVP/SVP (General) – Revised & Regularized)	6.	Nasal Drop Section	7.	Tablet (General Antibiotic)	8.	Capsule (General Antibiotic)	9.	Dry Suspension (Cephalosporin)	10.	Capsule (Cephalosporin)	11.	Sachet (Cephalosporin)	12.	Dry Powder Injectable SVP (Cephalosporin)	13.	Liquid Injectable SVP (General-II)	14.	Capsule Pellet Filling (General)	15.	Liquid Injectable SVP (Hormone)
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	16.	Tablet (Penicillin)		
	17.	Capsule (Penicillin)		
	18.	Dry Suspension (Penicillin)		
	19.	Cream/Ointment (General)		
	20.	Injectable (Steroid Hormone) (SVP) Ampoule		
	21.	Tablet (Steroid)		
	22.	Dry Powder Suspension (General)		
	23.	Liquid Nebulization Solution (General)		
	24.	Third Sterile Liquid Injection SVP (General)		
	<u>Decision of the Board:</u>			
The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License of M/s Geofman Pharmaceuticals, Plot No.23/107, Sector-20, Korangi Industrial Area, Karachi for the period 06-03-2026 to 05-03-2031 under Drug Manufacturing License No. 000090 (By way of Formulation) for the following sections:				
1. Tablet (General)				
2. Capsule (General)				
3. Liquid Syrup (General)				
4. Liquid Injectable SVP (General-I)				
5. Sterile Liquid Infusion LVP/SVP (General) (Revised & Regularized)				
6. Nasal Drop Section				
7. Tablet (General Antibiotic)				
8. Capsule (General Antibiotic)				
9. Dry Suspension (Cephalosporin)				
10. Capsule (Cephalosporin)				
11. Sachet (Cephalosporin)				
12. Dry Powder Injectable SVP (Cephalosporin)				
13. Liquid Injectable SVP (General-II)				
14. Capsule Pellet Filling (General)				
15. Liquid Injectable SVP (Hormone)				
16. Tablet (Penicillin)				
17. Capsule (Penicillin)				
18. Dry Suspension (Penicillin)				
19. Cream/Ointment (General)				
20. Injectable (Steroid Hormone) SVP Ampoule				
21. Tablet (Steroid)				
22. Dry Powder Suspension (General)				
23. Liquid Nebulization Solution (General)				
24. Third Sterile Liquid Injection SVP (General)				
The Board further approved the revised and regularized manufacturing sections as recommended by the inspection panel.				
16.	M/s High-Q Pharmaceuticals, Plot No.224 & 225/1, Sector-23, Korangi Industrial Area, Karachi. DML No.000597 (Formulation). Period: From 05.07.2026 to 04.07.2031	20-07-2026 & 28-07-2026	Good	1. Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Dr. Shahid Hussain Pechuho, Deputy Director, DRAP, Karachi.

Evaluator: - Abdullah (DD-Lic)			3. Mr. Muhammad Tahir Waqas, FID-I, DRAP, Karachi.																								
<u>Recommendations of the panel: -</u>																											
Based on the inspection of the manufacturing, quality control, quality assurance, warehousing, utilities, and other supporting systems, M/s High-Q Pharmaceuticals, is considered to be operating at a Good level of compliance with the current Good Manufacturing Practices (cGMP) requirements, hence the panel is the view to recommend the Renewal of firm’s Drug Manufacturing License (DML No. 000597) for the period from 05.07.2026 to 04.07.2031 in respect of the following sections:																											
<table><tr><th>Sr. No.</th><th>NAME OF SECTIONS DETAILS</th></tr><tr><td>1.</td><td>Tablet (General-I and II)</td></tr><tr><td>2.</td><td>Tablet (General Antibiotic/Quinolone)</td></tr><tr><td>3.</td><td>Tablet (Psychotropic)</td></tr><tr><td>4.</td><td>Capsules (General)</td></tr><tr><td>5.</td><td>Capsules (Cephalosporin)</td></tr><tr><td>6.</td><td>Oral Liquid (General)</td></tr><tr><td>7.</td><td>Sachet (General)</td></tr><tr><td>8.</td><td>Dry Powder Suspension (General)</td></tr><tr><td>9.</td><td>Oral Dry Powder Suspension (Cephalosporin)</td></tr><tr><td>10.</td><td>Dry Powder Injection Vials (Cephalosporin)</td></tr><tr><td>11.</td><td>Dry Powder Injection (Carbapenem)</td></tr></table>				Sr. No.	NAME OF SECTIONS DETAILS	1.	Tablet (General-I and II)	2.	Tablet (General Antibiotic/Quinolone)	3.	Tablet (Psychotropic)	4.	Capsules (General)	5.	Capsules (Cephalosporin)	6.	Oral Liquid (General)	7.	Sachet (General)	8.	Dry Powder Suspension (General)	9.	Oral Dry Powder Suspension (Cephalosporin)	10.	Dry Powder Injection Vials (Cephalosporin)	11.	Dry Powder Injection (Carbapenem)
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11.	Dry Powder Injection (Carbapenem)																										
Furthermore, based on the physical verification carried out during the inspection, the modifications incorporated in the approved revised layout plan of Plot No.224 were found to have been implemented in accordance with the approved application. The panel is also of the view to recommend the Revision of LOP of M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. (000597 – by way of formulation).																											
<u>Decision of the Board:</u>																											
The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License No. 000597 (By way of Formulation) of M/s High-Q Pharmaceuticals, Plot No.224 & 225/1, Sector-23, Korangi Industrial Area, Karachi, for the period from 05.07.2026 to 04.07.2031, for the following sections:																											
1. Tablet (General-I and II) 2. Tablet (General Antibiotic/Quinolone) 3. Tablet (Psychotropic) 4. Capsules (General) 5. Capsules (Cephalosporin) 6. Oral Liquid (General) 7. Sachet (General) 8. Dry Powder Suspension (General) 9. Oral Dry Powder Suspension (Cephalosporin)																											

	10. Dry Powder Injection Vials (Cephalosporin) 11. Dry Powder Injection (Carbapenem). The Board further, on the recommendation of the panel, approved the revision of the Layout Plan (LOP) of Plot No.224, Sector-23, Korangi Industrial Area, Karachi, under DML No.000597 (By way of Formulation).																																																											
17.	M/s Macquin’s International, F-2/H, P.T.C., Industrial Complex, S.I.T.E., Karachi. DML No.000497 (Formulation). Period: From 30.04.2022 to 29.04.2027 <i>Evaluator: - Abdullah (DD-Lic)</i>	24-07-2026	Good	1. Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Mr. Muhammad Tahir Waqas, FID-I, DRAP, Karachi.																																																								
<u>Recommendations of the panel: -</u> Keeping in view of above, based on the premises inspected, people met, documents reviewed and commitment of the management towards maintaining and continuously improving its pharmaceuticals quality system, the panel is of the view to recommend the Grant of Renewal of Drug Manufacture License (DML) No. 000497 By Way of Formulation and regularization of layout plan for the following sections to M/s Macquin’s International, F-2/H, P.T.C., Industrial Complex, S.I.T.E., Karachi:- <table><tr><th colspan="4">Section(s) / Area Name</th></tr><tr><td>1.</td><td>Tablet (General)</td><td>2.</td><td>Capsule (General)</td></tr><tr><td>3.</td><td>Oral Dry Powder Suspension (General)</td><td>4.</td><td>Oral Liquid Syrup (General)</td></tr><tr><td>5.</td><td>Sachet (General)</td><td>6.</td><td>Eye Drop (General)</td></tr><tr><td>7.</td><td>Dry Powder Injectable (Cephalosporin)</td><td>8.</td><td>Capsule (Cephalosporin)</td></tr><tr><td>9.</td><td>Dry Powder Suspension (Cephalosporin)</td><td>10.</td><td>Ointment / Cream (General)</td></tr><tr><td>11.</td><td>Liquid Injection Ampoule / Vial (General)</td><td>12.</td><td>Warehouse (General)</td></tr><tr><td>13.</td><td>Warehouse (Cephalosporin)</td><td>14.</td><td>Q.C Lab</td></tr></table> <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved regularization and renewal of Drug Manufacturing License No. 000497 (By way of Formulation) of M/s Macquin’s International, F-2/H, P.T.C., Industrial Complex, S.I.T.E., Karachi, together with regularization of the layout plan for the following sections: <table><tr><th colspan="4">Section(s) / Area Name</th></tr><tr><td>1.</td><td>Tablet (General)</td><td>2.</td><td>Capsule (General)</td></tr><tr><td>3.</td><td>Oral Dry Powder Suspension (General)</td><td>4.</td><td>Oral Liquid Syrup (General)</td></tr><tr><td>5.</td><td>Sachet (General)</td><td>6.</td><td>Eye Drop (General)</td></tr><tr><td>7.</td><td>Dry Powder Injectable (Cephalosporin)</td><td>8.</td><td>Capsule (Cephalosporin)</td></tr><tr><td>9.</td><td>Dry Powder Suspension (Cephalosporin)</td><td>10.</td><td>Ointment / Cream (General)</td></tr></table>					Section(s) / Area Name				1.	Tablet (General)	2.	Capsule (General)	3.	Oral Dry Powder Suspension (General)	4.	Oral Liquid Syrup (General)	5.	Sachet (General)	6.	Eye Drop (General)	7.	Dry Powder Injectable (Cephalosporin)	8.	Capsule (Cephalosporin)	9.	Dry Powder Suspension (Cephalosporin)	10.	Ointment / Cream (General)	11.	Liquid Injection Ampoule / Vial (General)	12.	Warehouse (General)	13.	Warehouse (Cephalosporin)	14.	Q.C Lab	Section(s) / Area Name				1.	Tablet (General)	2.	Capsule (General)	3.	Oral Dry Powder Suspension (General)	4.	Oral Liquid Syrup (General)	5.	Sachet (General)	6.	Eye Drop (General)	7.	Dry Powder Injectable (Cephalosporin)	8.	Capsule (Cephalosporin)	9.	Dry Powder Suspension (Cephalosporin)	10.	Ointment / Cream (General)
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18.	M/s Z-Jans Pharmaceutical (Pvt.) Ltd., 148-A, Industrial Area Hayatabad, Peshawar. DML No.000485 (Formulation). Period: From 11.04.2026 to 10.04.2031 <i>Evaluator: - Abdul Ghaffar (DD-Lic)</i>	10-06-2026	Good 1. Mr. Faisal Shahzad, Additional Director, DRAP, Peshawar. 2. Mr. Shahid Nawaz, FID, DRAP, Peshawar.																								
<u>Recommendations of the panel: -</u> Keeping in view of the above inspection details, the panel unanimously recommends the grant of Renewal of DML No. 000485 by way of formulation to M/s Z-Jans Pharmaceuticals (Pvt.) Ltd., 148-A, Industrial Area Hayatabad, Peshawar for the following section: <table border="1"> <thead> <tr> <th>Sr. No.</th><th>Name of the section</th><th>Sr. No.</th><th>Name of the section</th></tr> </thead> <tbody> <tr> <td>1.</td><td>Liquid Syrup/ Suspension section</td><td>2.</td><td>Tablet General Section</td></tr> <tr> <td>3.</td><td>Tablet Psychotropic section</td><td>4.</td><td>Dry suspension General section</td></tr> <tr> <td>5.</td><td>Cream/Ointment general section</td><td>6.</td><td>Capsule General section</td></tr> <tr> <td>7.</td><td>Capsule Cephalosporin section</td><td>8.</td><td>Dry Powder Suspension Cephalosporin sections</td></tr> <tr> <td>9.</td><td>Liquid Injection (Ampoule and small volume infusion) section</td><td>10.</td><td>Dry Powder Injection Cephalosporin section</td></tr> </tbody> </table> <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License No. 000485 (By way of Formulation) of M/s Z-Jans Pharmaceutical (Pvt.) Ltd., 148-A, Industrial Area Hayatabad, Peshawar, for the period 11.04.2026 to 10.04.2031, for the following sections: 1. Liquid Syrup/ Suspension section 2. Tablet General Section 3. Dry suspension General section 4. Cream/Ointment general section 5. Capsule General section 6. Capsule Cephalosporin section 7. Dry Powder Suspension Cephalosporin section 8. Liquid Injection (Ampoule and small volume infusion) section 9. Dry Powder Injection Cephalosporin section 10. Tablet Psychotropic section* <i>*Subject to submission of NOC from the Ministry of Interior and Narcotics Control in the light of Ministry of Interior and Narcotics Control letter No.5-8/2012-Policy-I dated 06-11-2020 and Division of Controlled Drugs, DRAP letter No.5-4/2020-CD dated 10-11-2020.</i>				Sr. No.	Name of the section	Sr. No.	Name of the section	1.	Liquid Syrup/ Suspension section	2.	Tablet General Section	3.	Tablet Psychotropic section	4.	Dry suspension General section	5.	Cream/Ointment general section	6.	Capsule General section	7.	Capsule Cephalosporin section	8.	Dry Powder Suspension Cephalosporin sections	9.	Liquid Injection (Ampoule and small volume infusion) section	10.	Dry Powder Injection Cephalosporin section
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19.	M/s Haarolds Pharmaceuticals (Pvt.) Ltd., Plot No.60C, 61C, 62C, 63C & 64C, Small Industrial Estate Bhimber, AJK. DML No.000921 (Formulation). Period: From 26.10.2025 to 25.10.2030 <i>Evaluator: Abdul Ghaffar (DD-Lic)</i>	22-07-2026	Good	1. Mr. Abdullah Abro, Additional Director (Licensing), DRAP, Islamabad. 2. Mrs. Tehreem Sara, Area FID, DRAP, Islamabad. 3. Mr. Mubashir Iqbal, Deputy Director (H&OTC), DRAP, Islamabad.
<u>Recommendations of the panel: -</u> In view of the satisfactory maintenance of the manufacturing facility and infrastructure, the firm has continued to maintain the required systems and has demonstrated its commitment to compliance with the applicable regulatory and Good Manufacturing Practices (GMP) requirements. The observations noted during the inspection are minor in nature, relate primarily to procedural and system improvements, and may be verified during routine GMP surveillance inspections. The panel, on the basis of the inspection conducted and the satisfactory compliance observed, is of the opinion that the firm has maintained satisfactory facilities with respect to infrastructure, approved manufacturing sections, Quality Management System, Quality Control Laboratory, production facilities, warehousing, and essential utilities in accordance with the applicable regulatory requirements. Therefore, it is <u>recommended</u> that the renewal of Drug Manufacturing License (DML No. 000921) by way of formulation for the manufacture of Veterinary Drugs only, for the period 26 October 2025 to 25 October 2030, in the following approved manufacturing sections for onward consideration by the Central Licensing Board: 1) Bulk Dry Powder Section-I (Veterinary) 2) Bulk Dry Powder Section-III (Veterinary) 3) Oral Liquid Section-I (Veterinary) 4) General Liquid Injection Section (Veterinary) 5) Bulk Dry Powder Penicillin Section (Veterinary) 6) Liquid Injectable Penicillin Section (Veterinary) 7) Topical Spray Section (Veterinary) <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License No. 000921 (By way of Formulation) of M/s Haarolds Pharmaceuticals (Pvt.) Ltd., Plot No.60C, 61C, 62C, 63C & 64C, Small Industrial Estate Bhimber, AJK, for the period 26.10.2025 to 25.10.2030, for the manufacture of Veterinary Drugs only, for the following sections: 1. Bulk Dry Powder Section-I (Veterinary) 2. Bulk Dry Powder Section-III (Veterinary) 3. Oral Liquid Section-I (Veterinary) 4. General Liquid Injection Section (Veterinary) 5. Bulk Dry Powder Penicillin Section (Veterinary)				

	6. Liquid Injectable Penicillin Section (Veterinary) 7. Topical Spray Section (Veterinary)			
20.	M/s Innvotek Pharmaceuticals., Plot No.35, Industrial Triangle Kahuta Road, Islamabad. DML No.000487 (Formulation). Period: From 05-05-2026 to 04-05-2031 s <i>Evaluator: Abdul Ghaffar (DD-Lic)</i>	14-07-2026	Good	1. Dr. Noor Muhammad Shah, Director Licensing, DRAP, Islamabad. 2. Mr. Abdul Ghaffar, Deputy Director, DRAP, Islamabad. 3. Mr. Zia Ullah, Deputy Director-I/FID-I, DRAP, Islamabad.
<u>Recommendations of the panel: -</u> In view of the findings of inspection, the documentation reviewed, the manufacturing area and utilities inspected, the facilities installed for manufacturing and quality control of the dosage forms manufactured, qualified personnel employed in key departments, documented systems established for major GMP activities including document control, change control, deviation management, CAPA, quality risk management, internal audits, complaints and recalls, qualification and validation, environmental control and monitoring measures in place, the management commitment for continuous improvement to further enhance the cGMP compliance level and hence meet the requirements for the renewal of Drug Manufacturing License as provided the Drugs Act 1976, the Drug Act 2012 and the rules framed thereunder, therefore, unanimously recommends the renewal of Drug Manufacturing License of M/s Innvotek Pharmaceuticals, Plot No. 35, Industrial Triangle, Kahuta Road, Islamabad for following sections : 1) Capsule Section (General) 2) Tablet Section (General) 3) Eye Ointment/Cream (Sterile General) 4) Eye Drop Section (General) <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License No. 000487 (By way of Formulation) of M/s Innvotek Pharmaceuticals, Plot No.35, Industrial Triangle Kahuta Road, Islamabad, for the period 05.05.2026 to 04.05.2031, for the following sections: 1. Capsule Section (General) 2. Tablet Section (General) 3. Eye Ointment/Cream (Sterile General) 4. Eye Drop Section (General)				
21.	M/s Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd., 137, Shahrah Maulana Jalaluddin Roomi, Lahore. DML No.000064 (Formulation).	09-06-2026	Good	1. Mr. Faisal Mehmood, Chief Drugs Controller Punjab. 2. Ms. Ufaq Tanveer Butt, Deputy Director, DRAP, Lahore. 3. Mr. Muhammad Umar Latif, FID, DRAP,

Period: From 31-12-2021 to 30-12-2026 <i>Evaluator: Zunaira Faryad (DD-Lic)</i>			Lahore.
<u>Recommendations of the panel: -</u> In view of the inspection of the building, facility, layout, and evaluation of equipment installed, technical personnel interviewed, quality management system, quality assurance practices, practices in production and quality control, utilities and documentation reviewed at the time of inspection and on the basis of overall risk based approach, the panel is of the opinion to recommends the facility for Renewal of Drug Manufacturing License No.000064 (By Way of Formulation) with reference to DRAP, Islamabad letter Tracking ID 8ZJ-BWU-Z7TL dated 25-08-2025, to M/s Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd., 137, Shahrah Maulana Jalaluddin Roomi, Lahore for the following sections: 1. Tablet Section (General) 2. Oral Liquid Section (General) 3. Liquid Infusion (SVP) Section (General) 4. Liquid Injectable (Ampoule) Section 5. Eye/Ear Drop Section 6. External Preparation Section (Ointment/Cream) (General) 7. Capsule Section (General) 8. Dry Suspension Section (General) <u>Decision of the Board:</u> The Board, on the recommendation of the Panel of experts / Inspectors, approved the renewal of Drug Manufacturing License No. 000064 (By way of Formulation) of M/s Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd., 137, Shahrah Maulana Jalaluddin Roomi, Lahore, for the period of 31.12.2021 to 30.12.2026, for the following sections: 1. Tablet Section (General) 2. Oral Liquid Section (General) 3. Liquid Infusion (SVP) Section (General) 4. Liquid Injectable (Ampoule) Section 5. Eye/Ear Drop Section 6. External Preparation Section (Ointment/Cream) (General) 7. Capsule Section (General) 8. Dry Suspension Section (General)			

Item No.III MISCELLANEOUS CASE(s)

Case No.1. SUSPENSION OF DRUG MANUFACTURING LICENSE (DML NO. 000624) ISSUED IN FAVOUR M/S HISUN PHARMACEUTICALS INDUSTRIES, 37-A, R-2, INDUSTRIAL ESTATE, GADOON

Kindly refer to the subject

1. It is submitted that the Inspector of Drugs, Islamabad, during inspection of M/s Pharmacy+ situated in AD Bakht Plaza, Ghouri Town, Islamabad drew the sample of **Cap. Lanroz 30mg**, Batch No. C-032 manufactured by M/s HISUN Pharmaceutical Industries, 37-A, R-2, Industrial Estate, Gadoon, for the purpose of testing. DTL, Rawalpindi declared the sample as **“Adulterated/Substandard”** (Omeprazole identified alongwith Lansoprazole) (Copy of report attached).
2. The said drug was supplied by the above-mentioned manufacturer vide invoice/bill NO. 001, dated 25-10-2024 (copy attached) to the retailer. The manufacturer and warrantor portion was forwarded to the said firm and the manufacturer confirmed the genuineness of the drug sample (copy attached).
3. Accordingly, the matter was referred to the Quality Control Board, Islamabad u/s 19 of the Drugs Act, 1976. The case was placed before the quality Control Board, Islamabad in its 60th meeting held on 17-06-2026. The Board, after considering facts available on record has decided as under;
“Mr. Rasheed Aslam (QC Incharge) and Muhammad Shakeel (Production Incharge) appeared before the Board; however, they failed to produce any scientific justification in their defense. The board unanimously decided to refer to CLB, DRAP with recommendations for suspension of Drug Manufacturing License (DML) for appropriate period.”
4. In view of above referred decision of Quality Control Board, Islamabad taken in exercise of the powers conferred u/s 11 Drugs Act 1976, read with Rule 4 of the ICT Drug Sale Rules, 2013, the matter is referred to you for further necessary action, as recommended above, after fulfillment of all legal and codal formalities in this regard as the said violation explicitly reveals gross violation of cGMP and other applicable standards.
5. The Drug Inspector concerned is directed to share the relevant record with the Secretary, Licensing Board and extend full cooperation, if so required.
6. This issue in compliance with the decision of the Quality Control Board, Islamabad taken during its 60th meeting held on 17-06-2026.

Decision of the Board:

The Board, observed that contamination / adulteration is of Omeprazole with Lansoprazole which both are Proton Pump Inhibitors (PPIs) and therefore, after threadbare deliberation, decided to authorize Chairman CLB to constitute a panel from the Division of Registration, Division of QA/LT and Division of Drug Licensing for investigation and submission of report in the matter.

Case No.2. WITHDRAWAL OF LICENSED SECTION OF M/S SAFE PHARAMACEUTICAL (PVT.) LTD., KARACHI

The firm M/s Safe Pharmaceutical (Pvt.) Ltd., Plot No.C-I-20, Sector 6-B, North Karachi Industrial Area, Karachi under the DML No. 000349 (Formulation) has submitted application for withdrawal of following Licensed section:

1. Sachet Section

Decision of the Board:

The Board acceded to the request of the firm for withdrawal of Sachet Section M/s Safe Pharmaceutical (Pvt.) Ltd., Plot No.C-I-20, Sector 6-B, North Karachi Industrial Area, Karachi under the DML No. 000349 (Formulation) and directed to inform the Drug Registration Board.

Case No.3. WITHDRAWAL OF LICENSED SECTION OF M/S UNEXO LABS (PVT.) LTD., LAHORE

The firm M/s Unexo Labs (Pvt.) Ltd., 9.5 Km, Sheikhpura Road, Lahore under the DML No. 000065 (Formulation) has submitted application for withdrawal of following Licensed section:

1. Capsule (Ceph)

Decision of the Board:

The Board acceded to the request of the firm for withdrawal of Capsule (Ceph) M/s Unexo Labs (Pvt.) Ltd., 9.5 Km, Sheikhpura Road, Lahore under the DML No. 000065 (Formulation) and directed to inform the Drug Registration Board.

Case No.4. GRANT OF REPACKING ITEMS TO M/S MICKO INDUSTRIAL CHEMICAL COMPANY PVT LTD, LAHORE UNDER DML NO. 000193

M/s Industrial Chemical Company Pvt Ltd, 28-km Ferozepur Road, Lahore under DML No. 000183 (Formulation) has submitted request for approval of following items for repacking:

Sr. No.	Item	Available in Schedule D
1.	Acridlavine Neutral	No
2.	Ammonium Bicarbonate	Yes
3.	Ammonium Chloride	Yes
4.	Aspirin	No
5.	Benzoic Acid	Yes
6.	Boric Acid	Yes
7.	Castor Oil	Yes
8.	Gentian Violet	Yes
9.	Glycerin	Yes
10.	Iodine	Yes

Sr. No.	Item	Available in Schedule D
11.	Ichthammol	Yes
12.	Kaolin	Yes
13.	Liquid Paraffin (Heavy)	Yes
14.	Magnesium Sulphate	Yes
15.	Sodium Bicarbonate	Yes
16.	Spirit Methylated	No
17.	Sulphur Precipitated	Yes
18.	Tannic Acid	Yes
19.	Zinc Oxide	Yes

Decision of the Board:

The Board considered and approved following drugs of repacking to M/s Industrial Chemical Company Pvt Ltd, 28-km Ferozepur Road, Lahore under DML No. 000183 (Formulation):

S. No	Item	Available in Schedule D
1.	Ammonium Bicarbonate	Yes
2.	Ammonium Chloride	Yes
3.	Benzoic Acid	Yes
4.	Boric Acid	Yes
5.	Castor Oil	Yes
6.	Gentian Violet	Yes
7.	Glycerin	Yes
8.	Iodine	Yes
9.	Ichthammol	Yes
10.	Kaolin	Yes
11.	Liquid Paraffin (Heavy)	Yes
12.	Magnesium Sulphate	Yes
13.	Sodium Bicarbonate	Yes
14.	Sulphur Precipitated	Yes
15.	Tannic Acid	Yes
16.	Zinc Oxide	Yes

The Board further decided that the firm shall perform on every batch/consignment of Glycerin for detection of impurities (like diethyl glycol & ethylene glycol impurities etc).

Case No.5. CORRECTION IN MINUTES OF 315TH MEETING OF CENTRAL LICENSING BOARD HELD ON 04-03-2026

The Panel of Experts/Inspectors, recommended the renewal of Drug Manufacturing License No. (000025-By way of Formulation) of M/s Lucky Core Industries Limited, B-2, S.I.T.E., Karachi for the following sections:

- i. Tablet (General) Section
- ii. Capsule (General) Section

- iii. Oral Liquid (General) Section
- iv. Ointment/Gel/Lotions Section
- v. Dry Powder Suspension (General) Section (Oral)
- vi. Bulk Packaging Section
- vii. Quality Control Laboratory

The Board in its 315th meeting held on 04-03-2026 granted renewal of Drug Manufacturing License for the duration from 22.06.2025 to 21.06.2030 for the following sections:

- 1. Tablet (General)
- 2. Capsule (General)
- 3. Oral Liquid (General)
- 4. Ointment/Gel/Lotions
- 5. Oral Dry Powder Suspension (General)

It has been observed that the Panel had also recommended the Bulk Packaging Section and Quality Control Laboratory; however, these sections were not reflected in the decision of the Board. Subsequently, renewal letter was issued with these two sections.

It is pertinent to mention that as per practice, Quality Control Laboratories, warehouses/stores and other ancillary technical areas are not specifically mentioned in the cover letter of grant or renewal of Drug Manufacturing License, as these constitute integral requirements of a licensed pharmaceutical manufacturing facility as per the Drugs Act, 1976, the Drugs (Licensing, Registering and Advertising) Rules, 1976. Accordingly, only the approved pharmaceutical dosage form/manufacturing sections are ordinarily reflected in cover letter of grant or renewal Drug Manufacturing License. Therefore, the omission of the Quality Control Laboratory from the Board's decision and the renewal letter does not require any rectification, and the firm may be informed accordingly.

However, the **Bulk Packaging Section** is a distinct licensed manufacturing activity, particularly in cases where pharmaceutical products are imported in bulk and subsequently packed/repacked into finished market packs. Since the Panel had specifically recommended this section but it was inadvertently omitted from the decision of the Board.

Decision of the Board:

The Board approved the correction in 315th meeting and decided to grant renewal of Drug Manufacturing License for the duration from 22.06.2025 to 21.06.2030 for Bulk Packaging Section.

Case No.6. REQUIREMENT FOR APPOINTMENT OF QUALITY CONTROL INCHARGE FOR TWO LICENSES ISSUED UNDER RULE 11(3) OF THE DRUGS (LICENSING, REGISTERING & ADVERTISING) RULES, 1976

The Central Licensing Board in its 315th meeting held on was held on 31st December, 2025 considered the case of M/s Biogen Life Sciences, 8-km RCB Road, Rawat Rawalpindi and decided as under;

“The Board, on the recommendation of the Panel of experts / Inspectors approved the grant of Drug Manufacturing License-By way of ***Semi-Basic Manufacturing***, in the name of M/s Biogen Life Sciences, 8-km RCB Road, Rawat Rawalpindi, for following molecules with permission to utilize the common Quality Control Department as per rule 11(3):

Soft Gel Capsule Bulk Manufacturing Facility – Steroidal

1. Dutasteride soft Gel capsule

- *The Board further directed to sale Dutasteride soft gel capsule to the firms having registration of Dutasteride soft gel capsule plus Tamsulosin pellets in combination.*
- *The Board also directed to take opinion of Legal Affairs Division regarding appointment of separate Quality Control In charge.”*

It is submitted that the firm intended to appoint Ms. Sadia Yasmeen (M.Sc. Biochemistry), who is presently approved as Quality Control Incharge of M/s Biogen Life Sciences, 8-Km RCB Road, Rawat, Rawalpindi, under Drug Manufacturing Licence (DML) No. 000911 (by way of formulation), as Quality Control Incharge for its Drug Manufacturing Licence (by way of Semi-Basic Manufacturing) as well. *(However the firm then submitted application for approval of another QC Incharge and approved and license was issued accordingly).*

As per Rule 15 of the Drugs (Licensing, Registering & Advertising) Rules, 1976, an applicant is required to establish an independent Quality Control Department with separate staff, premises, and adequate laboratory facilities for testing the strength, potency, quality, and purity of substances used in manufacture, including in-process control protocols.

Furthermore, the said rule provides that the Quality Control Department shall remain independent of the manufacturing units, and its Incharge must be a whole-time employee possessing a degree in Pharmacy or Chemical Engineering, or a Master's degree in Chemistry, along with at least ten (10) years' experience in basic or semi-basic manufacturing from a university recognized by the Federal Government, and shall be independent of the Production Incharge.

It is also pertinent to mention that Rule 11(3) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 stipulates that where a person holds more than one type of manufacturing licence within the same premises, a single Quality Control Department may be established to serve the purpose of both licences.

In view of the above, and in light of the decision of the Board, opinion of the Legal Affairs Division regarding the requirement for appointment of a separate Quality Control Incharge or otherwise was sought.

The Legal Affairs Division submitted their response which is reproduced as under;

Reference to para 6/N, the Central Licensing Board (CLB) in its **315th meeting held on 31st December 2025** approved the new Semi-Basic Manufacturing license (on the recommendation of the inspection panel) but specifically directed the Licensing Division to obtain the opinion of the Legal Affairs Division.

*The issue at hand is whether **Rule 11(3)** of the Drugs (Licensing, Registering & Advertising) Rules, 1976 permits a single QC Department and a single QC Incharge to serve both a Formulation licence and a Semi-Basic Manufacturing licence located on the same premises, or whether **Rule 15** mandates a separate, dedicated QC Incharge with specific qualifications and experience for the Semi-Basic licence, thereby overriding **Rule 11(3)**.*

ii. The Drugs (LRA) Rules 1976 in **Rule 11(3)** provides a general permission for shared QC arrangements by stating that if a person possesses or applies for more than one type of licence to manufacture drugs in the same premises, he may establish one Quality Control Department for the purpose of both the licences. This rule is permissive in nature and serves as a general administrative convenience provision. In contrast, **Rule 15** sets out specific and mandatory conditions exclusively for basic or semi-basic manufacturing licences. Under **Rule 15(1)(d)**, the applicant shall establish an independent Quality Control Department with separate staff, premises, and adequate laboratory equipment for carrying out tests of the strength, potency, quality, and purity of the substances being or to be used in the manufacture. Moreover, **Rule 15(1)(e)** requires that the QC Department shall be independent of the manufacturing units and its Incharge shall be a whole-time employee possessing a degree in pharmacy or chemical engineering or a master's degree in chemistry, along

with at least ten years' experience in basic or semi-basic manufacturing from a university recognized by the Federal Government, and shall be independent of the Production Incharge. The **Rule 16**, which applies to Formulation licences, requires a QC Incharge with ten years' experience in testing of the types of drugs intended to be manufactured but does not explicitly demand experience in semi-basic manufacturing.

iii. The critical facts from the note sheet indicate that the firm already holds a Formulation licence under DML No. 000639 at 8-km RCB Road, Rawat, Rawalpindi, and is now seeking a new Semi-Basic Manufacturing licence for a **Soft Gelatin Capsule Section** at the exact same premises. The proposed QC Incharge for the new licence is **Ms. Sadia Yasmeen**, who holds an M.Sc. in Biochemistry and has been approved as QC Incharge only for the existing Formulation licence. There is no indication on record that she possesses ten years' experience specifically in basic or semi-basic manufacturing.

iv. It is pertinent to note that **Rule 11(3)** does not override **Rule 15** because the former is a general provision applicable across licence types while the latter is a specific provision exclusively for basic and semi-basic manufacturing licences. Under established principles of statutory interpretation, specific provisions prevail over general ones. Even if **Rule 11(3)** permits a shared QC Department, the mandatory and stricter requirements of **Rule 15** must be independently satisfied for the Semi-Basic licence. Ms. Sadia Yasmeen does not satisfy **Rule 15(e)** because an M.Sc. in Biochemistry is not explicitly listed as equivalent to a master's degree in chemistry, and there is no evidence that she has the required ten years' experience in basic or semi-basic manufacturing. **Rule 11(3)** allows a single physical QC Department but does not waive the qualification and experience requirements for the Incharge of that department for each licence type. If a single QC Department is to serve both licences, the same QC Incharge must meet the distinct criteria of both **Rule 16** for Formulation and **Rule 15** for Semi-Basic. Failure to meet **Rule 15(e)** means the Semi-Basic licence cannot be granted regardless of **Rule 11(3)**.

v. Foregoing in view, it is opined that **Rule 11(3)** does not override the mandatory and specific requirements of **Rule 15** for semi-basic manufacturing. A single Quality Control Department may serve both licenses only if the Incharge of that department satisfies the stricter qualifications and experience required under **Rule 15(e)**. The current proposed QC Incharge does not meet those requirements.

The Central Licensing Board (CLB) in its 317th meeting held on 27th April 2026 deferred the matter for further deliberation.

It is submitted that Rule 11(3) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 specifically provides that where a person possesses more than one type of manufacturing licence within the same premises, one Quality Control Department may be established for the purpose of both licences. The expression "one Quality Control Department" encompasses the complete Quality Control system, including its approved Quality Control Incharge, technical personnel, laboratory facilities, equipment, documentation system and quality management processes, and not merely the physical laboratory.

The rationale of Rule 11(3) is to avoid unnecessary duplication of Quality Control infrastructure and human resources where different manufacturing activities are carried out by the same licensee under the same management and at the same premises. Since the Quality Control Department functions as an independent unit, the same department is responsible for sampling, testing, release and documentation for all products manufactured under the licences.

In practical terms, the Quality Control Department already performs analytical testing of raw materials, intermediates, Active Pharmaceutical Ingredients (APIs), finished products, in-process samples even packing material using the same approved laboratory, equipment, analytical methods and qualified personnel.

Since Rule 11(3) permits establishment of a common Quality Control Department, the same department should ordinarily function under a single Quality Control Incharge, who shall exercise overall responsibility for the Quality Control operations of all licences operating from the same premises. This interpretation ensures uniform implementation of the Pharmaceutical Quality System, maintains a clear chain of responsibility and accountability, strengthens data integrity and Good Manufacturing Practices, and is consistent with the object and intent of Rule 11(3).

Accordingly, where multiple manufacturing licences are held by the same licensee at the same premises and are served by a common Quality Control Department established in accordance with Rule 11(3), appointment of one Quality Control Incharge for such common Quality Control Department may be considered sufficient.

The Board, after deliberation, approved that the existing Quality Control Department and the same Quality Control Incharge may be responsible for both the Formulation and Semi-Basic Manufacturing Drug Manufacturing Licenses operating at the same premises, in terms of Rule 11(3) of the Drugs (Licensing, Registering & Advertising) Rules, 1976, subject to fulfillment of all applicable regulatory requirements.

Decision of the Board:

The Board deliberated the matter in light of the provision of Rule 11(3) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which reads as under:

“(3) if a person possesses, or applies for, more than one type of licences to manufacture drugs in the same premises, he may establish one Quality Control Department for the purpose of both the licences”.

Keeping in view the above rule position, the Board decided that in such cases one Quality Control In-charge approved by CLB shall be sufficient for both the licenses.

Case No.7. NOC FROM MINISTRY OF INTERIOR AND NARCOTICS CONTROL REQUIREMENT FOR CHANGE IN MANAGEMENT OF DRUG MANUFACTURING LICENSE

Case background

The case was presented before the Central Licensing Board in its 28th meeting December 10-11, 2020 which is reproduced as under;

“Ministry of Narcotic Control, Islamabad vide letter No. 5-8/2012-Ppoilic-I dated 06/11/2020 along with letter from Anti Narcotics Force, Rawalpindi Letter No. 37(1) ANF/I&E/2020 dated 02/11/2020 have forwarded decision of Committee of Allocation Quota of Controlled Substance in its 71st Meeting held on 14/10/2020. Content of the letter is reproduced as under.

“During 71st Meeting of CAQCS it has been observed that NOCs for allocation of controlled / narcotic / psychotropics substances have issued to persons allegedly involved in illegal activities in the past. In order to avoid recurrence of such incidents/cases in future, it is suggested that MCNC should take up the case with Central Licensing Board to issue licenses to pharmaceutical firms that are manufacturing / importing / exporting / using controlled, narcotic and psychotropic substances subject to NOC from ANF. Same shall also be applied to applicants who apply for change of ownership during business.”

Similarly, Division of Controlled Drugs, DRAP vide letter no. 5-4/2020-CD date 10/11/2020 also forwarded decision of Committee of Allocation Quota of Controlled Substance in its 71st Meeting held on 14/10/2020 which is reproduced as under;

“Please refer to the subject cited above and to the Headquarters Anti Narcotics Force’s letter Case No.37(1)ANF/I&E/2020 dated 14th October, 2020 on the subject cited above regarding the share holding of Mr. Ansar Farooq S/o Muzammil Hussain in M/s Medizan

Laboratories (Pvt.) Ltd. Islamabad, who happens to be a prime accused in Case FIR No.40/2011 PS ANF Rawalpindi with the allegation to get huge quantity of chemical precursor i.e. Ephedrine and its diversion/sale to smugglers.

A. *After confirmation of the shareholding of Mr. Ansar Farooq s/o Muzammil Hussain in the management of M/s Medizan Laboratories (Pvt.) Ltd. Islamabad, from Drugs Licensing Division of DRAP, as per recommendation of ANF, the matter of cancellation of import permits/authorizations granted to the company in the light of decisions of the 70th meeting of the Committee for Allocation of Quota of Controlled Substances (CAQCS) held on 20-08-2020 was placed before the CAQCS in its 71st meeting held on 28th October, 2020. The meeting was Chaired by the Secretary, Ministry of Narcotics Control, Islamabad. **The Committee discussed the matter in detail and decided as follows:***

- (i) The ANF shall conduct ground check inspection of the premises of M/s Medizan Laboratories (Pvt.) Ltd. Islamabad and Area Federal Inspector of Drugs may be co-opted for the said purpose, if required for technical input during the inspection.*
- (ii) The ANF shall prepare reference to be forwarded to the Law and Justice Division for legal opinion regarding the quota allocation of controlled substance to the pharmaceutical firm (s) / individuals involved in Ephedrine Scam that took place in the year 2012.*
- (iii) The Drug Licensing and PE&R Division of the DRAP shall also oversee their policy for grant of Psychotropic Section and the registration of products containing controlled substances to the firms. The Psychotropic Section and the registration of products containing controlled substances to the firms shall be given to the applicant firms after issuance of NOC from Ministry of Narcotics Control. The cases of the firms already possessing the Psychotropic Sections and registrations of the products containing controlled substances should be forwarded to MNC for seeking the NOC to regularize the procedure.*

B. *It is therefore requested that the above said decision of the competent forum i.e. Committee for Allocation of Quota of Controlled Substances (CAQCS) shall be complied with in letter and spirit."*

Decision of the Central Licensing Board in 278th meeting

The Board considered and decided to inform Pharma Bureau and Pakistan Pharmaceutical Manufacturing Association (PPMA) for compliance of the decision of Committee of Allocation Quota of Controlled Substance (CAQCS) and letter of Ministry of narcotics Control."

In light of the above decision, the Board approves the grant of additional sections & renewal of Psychotropic /Narcotic sections and accepts the change of management {of those firms having Psychotropic /Narcotic section(s)} for record purposes, subject to the provision of No Objection Certificate (NOC) from the MNC.

However, the Central Licensing Board in its 310th meeting held on 18th July, 2025 wherein the the Board was apprised that the authority to approve or change the management of a firm lies with the SECP, the Registrar of the firm, etc., as the case may be, therefore, the Board may authorize the Chairman CLB to recommend change of management of the firm after approval of the competent authority, as the case may be.

The Board deliberated the matter of change of management of firm. After threadbare deliberation, the Board decided to delegate its powers to the Chairman CLB for accepting and recording

documents related to change of management of firms, solely for record purposes. This delegation was intended to streamline the process and ensure timely updating of records without requiring case-by-case Board approval in non-technical matters.

In light of the above, the application for change of management is being processed only for record purposes. Clarification is, therefore, solicited as to whether a firm having a psychiatric section is still required to submit a No Objection Certificate (NOC) from the relevant Ministry.

Decision of the Board:

The Board deferred the matter for further deliberation.

Case No.8. APPROVAL OF LAYOUT PLAN OF M/S CYGNUS PHAMRACEUTICALS, KARACHI

The firm M/s Cygnus Pharmaceuticals, Plot No.K/212, S.I.T.E., Phase-II, Karachi, has applied for the approval of layout plan tab vide eApp. The layout plan was approved vide letter No.F.2-5/2016-Lic dated 27th February, 2017 for the following sections:

S.No.	Sections (Basement)	S.No.	Sections (Ground Floor)
1.	Warehouse (Raw material store, packaging material store)	13.	Injectable (Veterinary)
	Sections (First Floor)	14.	Oral Liquid (Veterinary)
2.	Injectable (Cortisone)	15.	Cream / Ointment (General)
3.	Tablet (Cortisone)	16.	Dry Suspension (General)
4.	Dry Suspension (Cephalosporin)	17.	Injectable (General)
5.	Capsule (Cephalosporin)	18.	Oral Liquid Syrup (General)
6.	Injectable (Cephalosporin)	19.	Tablet (General)
7.	Capsule (Psychotropic)	20.	Capsule (General)
8.	Tablet (Psychotropic)	21.	Sachet (General)
9.	Injectable (Psychotropic)	22.	External Preparation (General)
10.	Dry Suspension (Penicillin)	23.	QC Lab
11.	Capsule (Penicillin)	24.	Warehouse
12.	Warehouse		

The firm has submitted its response vide tracking ID 5BY-H45-R9WM that they are ready for inspection for the following sections:

GROUND FLOOR

1. Injectable (Veterinary)
2. Oral Liquid (Veterinary)
3. Cream / Ointment (General)
4. Dry Suspension (General)
5. Injectable (General)
6. Oral Liquid Syrup (General)
7. Tablet (General)
8. Capsule (General)
9. Sachet (General)
10. External Preparation (General)
11. QC Lab
12. Warehouse

BASEMENT

1. Warehouse (Raw material store, packaging material store)

It is pertinent to mention that the Central Licensing Board, in its 305th meeting, decided that the following procedure shall be adopted for processing cases relating to layout plans approved prior to the policy decision taken in the 302nd meeting held on 20th November, 2024:

- i. Where an applicant applies for panel inspection within five (05) years from the date of approval of the layout plan, the Chairman, CLB shall proceed with the constitution of the inspection panel, subject to fulfillment of all other codal formalities.
- ii. Where a request for panel inspection is made after the lapse of five (05) years from the date of approval of the layout plan, the case shall be placed before the Central Licensing Board along with the firm's justification for the delay, for consideration and decision by the Board. In the instant case, the approvals of the relevant layout plans fall beyond the prescribed five-year period.

Decision of the Board:

The Board authorized the Chairman CLB to decide the instant case and further such cases in future.

Case No.9. APPROVAL OF LAYOUT PLAN OF M/S NEPTUNE PHARMACEUTICAL, KARACHI

The firm M/s Neptune Pharmaceutical, Plot No.K/234, S.I.T.E., Super Highway Phase-II, Karachi, has applied for the approval of layout plan tab on eApp. The layout plan was approved vide letter No.F.2-8/2018-Lic dated 30th April, 2019 for the following sections:

Ground Floor		First Floor	
S.No.	Name	S.No.	Name
1.	Tablet (General)	1.	Tablet (Hormone)
2.	Capsule (General)	2.	Capsule (Hormone)
3.	Sachet (General)	3.	Liquid Injectable (Hormone)
4.	Liquid Syrup (General)	4.	Ointment/cream (Hormone)
5.	Dry Syrup (General)	5.	Tablet (cortisone)
6.	Liquid External (General)	6.	Ointment/cream (Cortisone)
7.	Liquid Injectable (General)	7.	Dry Powder Injectable (Cortisone)
8.	Dry Powder Injectable (General)	8.	Liquid Injectable (Cortisone)
9.	Eye/ear drops (General)	9.	Dry Powder Injectable (Cephalosporin)
10.	Eye/ear drops sterile (General)	10.	Dry Powder Suspension (Cephalosporin)
11.	Ointment/cream (General)	11.	Capsule (Cephalosporin)
12.	Tablet Section (Psychotropic)	12.	Dry Powder Injectable (penicillin)
13.	Capsule Section (Psychotropic)	13.	Dry Powder Suspension (penicillin)
14.	Injectable Section (Psychotropic)	14.	Capsule (penicillin)
15.	Quality Control Laboratory		*****
Basement			
1.	Warehouse		

The firm has submitted their response vide tracking ID N4M-GPL-GPRY that they are ready for inspection for the following sections:

GROUND FLOOR

1. Tablet (General)
2. Capsule (General)
3. Sachet (General)
4. Liquid Syrup (General)
5. Dry Syrup (General)
6. Liquid External (General)
7. Liquid Injectable (General)
8. Dry Powder Injectable (General)
9. Eye/ear drops (General)
10. Eye/ear drops sterile (General)
11. Ointment/cream (General)
12. Tablet Section (Psychotropic)
13. Capsule Section (Psychotropic)
14. Injectable Section (Psychotropic)
15. Quality Control Laboratory

BASEMENT

1. Warehouse (Raw material store, packaging material store)

It is pertinent to mention that the Central Licensing Board, in its 305th meeting, decided that the following procedure shall be adopted for processing cases relating to layout plans approved prior to the policy decision taken in the 302nd meeting held on 20th November, 2024:

- i. Where an applicant applies for panel inspection within five (05) years from the date of approval of the layout plan, the Chairman, CLB shall proceed with the constitution of the inspection panel, subject to fulfillment of all other codal formalities.
- ii. Where a request for panel inspection is made after the lapse of five (05) years from the date of approval of the layout plan, the case shall be placed before the Central Licensing Board along with the firm's justification for the delay, for consideration and decision by the Board. In the instant case, the approvals of the relevant layout plans fall beyond the prescribed five-year period.

Decision of the Board:

The Board authorized the Chairman CLB to decide the instant case and further such cases in future.

Case No.10. APPROVAL OF LAYOUT PLAN OF M/S PAK PHARMACEUTICAL, KARACHI

The firm M/s Pak Pharmaceutical, Plot No.K/234, S.I.T.E., Super Highway Phase-II, Karachi, has applied for the approval of layout plan tab on eApp. The layout plan was approved vide letter No.F.2-8/2018-Lic dated 30th April, 2019 for the following sections:

Ground Floor			
S.No.	Name	S.No.	Name

1.	Tablet (General) Section	6.	Capsule (Penicillin) Section
2.	Capsule (General) Section	7.	Oral Dy Suspension (Penicillin) Section
3.	Sachet (General) Section	8.	Warehouse (Penicillin)
4.	Cream/Ointment (General) Section	9.	Quality Control Laboratory
5.	Warehouse (General) Section	10.	Oral Liquid (General) Section

Amendments in approved lay plan were issued vide letter No.2-5/2013-Lic dated 01st April, 2016 for following sections

At GROUND FLOOR	
S.No.	Name
1.	Capsule (Psychotropic) in place of Capsule (Penicillin) Section
2.	Injectable (Psychotropic) in place of Oral Dry Suspension (Penicillin)
3.	Tablet (Psychotropic) in place of Warehouses (Penicillin) Section

The firm has again applied for amendments/new section and layout was approved vide letter No.2-5/2013-Lic dated 10th May, 2018 for following sections:

(FRIST FLOOR)		(BASEMENT FLOOR)	
S.No.	Name	S.No.	Name
1.	Dry Powder Suspension (Cephalosporin) Section	1.	Raw Material Store (Psychotropic)
2.	Capsule (Cephalosporin) Section	2.	Raw Material Store (Penicillin)
3.	Powder Injectable (Cephalosporin)	3.	Raw Material Store (General)
4.	Tablet (Penicillin) Section	4.	Raw Material Store (Hormone)
5.	Capsules (Penicillin) Section	5.	Raw Material Store (Cortisone)
6.	Powder Injectable (Penicillin) Section	6.	Packing Material Store
7.	Dry Powder Suspension (Penicillin) Section	7.	Finished GoodsStore
8.	Tablet (Hormone) Section	(GROUND FLOOR)	
9.	Capsules (Hormone) Section	1.	Dry Powder Suspension (General) in place of Finished Goods Store (Finished Goods Store placed at Basement Floor)
10.	Hormonal Ointment / Cream Section	2.	Capsule (General) Section (Amendments)
11.	Liquid Ampoule (Hormonal) Section	3.	Sachet (General) Section (Amendments)
12.	Powder Injectable (Cortisone) Section	(TOP FLOOR)	
13.	Liquid Injectable (Cortisone) Section	1.	External preparation (Powder) Section
14.	Eye / Ear Drops (Cortisone) Section	2.	External preparation (Liquid) Section
15.	Ointment / Cream (Cortisone) Section		*****

Following amendments/new sections were approved vide letter No.F.2-5/2013-Lic dated 25th May, 2021:

S.No.	Name	S.No.	Name
i.	Liquid External Preparation (General) - Revised	ii.	Powder External Preparation (General) - Revised
iii..	Ware House (Penem) – New	iv.	Dry Powder Injection (Penem) - New
v.	Eye/Ear Drops - New	vi.	Liquid Ampoule (General) SVP - New
vii.	Liquid vial (General) - New		*****

The firm has submitted their response vide tracking ID N4M-GPL-GPRY that they are ready for inspection for the following sections:

GROUND FLOOR

1. Tablet (General)
2. Capsule (General)
3. Sachet (General)
4. Dry Powder Suspension (General)
5. Cream / Ointment (General)
6. Quality Control Laboratory
7. Oral Liquid (General)
8. Capsule (Psychotropic)
9. Injectable (Psychotropic)
10. Tablet (Psychotropic)

FIRST FLOOR

1. Dry Powder Suspension (Cephalosporin)
2. Capsule (Cephalosporin)
3. Powder Injectable (Cephalosporin)
4. Tablet (Penicillin)
5. Capsule (Penicillin)
6. Powder Injectable (Penicillin)
7. Dry Powder Suspension (Penicillin)
8. Tablet (Hormone)

It is pertinent to mention that the Central Licensing Board, in its 305th meeting, decided that the following procedure shall be adopted for processing cases relating to layout plans approved prior to the policy decision taken in the 302nd meeting held on 20th November, 2024:

- i. Where an applicant applies for panel inspection within five (05) years from the date of approval of the layout plan, the Chairman, CLB shall proceed with the constitution of the inspection panel, subject to fulfillment of all other codal formalities.
- ii. Where a request for panel inspection is made after the lapse of five (05) years from the date of approval of the layout plan, the case shall be placed before the Central Licensing Board along with the firm's justification for the delay, for consideration and decision by the Board. In the instant case, the approvals of the relevant layout plans fall beyond the prescribed five-year period.

Decision of the Board:

The Board authorized the Chairman CLB to decide the instant case and further such cases in future.

Case No.11. REQUEST FOR ISSUANCE OF CORRIGENDUM OF VETERINARY VACCINE SECTION OF M/S INTERVAC (PVT.) LTD, LAHORE

M/s Intervac (Pvt.) Ltd. Lahore initially applied for approval of the layout plan for a Veterinary Vaccine Section on 15-09-2005, which was duly approved. Subsequently, the manufacturing facility was inspected, and the panel of experts recommended approval of the following manufacturing sections:

- Viral Vaccine (Poultry Vaccine); and
- Veterinary Bacterial Vaccine.

On the recommendations of the inspection panel, the Central Licensing Board (CLB), in its 216th meeting held on 28-02-2009, approved the following additional manufacturing sections:

- Viral Vaccine (Poultry Vaccine); and
- Bacterial Vaccine.

Thereafter, during renewal of the Drug Manufacturing License for the period 18-07-2012 to 17-07-2017, the inspection panel recommended renewal of only the Vaccine Section. Accordingly, the CLB, in its 253rd meeting held on 15–16th May 2017, approved renewal of the Vaccine Section (Veterinary).

Subsequently, the firm applied for renewal of its DML for the period 18-07-2022 to 17-07-2027 under the Vaccine Section (Veterinary). Based on the recommendations of the panel of experts/inspectors, the CLB, in its 312th meeting held on 04-11-2025, approved renewal of the Drug Manufacturing License with the Vaccine Section (Veterinary).

The firm has requested for issuance of corrigendum letter stating that the panel inspection conducted on 27th February, 2025 recorded that Veterinary Vaccine Section is divided into following sub categories:

1. Killed Bacterial Vaccine
2. Killed Viral Vaccine
3. Live Viral Vaccine ♦

Decision of the Board:

The Board decided that the title of the Vaccine Section of M/s Intervac (Pvt.) Ltd., Lahore, shall be corrected to include the following categories:

- 1. Killed Bacterial Vaccine**
- 2. Killed Viral Vaccine**

The Board further decided that area FID, DRAP, Lahore shall conduct verification of the manufacturing facility of M/s Intervac (Pvt.) Ltd., Lahore, with respect to the requirements for Live Viral Vaccine and submit its report to CLB for further consideration.

Item No.IV CASES RELATED TO DIVISION OF QUALITY ASSURANCE AND LABORATORY TESTING (QA<)

S. No.	Case Title
1.	Permission For Prosecution in The Drug Court of Peshawar in Violation of Section 23 of The Drugs Act 1976.
2.	Order Of the Licensing Authority-Consumption Verification of Tramadol Imported By M/S Fahmir Pharma (Pvt) Ltd., Sheikhpura.
3.	Manufacture And Sale Of Spurious S-Kyne Tablet Batch No. 335, Reg No. 100245 Manufactured By M/s Weather Folds Pharmaceuticals, Haripur (PQCB, Punjab Case)
4.	Manufacturing, Storage And Sale Of Unregistered Drugs Recovered From Unlicensed Premises At House No 961-A, Street No 34, Ghouri Town, Islamabad.

Case No.1. PERMISSION FOR PROSECUTION IN THE DRUG COURT OF PESHAWAR IN VIOLATION OF SECTION 23 OF THE DRUGS ACT 1976

The then area Federal inspector of Drugs Peshawar Mr. Ziaullah on 02-08-2018 during routine inspection of M/s Iceberg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur, seized stock of tablet Ei-ram 10mg, on Form-2. The stock was also ordered "Not to dispose off" on Form-1 under section 18 (1) (i) of the Drugs Act 1976 read with Schedule-V of DRAP Act 2012, as the registration of the said product was cancelled by the Drug Registration Board, DRAP Islamabad in its 279th meeting held on 28th February to 2nd March, 2018. The decision was conveyed to the firm vide letter F.No.03-33/2016-QC dated 3rd May.2018 and subsequently vide letter No.F.11-95/2018-Iceberg-DRAP(P) 1933 dated 17th May,2018 by the then FID Peshawar Mr. Zia Ullah. Details of sample are:

Name of Product	Quantity	Purported to be Manufactured by	Batch No.	Mfg. Date	Expiry Date
Ei-ram 10mg	1500 Packs	M/s Iceberg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur	C-126	07-18	17-2020

2. The QA & LT Division DRAP Islamabad vide letter No.F.4-124/2015-QA dated 28-08-2018 suspended the production activities of the firm and issued show cause notice. The firm submitted copy of the reply of show cause notice/ suspension of production order dated 01- 09-2018 (received dated 10-09-2018).

3. The Central Licensing Board granted permission to the then area FID DRAP to lodge FIR against the accused vide letter No. F.03-91/2018-QC (267-CLB) dated 22-03-2019. The permission for prosecution was not granted. The area FID send an application to SHO police station Risalpur District Nowshera for lodging of FIR vide letter No. F. 11-95/2019-Ice berg-DRAP(P)1333 dated 08th April 2019, and multiple reminders No F. 11-95/2019-Ice berg-DRAP(P) 2659 dated 26-08-2019, F. 11- 95/2019-Ice berg-DRAP(P)1110 dated 03-06-2021 and F. 11-95/2019-Ice berg-DRAP(P) 1089 dated 17-06-2022

4. The firm file an appeal in the Appellate Board and the said appeal was dismissed in the 166th meeting of the Appellate Board and the then area FID DRAP Peshawar was directed vide letter No. F.14-27/2024-AB(M-166) dated 01-07-2024 to initiate prosecution against old management of the firm for manufacturing of un-registered drug.

5. FID Peshawar (Mr. Adnan Shahid ullah) submitted the case, challan and index along with annexures, for legal vetting and for approval of the CEO, DRAP, prior to submission before the Honorable Drug Court, Peshawar against following accused persons:

- i. M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur,
- ii. Haji Muhammad Fayaz s/o Kach Kol (CEO M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur, CNIC 17101-7193842-7 R/o Mohallah Shabi Khel Charsadda Town, Charsadda)
- iii. Mr. Kamran Khan (production in-charge) M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur,
- iv. Mr. Haseeb Ul Haq (Quality control in-charge M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur.

6. Consequently, Division of QA< issued Show Cause Notices to the above mentioned accused persons vide letter No.F.04-04/2024-QC dated 21st April 2026, for violation of the section 23(1)(a)(vii), 23(1)(a)(x) & 23(1)(i) of the Drugs Act 1976 read with Schedule II-A(1)(a)(vii), II-A(1)(a)(x) and II-A(1)(i) of the DRAP Act, 2012 which is punishable under section 27(1)(a) and 27(4) of the Drugs Act, 1976 read with Schedule-III(1)(a) & III (4) of DRAP Act, 2012. However, no reply has been received till date.

7. Accordingly, the firm has been issued notice of personal hearing to appear before the Board, vide office letter F.03-32/2026-QALT (319-CLB) dated 31st July 2026.

8. **Proceedings of 319th Meeting of CLB:**

Division of QA< presented the case before the Board. Mr. Jamil Ahmad and Mr. Adil Ghaffar appeared before the Board and apprised about the change of name of the firm from M/s Ice Berg Pharmaceuticals (Pvt) Ltd., to M/s JSK Medical (Pvt) Ltd., as well as change of management. Mr. Haseeb-ul-Haq, Quality Control Incharge on behalf of former M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur, appeared before the Board and informed that he had reached out to Haji Muhammad Fayaz s/o Kach Kol (CEO) of former M/s Ice Berg Pharmaceuticals (Pvt) Ltd., and Mr. Kamran Khan (production in-charge) of former M/s Ice Berg Pharmaceuticals (Pvt) Ltd, both of whom communicated to him that they were unavailable for the CLB meeting. Mr. Haseeb further stated that the management of the firm had not communicated the decision of the Registration Board to cancel the Registration of tablet Ei-ram 10mg to the technical staff. The Board considered this casual attitude of the management of former M/s Ice Berg Pharmaceuticals (Pvt) Ltd totally unacceptable.

Decision of the Board:

Keeping in view the facts and proceedings of the case, the Board after thorough deliberation decided as follows: -

1. **Granted permission for prosecution against the following accused persons and management of the firm:**
 - i. **Former M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur, through**
 - ii. **Haji Muhammad Fayaz s/o Kach Kol (CEO former M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur, CNIC 17101-7193842-7 R/o Mohallah Shabi Khel Charsadda Town, Charsadda)**
 - iii. **Mr. Kamran Khan (production in-charge) former M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur.**
 - iv. **Mr. Haseeb Ul Haq (Quality control in-charge former M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Nowshera Industrial Estate, Risalpur.**

Case No.2. ORDER OF THE LICENSING AUTHORITY-CONSUMPTION VERIFICATION OF TRAMADOL IMPORTED BY M/S FAHMIR PHARMA (PVT) LTD., SHEIKHUPURA

The inspection of firm M/s. Fahmir Pharma Pvt. Ltd was conducted on 21st April 2025 for verification of consumption record of Tramadol. The inspection panel observed serious violations, including:

- i. Discrepancies between consumption records submitted through PSW and physical ledgers.
 - ii. Maintenance of separate manual registers for Tramadol consumption.
 - iii. Incomplete and missing Batch Manufacturing Records (BMRs).
 - iv. Absence of retained samples of Tramadol products for export.
 - v. Export of Tramadol-containing products to Afghanistan without Goods Declaration and without obtaining Export NOCs from DRAP.
 - vi. Failure to provide verifiable documentary evidence of lawful export and utilization of imported Tramadol.
 - vii. The above violations attract the provision of Rule 11 of the Drugs (Import & Export) Rules, 1976 and reflect serious non-compliance.
2. Accordingly, a Show Cause Notice No. 3403/2025 (I&E/LHR) dated 05-11-2025 was issued, directing submission of a written reply and appearance before the Licensing Authority on 12-11-2025. However, neither a written response was received, nor any representative appeared before Licensing Authority on the said date and time.
3. Final Show Cause Notice dated 05-01-2026 was issued with directions to submit reply within three (03) days and appearance before the Licensing Authority on 13-01-2026 at 11:00 AM at DRAP HQ, Islamabad.
4. Mr. Muhammad Shahid (Quality Control Manager) and Mr. Kashif Altaf (Regulatory Officer) appeared before Licensing Authority and submitted a written reply.
5. After personal hearing under Rule 16 of the Drugs (Import & Export) Rules, 1976, and perusal of available record, and written reply submitted by the firm M/s Fahmir Pvt. Ltd, Licensing Authority, has decided:

- i. *The Import License (Form 5) for Tramadol issued to M/s Fahmir Pharma Pvt. Ltd. is suspended with immediate effect.*
- ii. *The firm is prohibited from importing Tramadol in any form until further orders.*
- iii. *The case is referred to the Central Licensing Board (CLB) for cancellation of the Drug Manufacturing License under Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.*

6. In compliance to decision of Licensing Authority, Division of QA< issued Show Cause Notice vide letter No. F.No.04-10/2026-DD(QALT) dated 29th April 2026, under Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for cancellation of DML

7. In response to said show cause, M/s. Fahmir Pharma Pvt. Ltd vide letter No. FP/51/2026 dated 30th April 2026 submitted reply.

8. The firm has been issued notice of personal hearing to appear before the Board, vide office letter No. F.03-32/2026-QALT (319-CLB) dated 31st July 2026

Proceedings of 319th Meeting of CLB:

Division of QA< presented the case before the Board. No one on behalf of the firm appeared before the Central Licensing Board.

Decision of the Board:

The Board in the light of available record, facts of the case, recommendations of the Licensing Authority to cancel the DML of the firm M/s Fahmir Pharma Pvt. Ltd., Main Mandianwala Stop, 26 Km, Lahore Jaranwala Road, Sheikhpura, DML# 000880 and considering that no one on behalf of the firm appeared before the Board, decided as follows:

- i. **The firm M/s Fahmir Pharma Pvt. Ltd., Main Mandianwala Stop, 26 Km, Lahore Jaranwala Road, Sheikhpura was found involved in the contravention of Rule 11 of the Drugs (Import & Export) Rules, 1976 and reflected serious non-compliance. Hence the Board decided to cancel the Drugs Manufacturing License of M/s Fahmir Pharma Pvt. Ltd., Main Mandianwala Stop, 26 Km, Lahore Jaranwala Road, Sheikhpura (DML No. 000880) under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**

Case No.3. MANUFACTURE AND SALE OF SPURIOUS S-KYNE TABLET BATCH NO. 335, REG NO. 100245 MANUFACTURED BY M/S WEATHER FOLDS PHARMACEUTICALS, HARIPUR (QCB, PUNJAB CASE)

1. Provincial Quality Control Board, Punjab vide No. PQCB/MSS-211804/2025 had informed that Provincial Inspector of Drugs, Tehsil Pind Dadan Khan, District Jhelum, took sample of following drug on Form-4 for the purpose of test and analysis from the premises of M/s Butt Pharmacy, situated near Masjid Bilal, Main Bazar Dharyala Jalap, Tehsil Pind Dadan Khan, District Jhelum,
2. The sample had been declared “*Spurious*” by Drug Testing Laboratory, Punjab Rawalpindi vide test report No. 01-74012721/DTL dated 17-01 2025

Name of Drug	Manufactured by	Batch No	Mfg. Date	Exp. Date	DTL Test Report Details
Tablet S-Kyne (Each Film Tablet contains: Dydrogesterone 10mg) Reg# 100245	M/s Weather Folds Pharmaceuticals, HARIPUR. K.P.K	335	11-2023	11-2025	Physical Description: White colored, round shaped, biconvex tablets, plain from both sides, packed in ALU/ALU blister of 1*10's pack, further packed in labelled outer carton. (20 tablets) IDENTIFICATION: Dydrogesterone is not identified (FTIR) (USP-2024) (Does Not Comply) Assay: Stated: 10mg/Tablet Determined: 0.000 mg/ Tablet (HPLC) (USP-2024) Percentage: 0.00% (DOES NOT COMPLY) Limit: 90.0-110.0% RESULT: <i>The above sample is "Spurious" as defined under clause (i) of sub-section (z-b) of section 3 of The Drugs Act 1976</i>

3. The case was presented by the Provincial Quality Control Board in its 293rd meeting held on 25-09-2025. The Board after perusal of case record and scrutiny of DTL report observed that sample of Tablet S-Kyne Batch No. 335 was declared *Spurious* by DTL, Rawalpindi and the Licensed Manufacturer M/s Weather Folds Pharmaceuticals, Haripur. K.P.K committed the offense of Manufacturing and sale of *Spurious* drug.
4. The Provincial Quality Control Board, Punjab recommended to the Drug Regulatory Authority of Pakistan, for cancellation of the DML of the firm M/s Weather Folds Pharmaceuticals, Haripur for manufacturing of *Spurious* drug.
5. Division of QA< issued Show Cause Notice No. F.04-1/2026-AD(QALT) dated 7th January, 2026 under Section 41 of the Drugs Act 1976.
6. In response to said show cause, Weather Folds Pharmaceuticals vide letter nil dated 22nd January 2026 replied as under:

“With reference to your letter No. F.04-1/2026-AD(QALT) dated 7th January, 2026, received on 15th January, 2026, we, M/s Weather Folds Pharmaceuticals, respectfully submit our reply as under: The declared product S-KYNE Tablets (Batch No. 335, Manufacturing Date: November 2023, Expiry

Date: November 2025) was manufactured at Weather Folds Pharmaceuticals, Hattar, as per our manufacturing records.

At the outset, we would like to clarify that the imported API used for this product was duly approved by CDL Karachi, in accordance with DRAP Policy, vide Report No. RM-6-22-000010 dated 27th June, 2022. The API was declared as compliant with USP specifications, and the relevant documents are attached as Annexure-I.

Subsequently, a pilot batch of 500 packs of S-KYNE Tablets was manufactured exclusively for market survey purposes. The batch was tested repeatedly at our Quality Control laboratory, and all quality parameters were found to be within USP limits. Copies of our internal analytical reports are attached for reference.

We further submit that at the time the product was declared sub-standard, or thereafter, no portion of the official sample was provided to us for verification. Therefore, while we confirm that Batch No. 335 (November 2023) was manufactured by us, it cannot be conclusively established that the sample tested by the Drug Testing Laboratory (DTL) was indeed manufactured by Weather Folds Pharmaceuticals, in the absence of a manufacturer's warranty sample.

Although the product has since expired, we again performed assay and dissolution testing on the retained samples available at our premises. The results were found to be within USP Specification limits. The reported result of 0% assay strongly indicates that the tested sample was not manufactured by us, as such a result is practically impossible for a finished pharmaceutical product manufactured under controlled GMP conditions. This leads us to believe that the product may have been counterfeit or falsely attributed by an unauthorized source using similar batch details.

It is also pertinent to mention that we formally requested that the samples be referred to NIH for further investigation, which was unfortunately rejected by the Board. Moreover, the mandatory requirement of providing a manufacturer's warranty sample was not fulfilled by the DTL, rendering the case incomplete and inconclusive.

In view of the above facts, we respectfully submit that the present case does not warrant holding Weather Folds Pharmaceuticals responsible for the alleged manufacture of a spurious drug. We therefore humbly request that the Show Cause Notice may kindly be withdrawn, and the DTL may be directed to re-test the retained samples available in our QC store (although expired, yet analytically compliant). We further request that the samples may be referred to NIH for independent verification in the interest of transparency, impartiality, and justice. We trust that our submission will be considered objectively, ensuring fairness and preservation of the reputation of our esteemed manufacturing unit.

7. Division of QA< issued a notice of personal hearing vide letter F.03-21/2026-QALT (317-CLB) dated 21st April, 2026 under Section 41 of the Drug Act 1976.

8. The case was presented before Central Licensing Board in its 317th meeting in which the Board decided as follows:

“The Board after considering the facts of the case and after thorough deliberations decided to refer the case to Registration Board, being registered drug under Section 7 of the Drugs Act, 1976 and Rules framed thereunder, for further necessary action.”

9. Accordingly, the case was presented before Registration Board in its 359th meeting in which the Board decided as follows:

“The Board, after considering the facts of the case and after thorough deliberation, decided to refer the matter to the Legal Division for its opinion on whether a Board to whom recommendation had been made by a Provincial Quality Control Board can refer a case to another Board.”

10. Consequently, the case was forwarded for legal opinion in the light of recommendations of the Registration Board to the Legal Affairs Division.

11. The Legal Affairs Division after examining the case furnished their opinion which is being reproduced below:

“The PQCB, Punjab recommended to the Central Licensing Board for cancellation of the DML of M/s Weather folds for manufacturing spurious drugs. The CLB in its 317th meeting decided to refer the case to the registration board through a non-speaking order. Now, the question asked from this Division as:

"whether a Board to whom recommendation had been made by a Provincial Quality Control Board can refer a case to another Board"

Section 11(5)(a) of the Drugs Act, 1976 unequivocally delineates the powers and functions of the Provincial Quality Control Board (PQCB). Under the said provision, where a contravention of the Drugs Act, 1976 or the rules framed thereunder is established, the PQCB is competent to recommend the suspension or cancellation of the manufacturing licence or sale licence of the concerned firm/company. The statutory role of the PQCB is, therefore, recommendatory in nature, whereas the final adjudicatory power rests with the competent licensing authority.

The instant matter squarely falls within the exclusive jurisdiction of the Central Licensing Board (CLB), which is the statutory authority vested with the power to consider and decide the recommendations of the PQCB. In discharging its statutory functions, the CLB is required to act strictly in accordance with Section 41 of the Drugs Act, 1976, read with Article 24 of the General Clauses Act, 1897, which empowers the authority competent to issue a licence to suspend, vary or rescind the same in the manner prescribed by law.

The power conferred upon the CLB is quasi-judicial in nature. Consequently, the CLB is under a legal obligation to independently evaluate the entire record, consider the recommendations of the PQCB, afford due opportunity of hearing to the affected party, and apply its own independent and judicious mind to the facts and applicable law before arriving at a conclusion. The CLB must determine the appropriate regulatory action, including suspension, cancellation, or any other measure permissible under the Drugs Act, 1976, keeping in view the gravity and nature of the violation.

It is a well-settled principle of administrative law that a statutory authority entrusted with the exercise of discretionary or quasi-judicial powers must exercise such powers itself and cannot abdicate or delegate its statutory responsibility unless such delegation is expressly authorized by law. The maxim delegatus non potest delegare squarely applies in the present matter. Since neither the Drugs Act, 1976 nor the rules framed thereunder authorize the CLB to transfer its adjudicatory function to another authority, the CLB is legally bound to decide the matter itself. Furthermore, it is equally well settled that every quasi-judicial determination affecting the rights of a person must be supported by cogent reasons. Recording reasons is an indispensable component of the principles of natural justice, ensuring transparency, fairness, and accountability in administrative decision-making. Accordingly, the decision of the CLB must be embodied in a well-reasoned and speaking order demonstrating due consideration of the evidence, the recommendations of the PQCB, the submissions of the affected party, and the relevant statutory provisions. In view of the foregoing, the CLB cannot lawfully transfer or refer the matter to any other forum or authority without first discharging its statutory obligation of adjudicating upon the recommendations of the PQCB. Any such transfer or abdication of its statutory responsibility would be contrary to the scheme of the Drugs

Act, 1976, offend the doctrine of delegatus non potest delegare, and be susceptible to judicial review for failure to exercise jurisdiction vested in the CLB by law.

12. Pursuant to the opinion furnished by the Legal Affairs Division, the case is re-submitted for the consideration of the Central Licensing Board.

13. **Proceedings of 319th Meeting of CLB:**

The Board was apprised on the case in detail as under:

- As per case submitted by the Quality Assurance & Lab Testing (QA<) Division , “Provincial Inspector of Drugs, Tehsil Pind Dadan Khan District Jhelum took sample of Tablet S-Kyne (Dydrogesterone 10mg), Batch No. 335 manufactured by M/s Weather Folds Pharmaceutical, Haripur, Khyber Pakhtunkhwa from the premises of M/s Butt Pharmacy, situated near Masjid Bilal main Bazar Dharyala Jalap, Tehsil Pind Dadan Khan District Jhelum, which was declared Spurious by the Drug Testing Laboratory Punjab Rawalpindi vide test report No. 01-74012721/DTL dated 17-01-2025.
- The case was presented by the Provincial Quality Control Board in its 293rd meeting held on 25-09-2025. The Board after perusal of case record and scrutiny of DTL report observed that sample of Tablet S-Kyne Batch No. 335 was declared *Spurious* by DTL, Rawalpindi and the Licensed Manufacturer M/s Weather Folds Pharmaceuticals, Haripur. K.P.K committed the offense of Manufacturing and sale of *Spurious* drug. The Provincial Quality Control Board, Punjab recommended to the Drug Regulatory Authority of Pakistan, for cancellation of the DML of the firm M/s Weather Folds Pharmaceuticals, Haripur for manufacturing of *Spurious* drug.
- Division of QA< issued Show Cause Notice No. F.04-1/2026-AD(QALT) dated 7th January, 2026 under Section 41 of the Drugs Act 1976.
- In response to said show cause, Weather Folds Pharmaceuticals vide letter nil dated 22nd January 2026 replied as under:
 - *“With reference to your letter No. F.04-1/2026-AD(QALT) dated 7th January, 2026, received on 15th January, 2026, we, M/s Weather Folds Pharmaceuticals, respectfully submit our reply as under:
The declared product S-KYNE Tablets (Batch No. 335, Manufacturing Date: November 2023, Expiry Date: November 2025) was manufactured at Weather Folds Pharmaceuticals, Hattar, as per our manufacturing records.*
 - *At the outset, we would like to clarify that the imported API used for this product was duly approved by CDL Karachi, in accordance with DRAP Policy, vide Report No. RM-6-22-000010 dated 27th June, 2022. The API was declared as compliant with USP specifications, and the relevant documents are attached as Annexure-I.*
 - *Subsequently, a pilot batch of 500 packs of S-KYNE Tablets was manufactured exclusively for market survey purposes. The batch was tested repeatedly at our Quality Control laboratory, and all quality parameters were found to be within USP limits. Copies of our internal analytical reports are attached for reference.*
 - *We further submit that at the time the product was declared sub-standard, or thereafter, no portion of the official sample was provided to us for verification. Therefore, while we confirm that Batch No. 335 (November 2023) was manufactured by us, it cannot be conclusively established that the sample tested by the Drug Testing Laboratory (DTL) was indeed manufactured by Weather Folds Pharmaceuticals, in the absence of a manufacturer’s warranty sample.*
 - *Although the product has since expired, we again performed assay and dissolution testing on the retained samples available at our premises. The results were found to be within USP*

Specification

limits.

The reported result of 0% assay strongly indicates that the tested sample was not manufactured by us, as such a result is practically impossible for a finished pharmaceutical product manufactured under controlled GMP conditions. This leads us to believe that the product may have been counterfeit or falsely attributed by an unauthorized source using similar batch details.

- It is also pertinent to mention that we formally requested that the samples be referred to NIH for further investigation, which was unfortunately rejected by the Board. Moreover, the mandatory requirement of providing a manufacturer's warranty sample was not fulfilled by the DTL, rendering the case incomplete and inconclusive.
 - In view of the above facts, we respectfully submit that the present case does not warrant holding Weather Folds Pharmaceuticals responsible for the alleged manufacture of a spurious drug.
 - We therefore humbly request that the Show Cause Notice may kindly be withdrawn, and the DTL may be directed to re-test the retained samples available in our QC store (although expired, yet analytically compliant). We further request that the samples may be referred to NIH for independent verification in the interest of transparency, impartiality, and justice. We trust that our submission will be considered objectively, ensuring fairness and preservation of the reputation of our esteemed manufacturing unit.
- Division of QA< issued a notice of personal hearing vide letter F.03-21/2026-QALT (317-CLB) dated 21st April, 2026 under Section 41 of the Drug Act 1976.
 - The case was presented before Central Licensing Board in its 317th meeting in which the Board decided as follows:

"The Board after considering the facts of the case and after thorough deliberations decided to refer the case to Registration Board, being registered drug under the Drugs Act, 1976 and Rules framed thereunder, for further necessary action."

- The case was presented before Registration Board in its 359th meeting in which the Board decided as follows:

"The Board, after considering the facts of the case and after thorough deliberation, decided to refer the matter to the Legal Division for its opinion on whether a Board to whom recommendation had been made by a Provincial Quality Control Board can refer a case to another Board."

- Consequently, the case was forwarded for legal opinion in the light of recommendations of the Registration Board to the Legal Affairs Division. The Legal Affairs Division after examining the case furnished their opinion which is being reproduced below:
"The PQCB, Punjab recommended to the Central Licensing Board for cancellation of the DML of M/s Weather folds for manufacturing spurious drugs. The CLB in its 317th meeting decided to refer the case to the registration board through a non-speaking order. Now, the question asked from this Division as:

"Whether a Board to whom recommendation had been made by a Provincial Quality Control Board can refer a case to another Board"

Section 11(5)(a) of the Drugs Act, 1976 unequivocally delineates the powers and functions of the Provincial Quality Control Board (PQCB). Under the said provision, where a contravention of the Drugs Act, 1976 or the rules framed thereunder is established, the PQCB is competent to recommend the suspension or cancellation of the manufacturing

licence or sale licence of the concerned firm/company. The statutory role of the PQCB is, therefore, recommendatory in nature, whereas the final adjudicatory power rests with the competent licensing authority.

The instant matter squarely falls within the exclusive jurisdiction of the Central Licensing Board (CLB), which is the statutory authority vested with the power to consider and decide the recommendations of the PQCB. In discharging its statutory functions, the CLB is required to act strictly in accordance with Section 41 of the Drugs Act, 1976, read with Article 24 of the General Clauses Act, 1897, which empowers the authority competent to issue a licence to suspend, vary or rescind the same in the manner prescribed by law.

The power conferred upon the CLB is quasi-judicial in nature. Consequently, the CLB is under a legal obligation to independently evaluate the entire record, consider the recommendations of the PQCB, afford due opportunity of hearing to the affected party, and apply its own independent and judicious mind to the facts and applicable law before arriving at a conclusion. The CLB must determine the appropriate regulatory action, including suspension, cancellation, or any other measure permissible under the Drugs Act, 1976, keeping in view the gravity and nature of the violation.

*It is a well-settled principle of administrative law that a statutory authority entrusted with the exercise of discretionary or quasi-judicial powers must exercise such powers itself and cannot abdicate or delegate its statutory responsibility unless such delegation is expressly authorized by law. The maxim *delegatus non potest delegare* squarely applies in the present matter. Since neither the Drugs Act, 1976 nor the rules framed thereunder authorize the CLB to transfer its adjudicatory function to another authority, the CLB is legally bound to decide the matter itself. Furthermore, it is equally well settled that every quasi-judicial determination affecting the rights of a person must be supported by cogent reasons. Recording reasons is an indispensable component of the principles of natural justice, ensuring transparency, fairness, and accountability in administrative decision-making. Accordingly, the decision of the CLB must be embodied in a well-reasoned and speaking order demonstrating due consideration of the evidence, the recommendations of the PQCB, the submissions of the affected party, and the relevant statutory provisions.*

*In view of the foregoing, the CLB cannot lawfully transfer or refer the matter to any other forum or authority without first discharging its statutory obligation of adjudicating upon the recommendations of the PQCB. Any such transfer or abdication of its statutory responsibility would be contrary to the scheme of the Drugs Act, 1976, offend the doctrine of *delegatus non potest delegare*, and be susceptible to judicial review for failure to exercise jurisdiction vested in the CLB by law.*

The Board was reminded that the case was sent to the Registration Board, due to the technical nature of the product (Dydrogesterone) and the steps being taken by the Registration Board in this specific drug, in addition to being a registered drug and as per procedure to be undertaken in such cases as per the Drugs Act, 1976 and Rules made thereunder. The CLB was informed that section 11(5)(b) of the Drugs Act, 1976, empowers the Provincial Quality Control Board to issue instructions to the Inspector as to the action to be taken after scrutinizing the report of Provincial Inspector in respect of contraventions of this Act and reports of the Government Analysts in respect of drugs sent to them by the Provincial Inspectors for test and analysis.

The CLB was also informed that the said clause of the Act, does not allow the PQCB to send it to the CLB for cancellation of license after scrutinizing report of analyst. The action of the CLB for sending the case to Registration Board was to see the root cause of the failure of this specific drug to comply the specifications in the analysis report of the Provincial Drug Testing Laboratory as the Board was informed that this batch raw material has been declared of standard quality as per claim of the representative of the firm.

The Board after thorough deliberation, opined and decided that:

- (a) The opinion of the Legal Affairs Division, *prima facie*, is not in line with section 11(5)(b) of the Drug Act, 1976.**
- (b) Being quality matter, the Chairman (CLB) is authorized to constitute a Panel of auditors from Division of PE&R, QA< and Drug Licensing to look into the technical aspect of this particular drug in general and its production by the claimed manufacturer i.e., M/s Weather Folds Pharmaceuticals in particular and give recommendations to the Board accordingly.**
- (c) Request PQCB Punjab for provision of detailed proceedings and record of the case.**
- (d) Requested the member of CLB Mr. Abid Ali, Additional Draftsman, (Representative of Ministry of Law & Justice, Islamabad) to give opinion after detailed deliberation in the matter.**

**Case No.4. MANUFACTURING, STORAGE AND SALE OF UNREGISTERED DRUGS
RECOVERED FROM UNLICENSED PREMISES AT HOUSE NO 961-A,
STREET NO 34, GHOURI TOWN, ISLAMABAD**

A raid was conducted on 13-07-2026, at the unlicensed premises located at house No. 961-A, having three floors (1, 2 & 3 Floor), Street No 34, Phase 4, Ghouri Town Islamabad, with reference to the complaint regarding illegal manufacturing of poultry medicine by a person namely Haroon Shahzad (0310-6671582) by the name of M/s. Bionics Care, received in the office of the area FID through official e-mail.

2. The said premises was suspected to be used as manufacturing, storage and sale facility for un-registered drugs of various manufacturers. The following officers of DRAP conducted the raid:

- i. Ms Tehreem Sara Additional Director/Area FID, DRAP, Islamabad
- ii. Mr. Malik Muhammad Asad, Deputy Director DRAP, Islamabad
- iii. Mr. Hafiz Sanaullah Babar, Deputy Director DRAP, Islamabad
- iv. Mr. Ishtiaq Shafiq, Deputy Director DRAP, Islamabad

3. During the visit, a person namely Shahid Mehmood (CNIC #36102-1918876-3), introduced himself being guest of Haroon Shahzad (36102-1719580-7) and two other persons namely Muhammad Arshad S/o Hakim Din (CNIC #61101-1468867-3) and Muhammad Faisal-ul-Rehman S/o Muhammad Safdar (CNIC #36102-5402410-1) were present at the time of visit.

4. On the ground floor, the business office was located where the record, cash memo book and ledger register were present along with the white filled unlabeled bottles of liquid suspected to contain veterinary unregistered medicine and 03 different labelled medicines (suspected to be un-registered). The 2nd floor consisting of three rooms was being used for the manufacturing, mixing and filling of suspected unregistered veterinary drugs as well as well Human homeo products (mother tincture).

5. From the ground floor, unlabeled filled white bottles, 3 labelled veterinary products (one carton each) and the available cash memo, ledger registers, one writing pad and visiting cards of Haroon Shahzad introducing him as the CEO of M/s. Bionexis bearing cell numbers 03207377214 & 03106671582 and mentioning business address at office No.104, 2nd floor Ghouri Mall plaza, Kalma Chowk Ghouri town, Phase 4, Islamabad were seized by the area FID. Remaining stocks of unlabeled and labeled stocks were “ordered not to dispose of”.

6. On the second floor, the available stocks of 11 suspected to be unregistered products and 03 cartons of labels and some representative quantity of these labels and primary packaging of medicines were seized. In addition to the aforementioned, team observed powder heap in mixing state present on the floor. Sample of the said powder and white unlabeled liquid bottles present on the ground floor were taken for the purpose of test/analysis.

7. In exercise of the powers conferred under Schedule V(1)(h) of the DRAP Act, 2012, read with Section 18(1)(h) of the Drugs Act 1976, FID-II, Islamabad in the presence of witnesses, sealed the unlicensed offices located on the ground floor and the unlicensed manufacturing and storage premises located on the second floor, comprising three rooms and one door leading to the roof. The sealing was

carried out in the presence of the witnesses named in the Sealing Memo on 13-07-2026. The sealed keys duly signed and marked were handed over to Muhammad Arshad S/o Hakim Din CNIC #61101-1468867-3 present at the premises and witnessed of all the activities

8. FID-II, Islamabad, sought safe custody of seized material, requested extension in order not to dispose of period, and requested permission to lodge FIR against the following accused persons vide letter No.F.6-1/2026-FID(II)ISD -0001 dated 14-07-2026.

- i. M/s. BIONEXIS office No.104, 2 floor Ghouri Mall plaza, Kalma Chowk Ghouri town, Phase 4, Islamabad / House No. 961-A, Street#34, Phase 4, Ghouri Town, Islamabad, through its owner/proprietor/CEO.
- ii. Haroon Shahzad (CNIC#36102-1719580-7), CEO of M/s. Bionexiscare, office No.104, 2 floor, Ghouri Mall plaza, Kalma Chowk, Ghouri town, Phase 4, Islamabad /House No. 961-A, Street #34, Phase 4, Ghouri Town, Islamabad.
- iii. Shahid Mehmood (CNIC#36102-1918876-3) introduced himself being guest of Haroon Shahzad CEO M/s. Bionexis care.
- iv. Muhammad Arshad S/o Hakim Din (CNIC#61101-1468867-3), allegedly involved in the manufacturing and sale of unregistered drugs, present at the premises and witnessed of all the activities.
- v. Muhammad Faisal-ul-Rehman S/o Muhammad Safdar (CNIC#36102-5402410-1), present at the time of visit.

9. Permission to lodge FIR was granted vide letter No.F.4-15/2026-DD(QALT-VI)-0001 dated 14-07-2026, whereas the extension in order not to dispose of period was granted vide letter No.F.4-15/2026-DD(QALT-VI)-0002 dated 21-07-2026, and permission of keeping safe custody was accorded vide letter No.F.4-15/2026-DD(QALT-VI)-0003 dated 21-07-2026 by the Competent Authority i.e., Director QA<, having been delegated the power by the Central Licensing Board (CLB) in its 273rd meeting.

10. FID-II, Islamabad also sought the extension in sealing period of the Portions/Rooms of unlicensed premises situated at House no 961-A, Street#34 Ghouri Town, Islamabad till the completion of investigation vide letter No.F.6-1/2026-FID(II)ISD -0001 dated 14-07-2026.

11. The case is submitted for the consideration of the Board under Rule 8(18) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

Proceedings of 319th Meeting of the Board:

QA< Division presented that case before the Board in the light of recommendations of area FID for extension in sealing period of the above said unlicensed premises till decision of the case under Rule 8(18) of Drugs (Licensing, Registering & Advertising) Rules, 1976 for further processing and investigation in the instant case.

Decision of the Board:

The Board deliberated the matter and decided to grant extension in sealing period of the unlicensed premises located at House No. 961-A, Street No. 34, Ghouri Town, Islamabad for a period of three months and directed the area FID to complete investigation within prescribed time period.

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