MINUTES OF 305TH MEETING OF CENTRAL LICENSING BOARD HELD ON 24TH JANUARY, 2025

305th meeting of the Central Licensing Board (CLB) was held on 24th January, 2024 in the Committee Room, Ground Floor, FDSL, Drug Regulatory Authority of Pakistan (DRAP), Prime Minister National Health Complex, Chak Shahzad, Islamabad. Mr. Sayyad Hussain Khan, Director (Licensing), Drug Regulatory Authority of Pakistan, Islamabad Chaired the meeting. Following members attended the meeting: -

S.No	Name & Designation	Status
1.	Ms. Urooj Fatima, Additional Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
2.	Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Government of Punjab, Lahore.	Member
3.	Mr. Mehtab Afsar, Chief Inspector of Drugs, Peshawar Government of Khyber Pakhtunkhwa	Member
4.	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Baluchistan, Quetta	Member
5.	Mr. Abdul Hafeez Tunio, Chief Inspector of Drugs, Government of Sindh, Karachi	Member (Zoom Link)
6.	Mr. Abid Ali, Deputy Draftsman, Ministry of Law & Justice Division, Islamabad	Member (Zoom Link)
7.	Mr. Ayyaz Ahmed, Additional Director (QA& LT) DRAP (Representative of Director QA&LT)	Member

Mrs. Urooj Fatima, Additional Director/Secretary Licensing Board presented the agenda before the Board. Mr. Akbar Ali, Deputy Director (Lic), Mrs. Zunaira Faryad, Deputy (Lic), Mr. Abdullah, Deputy Director (Lic), Mr. Sanaullah Babar, Deputy Director, QA&LT, Mrs. Mehwish Tanveer, Deputy Director (QA & LT) assisted the Secretary, Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 302nd, 303rd and 304th MEETINGS**

i. 302nd meeting of the Central Licensing Board (CLB) was held on 20th November, 2024. Draft Minutes of 302nd meeting were circulated through WhatsApp group and email for perusal and comments (if any). Majority of the members acceded to the draft minutes through WhatsApp/email and after approval of Chairman, CLB, final minutes were circulated among relevant Divisions/Section for implementation/ compliance.

ii. 303rd meeting of the Central Licensing Board (CLB) was held on 28th November, 2024. Majority of the members participated through Zoom Link and acceded to the decision recorded in the minutes. After approval of Chairman, CLB, final minutes were circulated to relevant Divisions/Section for implementation/ compliance.

iii. 304th meeting of the Central Licensing Board (CLB) was held through circulation on 4th December, 2024. After approval of Chairman, CLB, final minutes were circulated among relevant Divisions/Section for implementation/ compliance.

Minutes are submitted for formal confirmation of the Board, please.

Decision:-

The Board confirmed the minutes of:-

i. 302nd meeting of the Central Licensing Board (CLB) held on 20th November, 2024.
ii. 303rd meeting of the Central Licensing Board (CLB) held on 28th November, 2024.
iii. 304th meeting of the Central Licensing Board (CLB) held through circulation on 4th December, 2024

A. DRUG LICENSING DIVISION

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

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Westmont Pharmaceutical Industry, Mini Industrial Estate G.T. Road, Gujar Khan, Rawalpindi. (Grant of DML Afresh) (Evaluator: - Abdullah (DD-Lic)	**10-12-2024**	**Good**	1. Dr. Muhammad Ahsan Hafiz, Deputy Director (QA & LT), DRAP, Islamabad. 2. Mrs. Sabahat Zehra Qasmi, Assistant Director (NCLB), DRAP, Islamabad. 3. Mr. Zia Ullah, Deputy Director, DRAP, Islamabad.
	QC Incharge	Mr. Aman Ullah Khan (B-Pharm)		
	Production Incharge	Muhammad Afzal Bhatti (B-Pharm)		
	Recommendations of the panel: - Based on the inspection conducted by the panel including the review of the submitted documentation, keeping in view the positive attitude and intent of the management, the			

panel **recommends** the Re-grant of the Drug Manufacturing License (Afresh) by way of formulation to M/s Westmont Pharmaceutical Industry, situated at Mini Industrial Estate G.T. Road, Gujar Khan, Rawalpindi for the following sections, along with the Quality Control Laboratory and approved stores (Raw Material Store, Packaging Material Store, and Finished Goods Store):

i. Oral Powder Section (Veterinary)
ii. Oral Liquid Section (Veterinary)

Decision of the Central Licensing Board in its 305th meeting:

The Board considered the facts and on the recommendations of the panel of experts, approved the grant of Drug Manufacturing License (afresh) with the same DML Number, by way of Formulation, in the name of M/s Westmont Pharmaceutical Industry, Mini Industrial Estate G.T. Road, Gujar Khan, Rawalpindi, for the following sections:

i. Oral Powder Section (Veterinary)
ii. Oral Liquid Section (Veterinary)

This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature.

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
2.	M/s Haaks Vethum (Pvt.) Ltd., Plot No. 60-B (II), Phase 1A, M-3, Industrial City, FIEDMC, Faisalabad. (Grant of DML New) by way of formulation (Evaluator: - Zunaira Faryad (DD-Lic)	**22-11-2024 & 03-01-2025**	**Good**	1. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, DD, DRAP, Lahore.
	QC Incharge	Mr. Muhammad Zubair (Pharm-D)		
	Production Incharge	Mr. Tahir Mahmood (Pharm-D)		

Recommendations of the panel: -

In view of above inspection proceedings and the facilities verified, such as company profile, building, material management, production, in process controls, Quality Control Testing, machinery/equipment, air handling, water treatment system, personnel and documentation etc **the panel is of the opinion to recommend the grant of new Drug Manufacturing License** vide DRAP, Islamabad letter No.F.1-32/2022-Lic dated 30-10-2024, to HAAKS Vethum (Pvt.) Ltd., P-60 (B-II), Phase 1A, M-3, Industrial City, Sahianwala, FIEDMC, Faisalabad for the following sections:

	i. Oral Liquid Section (General) (Veterinary) ii. Oral Powder Section (General) (Veterinary) **Decision of the Central Licensing Board in its 305th meeting:** The Board considered the facts and on the recommendations of the panel of experts, approved the grant of Drug Manufacturing License, by way of Formulation, in the name of M/s HAAKS Vethum (Pvt.) Ltd., Plot No. 60-B (II), Phase 1A, M-3, Industrial City, FIEDMC, Faisalabad for the following sections: i. Oral Liquid Section (General) (Veterinary) ii. Oral Powder Section (General) (Veterinary)			
3.	M/s ZAC Laboratories (Pvt.) Ltd., Plot No. 270, Bhalwal Industrial Estate, Bhalwal. (Grant of DML New) by way of Semi-Basic (Evaluator: - Abdullah (DD-Lic)	**13-12-2024 & 03-01-2024**	**Good**	1. Faisal Shahzad, Additional Director, DRAP, Lahore 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, DD, DRAP, Lahore.
	QC Incharge	Mr. Rehan Ahmed (M.Sc Chemistry).		
	Production Incharge	Mr. Zahid Ali Rana (M. Sc Chemistry)		
	Recommendations of the panel: - Keeping in view the manufacturing facility, like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment plant, testing facilities, technical personnel and documentation, the panel of inspector's is of the opinion to **recommend** the grant of approval for the issuance of Drugs Manufacturing License (By way of Semi Basic Manufacture) vide DRAP, Islamabad letter No. F. 1-4/2020-Lic dated, 01-08-2024 to ZAC Laboratories (Pvt.) Ltd., Plot No. 270, Bhalwal Industrial Estate, Bhalwal for the following sections: 1. Multipurpose Purpose Block. Panel was given the mandate for following sections: - 1. Multipurpose plant line I, 2. Multipurpose plant line II, 3. Quality Control Laboratory. 4. Stores (RMS, PMS, FGS). **Decision of the Central Licensing Board in its 305th meeting:**			

	The Board considered the facts and on the recommendations of the panel of experts, approved the grant of Drug Manufacturing License, by way of Semi Basic Manufacture, to M/s. ZAC Laboratories (Pvt.) Ltd., Plot No. 270, Bhalwal Industrial Estate, Bhalwal, for the following sections, subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020: 1. Multipurpose Block			
4	M/s. Vetnicare Pharmaceutical, Khana Labana, 8-km, Sheikhupura Road, Muridke. (Grant of DML New) by way of Formulation Evaluator:- Abdullah (DD-Lic)	09-01-2025	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Government of the Punjab. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ishtaiq Shafiq, Deputy Director, DRAP, Lahore.
	Production Incharge	Mr. Rahmat Jamil Bohari		
	Quality Control Incharge	Mr. Nasir Ali		
	lusion In view of above inspection proceedings and the facilities verified, such as company profile, building, material management, production, in process controls, Quality Control Testing, machinery/equipment, air handling, water treatment system, personnel and documentation etc **the panel is of the opinion to recommend the grant of new Drug Manufacturing License** vide DRAP, Islamabad letter No. F.1-36/2022-Lic dated, 16-12-2024**,** to M/s. Vetnicare Pharmaceutical, Khana Labana, 8-km Sheikhupura Road, Muridke for the following sections. (i) Oral Liquid Section (General) (Veterinary) (ii) Oral Powder Section (General) (Veterinary) **Decision of the Central Licensing Board in its 305th meeting:** The Board considered the facts and on the recommendations of the panel of experts, approved the grant of Drug Manufacturing License, by way of formulation, to M/s. Vetnicare Pharmaceutical, Khana Labana, 8-km Sheikhupura Road, Muridke for the following sections: (i) Oral Liquid Section (General) (Veterinary) (ii) Oral Powder Section (General) (Veterinary)			
5	M/s ZAC Laboratories (Pvt.) Ltd., Plot No. 270, Bhalwal Industrial Estate, Bhalwal.	**13-12-2024 & 03-01-2024**	**Good**	1. Faisal Shahzad, Additional Director, DRAP, Lahore

	(Grant of DML New) by way of Semi Basic (Evaluator: - Abdullah (DD-Lic)			2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, DD, DRAP, Lahore.
	QC Incharge	Mr. Rehan Ahmed (M.Sc Chemistry).		
	Production Incharge	Mr. Zahid Ali Rana (M. Sc Chemistry)		

mmendations of the panel: -

Keeping in view the manufacturing facility, like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment plant, testing facilities, technical personnel and documentation, the panel of inspector's is of the opinion to **recommend** the grant of approval for the issuance of Drugs Manufacturing License (By way of Semi Basic Manufacture) vide DRAP, Islamabad letter No. F. 1-4/2020-Lic dated, 01-08-2024 to ZAC Laboratories (Pvt.) Ltd., Plot No. 270, Bhalwal Industrial Estate, Bhalwal for the following sections:

2. Multipurpose Purpose Block.

Panel was given the mandate for following sections: -

5. Multipurpose plant line I,
6. Multipurpose plant line II,
7. Quality Control Laboratory.
8. Stores (RMS, PMS, FGS).

The firm submitted flow chart and list of chemical to be used in the manufacturing of following 21 APIs,

Name of API	**Name of API**
1. Azithromycin	2. Metformin Hydrochloride
3. Ciprofloxacin Base	4. Montelukast Sodium
5. Ciprofloxacin Hydrochloride	6. Moxifloxacin Hydrochloride
7. Ciprofloxacin Lactate	8. Naproxen Sodium
9. Clarithromycin	10. Paracetamol
11. Diclofenac Potassium	12. Sitagliptin Phosphate Monohydrate
13. Diclofenac Sodium	14. Tramadol HCL
15. Flurbiprofen	16. Valsartan
17. Ibuprofen	18. Vildagliptin
19. Levofloxacin Hemihydrate	20. Ascorbic Acid
21. Mefenamic Acid	

Firm was asked to submit proper application along with fee for approval of said APIs.

The firm submit online application vide T ID EZG-17Y-RHSB on 20/01/2025 for approval of above mentioned API where they submitted flow chart and list of chemical to

	be used in the manufacturing of following 21 APIs. Therefore, firm was asked to submit following document/information of above mentioned APIs which are required as per SOP. However, as of today the firm did not submit their response. 1. Differential Fee Rs 1500/ API 2. Names and quantities of chemicals to recycled in manufacturing 3. Theoretical yield of manufacturing process. 4. Reference monograph and Testing method 5. List of Testing equipment 6. Shelf life of API 7. Material safety data sheet Meanwhile same inspection report was again forwarded by Additional Director, DRAP Lahore with same recommendation, however, flow chart and chemical to be used in the manufacturing of above APIs are also annexed with the inspection report. **Decision of the Central Licensing Board in its 305th meeting:** The Board observed that case is still incompete in light of SOP as well as applicable fee for approval of APIs, therefore, did not accede to the recommendations for approval of APIs in the name of the applicant as well as showed the displeasure on submission of recommendations by the panel without given mandate by the Division.			
6	M/s. Zamko Pharmaceuticals (Pvt.) Ltd., Plot No. 641-A, Sunder Industrial Estate, Lahore, Evaluator:- Abdullah (DD-Lic)	16-01-2025	**Good**	1. Mr. Faisal Shahzad, Additional Director, DRA, Lahore 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ishtaiq Shafiq, Deputy Director, DRAP, Lahore.
	Production Incharge	Dr. Faisal Razzaq, (Pharm.D)		
	Quality Control Incharge	Mr. Muhammad Aslam (MSc. Chemistry)		
	RECOMMENDATION Keeping in view the manufacturing facility, like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment plant, testing facilities, technical personnel, documentation, on the day of inspection, the panel of inspector's is of the opinion to **recommend the grant of Drug manufacturing License** by way of formulation(vide letter No. 1-62/2011-Lic dated 13-01-2025, to M/s. Zamko (Pvt.) Ltd., 43-E, Sundar Industrial Estate, Lahore for the following sections.			

	1 Tablet Section (General). 2 Capsule Section (General) 3 Oral Dry Powder Suspension Section (General). **Decision of the Central Licensing Board in its 305th meeting:** The Board considered the facts and on the recommendations of the panel of experts, approved the grant of Drug Manufacturing License (afresh), by way of formulation with the same DML number, to M/s. Zamko (Pvt.) Ltd., 43-E, Sundar Industrial Estate, Lahore for the following sections. 1. Tablet Section (General). 2. Capsule Section (General) 3. Oral Dry Powder Suspension Section (General). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature.			
7	M/s. Well Go Pharmaceuticals (Pvt.) Ltd., 5-km, Raiwind Manga Road, Lahore Evaluator:- Abdullah (DD-Lic)	27-12-2024 (Formulation)	**Good**	. Faisal Shahzad, Additional Director, DRAP, Lahore. . Azhar Jamal Saleemi, Chief Drugs Controller Punjab, Lahore 3 Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore.
	Production Incharge	Mr. Muhammad Naeem Mansoor (B.Pharm)		
	Quality Control Incharge	Mr. Sami Ullah Khan (Pharm.D)		
	RECOMMENDATION In view of the above inspection proceedings and the facility verification, such as company profile, building, material management, production, in process controls, quality control testing, machinery/equipment, air handling, water treatment system, personnel and documentation etc, the panel is of the opinion to **recommend** the grant of Drug Manufacturing License vide DRAP, Islamabad letter No. 1-37/2020-Lic dated 07-06-2024, to M/s. Well Go Pharmaceuticals (Pvt.) Ltd., 5-km, Raiwind Manga Road, Lahore for the following sections: 1 Liquid Injectable Vials Section (General). 2 Liquid Injection Ampoule (General) Section. 3 Sachet Section (General) 4 Liquid External Preparation Section (General) **Decision of the Central Licensing Board in its 305th meeting:**			

	The Board considered the facts and on the recommendations of the panel of experts, approved the grant of Drug Manufacturing License, by way of Formulation, to M/s. Well Go Pharmaceuticals (Pvt.) Ltd., 5-km, Raiwind Manga Road, Lahore for the following sections: 1 Liquid Injectable Vials Section (General). 2 Liquid Injection Ampoule (General) Section. 3 Sachet Section (General) 4 Liquid External Preparation Section (General)

Case No. 7 **GRANT OF DRUG MANUFACTURING LICENSE (BY WAY OF SEMI BASIC MANUFACTURE) MS. FUTURECEUTICALS, PLOT NO. 239, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD**

The Central Licensing Board in its 302nd meeting held on 20th November, 2024 considered the case of grant of DML (by way of Semi Basic Manufacture) of Ms. Futureceuticals, Plot No. 239, Industrial Triangle Kahuta Road, Islamabad and decided as under;

Decision of the Central Licensing Board in 302nd meeting:

The Board on the recommendations of the panel approved the grant of Drug Manufacturing License by way of Semi Basic Manufacture in the name of Ms. Futureceuticals, Plot No. 239, Industrial Triangle Kahuta Road, Islamabad for the following manufacturing facilities subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020, if applicable:

i. Semi-Basic manufacturing (General Unit-I)
ii. Semi-Basic manufacturing (General Unit-II)
iii. Semi-Basic manufacturing (General Unit-III)
iv. Product development Laboratory (R&D Lab)
v. Quality Control Laboratory
vi. Stores (Raw material store, packaging material store and Finished goods store)

The Board, on the recommendations of the panel at the first phase, also approved the grant of following established Active Pharmaceutical Ingredients (APIs) (Flow charts at Annexure-A) with the abovementioned condition:

Sr. No	***Name of API***	***Specifications***
1.	*Amlodipine Besylate*	*BP*

2.	*Ciprofloxacin (HCL Monohydrate/Lactate)*	*USP*
3.	*Levoflaxcin*	*USP*
4.	*Moxifloxacin*	*USP*
5.	*Caffein (Plain/Citrate)*	*USP*
6.	*Azithromycin*	*USP*
7.	*Mefenamic Acid*	*BP*
8.	*Tramadol HCl*	*USP*
9.	*Paracetamol*	*BP*
10.	*Naproxen Sodium*	*BP*
11.	*Ferrous Sulphate*	*USP*
12.	*Iron Sucrose*	*BP*
13.	*Ferric (Pyrophosphate/ Pyrohosphate Citrate)*	*USP*
14.	*Iron Hydroxide Polymaltose Complex*	*USP*
15.	*Quetiapine Fumarate*	*USP*
16.	*Montelukast Sodium*	*USP*
17.	*Domperidone Maleate*	*USP*
18.	*Metronidazole (Plain/Benzoate)*	*USP*
19.	*Pantaprazole (Sod/ Magnesium)*	*BP*
20.	*Bisoprolol Fumarate*	*USP*
21.	*Rosuvastatin Calcium*	*USP*
22.	*Atorvastan Calcium*	*EP*
23.	*Enrofloxacin*	*USP*
24.	*Aminophylline*	*USP*
25.	*Acefylline (Piprazine)*	*USP*
26.	*Naproxen Sodium*	*BP*
27.	*Ketorolac Tromethamine*	*USP*
28.	*Solifenacin Succinate*	*USP*
29.	*Sumatriptan Succinates*	*USP*
30.	*Povidone Iodine*	*USP*
31.	*Escitalopram Oxalate*	*USP*
32.	*Ondansetron HCL*	*USP*
33.	*Tretinoin*	*USP*
34.	*Oxfendazole*	*USP*
35.	*Glucosamine Sulphate (Sodium Chloride / Potasssium Chloride)*	*USP*
36.	*Calcium Carbonate (PPt)*	*USP*
37.	*Sodium Chloride*	*BP*
38.	*Lactulose*	*USP*
39.	*Riboflavin Sodium Phosphate*	*BP*

40.	*Methycobalamine*	*JP*

The Board deferred the remaining APIs for further review and deliberation.

a. In the light of above decision of the Board, firm was **asked to submit NOC** from Ministry of Narcotic Control for further necessary action.
b. In response, M/s Futureceuticals, Plot No. 239, Industrial Triangle, Kahuta Road, Islamabad, has submitted an application for approval of their products that do not contain or using any controlled ingredients for manufacturing of following APIs. The firm has specifically requested approval for the following Active Pharmaceutical Ingredients (APIs), stating that they do not use any controlled chemical for manufacturing of following APIs. The firm requested for issuance of approval letter for following APIs.

Sr. No.	Name of APIs
1	Amlodipine Besylate
2	Iron Sucrose
3	Ferric Pyrophosphate/Pyrophosphate Citrate
4	Aminophylline
5	Riboflavin Sodium Phosphate
6	Povidone Iodine
7	Calcium Carbonate
8	Sodium Chloride
9	Doxophylline
10	Lactulose

The firm submitted an undertaking on stamp paper that no controlled substance will be used in the semi-basic manufacturing process of above 09 approved API's and in case of any violation, management shall be held responsible. They further submitted that where Controlled chemical are used, they will obtain NOC from Quarter Concern (Ministry of Narcotic Control).

Decision of the Central Licensing Board in its 305th meeting:

The Board after detailed deliberations allowed issuance of DML and following 09 APIs to the firm based on their undertaking that no controlled substance is being used in the semi-basic manufacturing of these APIs:-

Sr. No.	Name of APIs
1	Amlodipine Besylate
2	Iron Sucrose
3	Ferric Pyrophosphate/Pyrophosphate Citrate
4	Aminophylline
5	Riboflavin Sodium Phosphate
6	Povidone Iodine
7	Calcium Carbonate
8	Sodium Chloride
9	Lactulose

II. Remaing APIs shall be considered subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020.

III. The Board also decided that to ensure the safety and quality parameters of APIs being manufactured locally, at one time, twenty APIs as per priority list of manufacturer will be granted. Remaining APIs will be considered after inspection of manufacturing units so as to check the safety and quality parameters.

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

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	**M/s Air Pharmaceuticals (Pvt) Ltd., Plot No. 74-75-A, Small Industrial Estate, Kasur.** **DML No. 000977** **(Formulation)** **Section (03):** **i. Tablet Section (General)** **ii. Capsule Section (General)** **ii. Sachet Section (General)** **Evaluator:- DD-Lic)**	**25-11-2024**	**Good**	**1. Mr. Muhammad Shamoon Chaudhary, Expert Member.** **2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.** **3. Mr. Ishtiaq Shafiq, Deputy Director, DRAP, Lahore.**
	Recommendations of the panel: In view of the above inspection proceedings and the facility verification, such as company profile, building, material management, production, in process controls, quality control testing, machinery/equipment, air handling, water system, personnel and documentation etc the panel is of the opinion to **recommend** the grant of following additional sections vide DRAP, Islamabad letter Tracking ID No. RVZ-M52-LPN2 dated, 07-10-2024 to M/s Air Pharmaceuticals (Pvt.) Ltd., Plot No. 74-75-A, Small Industrial Estate, Kasur. 1. Tablet Section (General) 2. Capsule Section (General) 3. Sachet Section (General).			

	Decision of the Central Licensing Board in its 305th meeting: The Board on the recommendations of the panel of experts, approved the following sections, in the name of M/s Air Pharmaceuticals (Pvt) Ltd., Plot No. 74-75-A, Small Industrial Estate, Kasur under DML No. 000977, by way of Formulation:- 1. Tablet Section (General) 2. Capsule Section (General) 3. Sachet Section (General).			
2	M/s Citi Pharma, 3.5-Km, Head Balloki Road, Phool Nagar, District Kasur. **DML No. 000429 (Semi-Basic)** **APIs (06):** 1. Metformin HCL (USP) 2. Duloxetine HCL (USP) 3. Omeprazole (USP) 4. Lansoprazole (USP) 5. Pantoprazole (USP) 6. Cefixime 3H2O (USP) new flow chart Evaluator:- Abdullah (DD-Lic)	**27-01-2024** **Received on 12-12-2024**	**Good**	1. Mr. Muhammad Tariq, Director DTL, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Deputy Director, DRAP, Islamabad.
	Recommendations of the panel: The firm M/s Citi Pharma (Pvt.) Ltd., 3-Km, Head Balloki Road, Phool Nagar Kasur has been granted a Drug Manufacturing License No.000429 by way Semi Basic Manufacturing under the Drugs Act 1976. Panel had thoroughly inspected the unit, evaluated the documentation provided by the firm on demand and discussed various technical aspects at length. Laboratory scale accelerated stability studies were conducted by the firm. On the panel's query; firm has given an undertaking that long term stability studies shall be conducted before start of commercial manufacturing of these new APIs (Original undertaking of the firm is attached with this report for perusal of Central Licensing Board). Manufacturing processes, process flow charts, differential specification of main input materials and final API, list of materials / chemicals intended to be used, undertaking by the firm to ensure the authorized use of all materials chemicals with proper records, details of equipment of production and quality control and list of technical staff duly signed by the management of the firm are attached with this report for perusal of the Central Licensing Board.			

	In view of the technical discussion held at length with the firm's management, documentations scrutinized as submitted by the management of the firm, physical inspection of the Multi-purpose block of the unit; Panel recommends the grant of approval for the following **new APIs by way of semi basic manufacturing method.** 1) Metformin HCL (USP) 2) Duloxetine HCL (USP) 3) Omeprazole (USP) 4) Lansoprazole (USP) 5) Pantoprazole (USP) 6) Cefixime 3H2O (USP) new flow chart **Decision of the Central Licensing Board in its 305th meeting:** The Board on the recommendations of the panel of experts, approved the following APIs, in the name of M/s Citi Pharma, 3.5-Km, Head Balloki Road, Phool Nagar, District Kasur under DML No. 000429, by way of semi-basic manufacturing subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020.:- 1) Metformin HCL (USP) 2) Duloxetine HCL (USP) 3) Omeprazole (USP) 4) Lansoprazole (USP) 5) Pantoprazole (USP) 6) Cefixime 3H2O (USP) new flow chart			
3.	M/s Carryfor Pharmaceutical (Pvt) Ltd., E-81, North Western Industrial Zone, Port Qasim, Karachi. **DML No. 000901 (Semi-Basic)** **APIs (55):** 1. Valsartan USP 2. Atenolol-USP/BP 3. Amlodipine – USP 4. Metformin Hydrochloride – USP 5. Sitaglipton Phosphate-USP 6. Vildaglipton-USP 7. Glimipride-USP 8. Linagliptin-USP 9. Ebastine-USP 10. Fexofenadine HCL-USP 11. Levocetirizine dihydrochloride-USP/BP 12. Cetirizine USP/BP 13. Loratadine Hydrochloride USP	**10-12-2024 & 23-12-2024**		1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Sindh. 2. Dr. Awais Ahemd, Assistant Director, DRAP, (Reporting & Coordinating Officer), DRAP, Karachi. 3. Mrs. Hira Bhutto, Assistant Director, DRAP, Karachi.

	14. Desloratadine-USP 15. Fluconazole-USP/BP 16. Itraconazole-USP 17. Voriconazole-USP 18. Terbinafine Hydrochloride-USP 19. Atrovastatin-USP 20. Rosuvastatin-USP 21. Losartan potassium-USP 22. Clopidogrel-USP 23. Flubiprofen-USP 24. Serratiopeptidase-USP 25. Diclofenac Pottasium USP/BP 26. Itopride-USP 27. Linezolid-USP 28. Ofloxacin-USP 29. Famotidine-USP 30. Piroxicam-USP 31. Piroxicam Beta Cyclodextrin-USP 32. Abscorbic Acid-USP 33. Thiamine Hydrochloride-USP/BP 34. Riboflavin 35. Pyridoxine Hydrochloride-USP/BP 36. Cholecalciferol-USP/BP 37. Pregabalin-USP/BP 38. Tranexamic Acid-USP 39. Esomeprazole Powder-USP 40. Omeprazole Powder-USP 41. Rabeprazole Powder-USP 42. Pantoprazle Powder-USP 43. Fluoxetine HCL-USP 44. Olazapine USP 45. Excitalopram Oxalate-USP 46. Citalopram Hydrobromide-USP 47. Paroxetine-USP/BP 48. Levosulpiride-USP/BP 49. Sertraline Hydrochloride-USP 50. Risperidone-USP 51. Lumefantrine-USP/BP 52. Clobetasol Propionate USP/BP 53. Triamcinolone Acetonide USP			

	54. Prednisolone-USP 55. Diclofenac Sodium Evaluator:- Abdullah (DD-Lic)			

Recommendations of the panel:

Keeping in view the above observations the infrastructure, machinery, capacity and technical staff, the panel **recommends** the grant of following 55 APIs under DML #000901 (By Way of Semi Basic Manufacturing):

S.No.	API Generic Name
1	Valsartan USP
2	Atenolol-USP/BP
3	Amlodipine – USP
4	Metformin Hydrochloride – USP
5	Sitagliptin Phosphate-USP
6	Vildagliptin-USP
7	Glimepiride-USP
8	Linagliptin-USP
9	Ebastine-USP
10	Fexofenadine HCL-USP
11	Levocetrizine Dihydrochloride-USP/BP
12	Cetirizine USP/BP
13	Loratadine Hydrochloride USP
14	Desloratadine-USP
15	Fluconazole-USP/BP
16	Itraconazole-USP
17	Voriconazole-USP
18	Terbinafine Hydrochloride-USP
19	Atrovastatin-USP
20	Rosuvastatin-USP
21	Losartan potassium-USP
22	Clopidogrel-USP
23	Flubiprofen-USP
24	Serratiopeptidase-USP
25	Diclofenac Pottasium USP/BP
26	Itopride-USP
27	Linezolid-USP
28	Ofloxacin-USP
29	Famotidine-USP
30	Piroxicam-USP
31	Piroxicam Beta Cyclodextrin-USP
32	Abscorbic Acid-USP
33	Thiamine Hydrochloride-USP/BP
34	Riboflavin
35	Pyridoxine Hydrochloride-USP/BP
36	Cholecalciferol-USP/BP
37	Pregabalin-USP/BP
38	Tranexamic Acid-USP
39	Esomeprazole Powder-USP

		40	Omeprazole Powder-USP		
		41	Rabeprazole Powder-USP		
		42	Pantoprazle Powder-USP		
		43	Fluoxetine HCL-USP		
		44	Olazapine USP		
		45	Excitalopram Oxalate-USP		
		46	Citalopram Hydrobromide-USP		
		47	Paroxetine-USP/BP		
		48	Levosulpiride-USP/BP		
		49	Sertraline Hydrochloride-USP		
		50	Risperidone-USP		
		51	Lumefantrine-USP/BP		
		52	Clobetasol Propionate USP/BP		
		53	Triamcinolone Acetonide USP		
		54	Prednisolone-USP		
		55	Diclofenac Sodium		
	Decision of the Central Licensing Board in its 305th meeting: The Board on the recommendations of the panel of experts, approved the twenty APIs as per priority of manufacturer from list of recommended APIs by the panel, in the name of M/s Carryfor Pharmaceutical (Pvt) Ltd., E-81, North Western Industrial Zone, Port Qasim, Karachi under DML No. 000901, by way of semi-basic manufacturing subject to submission of NOC from Ministry of Narcotics, in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020. 2. Inspection will be conducted to ensure safety and quality paratmeters of manufactured APIs before consideration of the remaining APIs.				
4	M/s Medwell Pharmaceuticals, 1-Km, Terbella Road, Lawrencepur Faqirabad. DML No. 000699 (Formulation). **Sections (03):** i. Tablet (General) ii. Capsule (General) iii. Cream, Ointment (General) Evaluator: - Zunaira Faryad (DD-Lic)	01-01-2025	**Good**	1. Mr. Shoaib, Deputy Director NCLB, DRAP, Islamabad. 2. Mrs. Gulnaz Yaqoob, Deputy Director, DRAP, Islamabad. 3. Mr. Umar Latif, Deputy Director, DRAP, Islamabad.	

Recommendations of the panel:

In view of the inspection conducted, reviewing the documents, interview of technical team, intent of the management and verification of manufacturing and testing facility such as FTIR, HPLC, UV Spectrometer, Dissolution apparatus, Karl Fisher, Polarimetry and other QC equipment along with stability chambers (list already attached) the panel unanimously **recommends** the grant of following additional sections of M/s Medwell Pharmaceuticals 1 Km Terbella Road, Lawrence Faqirabad:

Sr no.	Sections	Category
1.	Tablet	General
2.	Capsule	General
3.	Cream, Ointment	General

Decision of the Central Licensing Board in its 305th meeting:

The Board on the recommendations of the panel of experts, approved the following sections, in the name of M/s Medwell Pharmaceuticals, 1-Km, Terbella Road, Lawrencepur Faqirabad under DML No. 000699, by way of Formulation:-

Sr no.	Sections	Category
1.	Tablet	General
2.	Capsule	General
3.	Cream, Ointment	General

5	M/s Himont Pharmaceuticals (Pvt) Ltd., 17-Km, Ferozepur Road, Lahore. DML No. 000231 (Formulation). **Sections (01):** i. Liquid Injectable (Biological Section)- **New** Evaluator: - Zunaira Faryad (DD-Lic)	**20-08-2024 & 12-12-2024**	**Good**	1. Mr. Muhammad Arif Ch., DRAP, Islamabad. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.

Recommendations of the panel:

In view of the above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation e.t.c. the panel is of the opinion to **recommend** the additional section vide DRAP Islamabad letter Tracking ID: EL2-MRZ-GTJZ dated 03-06-2024 i.e., Liquid Injectable (Biological Section) to M/s Himont Pharmaceuticals (Pvt) Ltd., 17-Km, Ferozepur Road, Lahore by way of Formulation.

Decision of the Central Licensing Board in its 305th meeting:

	The Board on the recommendations of the panel of experts, approved the following section, in the name of M/s Himont Pharmaceuticals (Pvt) Ltd., 17-Km, Ferozepur Road, Lahore under DML No. 000231, by way of Formulation:- i. Liquid Injectable (Biological Section)- **New**			
6	M/s. Poulvet Pharmaceuticals (Pvt.) Ltd. 0.5-km, West Canal, 25-km, Pull Rango Lahore Road, Multan. Drug Manufactuing License No. 000970 (Formulation) Evaluator:- Abdullah (DD-Lic)	20-01-2025	**Good**	1. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drug, Lahore. 3. Mr. Ishtaiq Shafiq, Deputy Director, , DRAP, Lahore.
	<u>Recommendation/Conclusion</u> Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and Microbiology Laboratory, testing facilities, technical personnel met and documentation reviewed, the panel of inspectors is of the opinion to **recommend** the grant of additional section vide DRAP Islamabad letters No. F.1-62/2011-Lic dated 13-01-2025, to M/s. Poulvet Pharmaceuticals (Pvt.) Ltd., is situated at 0.5-km, West Canal, 25-km, Pull Rango Lahore Road, Multan for the following section only: ***i. Dry Powder Section (Penicillin) (Veterinary)*** **<u>Decision of the Central Licensing Board in its 305th meeting:</u>** The Board on the recommendations of the panel of experts, approved the following section, in the name of M/s. Poulvet Pharmaceuticals (Pvt.) Ltd. 0.5-km, West Canal, 25-km, Pull Rango Lahore Road, Multan under Drug Manufactuing Licens No. 000970, by way of Formulation:- i. Dry Powder Section (Penicillin) (Veterinary)			
7	M/s. ICU Pharmaceuticals (SMC-Pvt.) Ltd., Khewat No.13/13, Khatooni No.57/66, Mouza Mirpur	16-01-2025	**Good**	1. Azhar Jamal Saleemi, Chief Drug Controller Government of the Punjab. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.

	Kehna, Tehsil Sharkpur, District Sheikhupura. Drug Manufactuing License No. 000956 (Formulation) Evaluator:- Zunaira Faryad (DD-Lic)			3. MR. Ishtiaq Shafiq, Deputy Director, DRAP, Lahore.
	Recommendation/Conclusion Keeping in view the manufacturing facility like, building, HVAC system, production machinery, equipment in Quality Control and Microbiology Laboratory, water treatment plant, testing facilities, technical personnel, documentation on the day of inspection the panel of inspectors is of the opinion to recommend the grant of additional section by way of formulation (vide letters No. F. 1-24/2015-Lic dated 29-03-2024) to M/s. ICU Pharmaceuticals (SMC-Pvt.) Ltd., Khewat No.13/13, Khatooni No.57/66, Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura i.e. **Liquid Injectable (Vial) Section (General)(New)** **The panel did not recommend Liquid Injectable (Ampoule) Section (General) as process flow was found inadequate and redesigning of the section was required to meet GMP requirements.** **Decision of the Central Licensing Board in its 305th meeting:** The Board on the recommendations of the panel of experts, approved the following section, in the name of M/s. ICU Pharmaceuticals (SMC-Pvt.) Ltd., Khewat No.13/13, Khatooni No.57/66, Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura under Drug Manufactuing Licens No. 000956, by way of Formulation:- **i. Liquid Injectable (Vial) Section (General)(New)** 2. The Board under Rule 10 (4) (5) (6) & (7) of the Drugs (Licensing, Registering and Advertising) Rules, 1976, decided to reject the grant of following section based on the recommendations of the panel: i. **Liquid Injectable (Ampoule) Section (General)**			
8	M/s Arsons Pharmaceutical Industries (Pvt.) Ltd, 22-Km, Multan Road, Off 2.5-Km, Defence Road, Lahore. DML No. 000514 (Formulation).	15.11.2024	**Good**	1. Faisal Shahzad, Additional Director, DRAP, Lahore. 2. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab, Lahore.

	Evaluator: - Zunaira Faryad (DD-Lic)			3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: Keeping In view manufacturing facility, Like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment plant, testing facilities, technical personnel, documentation, the panel of inspector's is of the opinion to recommended the grant of renewal of Drug Manufacturing License by way pf formulation of the following sections vide DRAP, Islamabad letter No.F.1-9/2011-Lic (Vol-II) dated 10.05.2024 to M/s Arsons Pharmaceutical Industries (Pvt.) Ltd, 22-Km, Multan Road, Off 2.5-Km, Defence Road, Lahore. i. Tablet Section (General) (Renewal) ii. Capsule Section (Renewal) iii. Cream/Ointment/Gel Section (Renewal) iv. Tablet Section (Psychotropic) **The Panel also recommend the grant of following additional section to M/s Arsons Pharmaceutical Industries (pvt.) Ltd, 22-Km, Multan Road, Off 2.2-Km, Defence Road, Lahore.** **i. Sachet Section (General) (New)** **Decision of the Central Licensing Board in its 305th meeting:** The Board on the recommendations of the panel of experts, approved the following section, in the name of M/s Arsons Pharmaceutical Industries (Pvt.) Ltd, 22-Km, Multan Road, Off 2.5-Km, Defence Road, Lahore under DML No. 000514, by way of Formulation:- **i. Sachet Section (General) (New)**			
8	M/s. Fynk Pharmaceuticals, 19-Km, G.T Road, Kala Shah Kaku, Lahore. **DML No. 000494 (Formulation)** **Period:** Commencing on 11-10-2023 ending on 10-10-2028. Evaluator:- Zunaira Faryad (DD-Lic)	**30-08-2024 & 30-09-2024**	**Good**	1. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rasool Shaikh, FID, DRAP, Lahore. 1. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	QC Incharge	Mr. Muhammad Omer Kaleem Malik (M.Sc Chemistry)		
	Production Incharge	Mr. Abdul Rauf (Pharm-D)		
	Recommendations of the panel: Keeping in view the manufacturing facility, like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment			

	plant, testing facilities, technical personnel and documentation, the panel of inspector's is of the opinion to **recommend the grant of renewal of Drug Manufacturing License** vide DRAP Islamabad letter no.1-61/84-Lic (Vol-IV), dated 28-02-2024 to M/s. Fynk Pharmaceuticals, 9-Km, G.T Road, Kala Shah Kaku, Tehsil Ferozwala, District Sheikhupura for the following sections: 1. Liquid Syrup/Suspension Section (General) 2. Liquid Injectable (Ampoule) Section (General) 3. Dry Powder Injection Section (Cephalosporin) 4. Dry Powder Suspension Section (Cephalosporin) 5. Capsule Section (Cephalosporin) 6. Cream. Ointment Section (General) 7. Cream. Ointment Section (Steroidal) 8. Tablet Section (General) 9. Capsule Section (General) 10. Oral Dry Powder Suspension Section (General) 11. Sachet Section (General) 12. Dry Powder Injection Section (General) 13. Capsule Section (Penicillin) 14. Dry Powder Injection Section (Penicillin) 15. Dry Powder Suspension Section (Penicillin) 16. Dry Powder Injection Section (Carbapenem) 17. Research and Development Facility 18. **Liquid Injectable-II (Ampoule) (General) Section (New)** in place of licensed Liquid Injectable (Ampoule) (Psychotropic) Section. **<u>Decision of the Central Licensing Board in its 305th meeting:</u>** The Board, on the recommendations of the panel of experts, approved the following section, in the name of M/s Fynk Pharmaceuticals, 19-Km, G.T Road, Kala Shah Kaku, Lahore:- 1. **Liquid Injectable-II (Ampoule) (General) Section (New)** in place of licensed Liquid Injectable (Ampoule) (Psychotropic) Section. The Board also decided to notify the Drug Registration Board to take the necessary action.

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

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

<table>
<tr><th>S #</th><th>Name of the firm</th><th>Date of Inspection</th><th>Ranking/ Evaluation</th><th>Inspection Panel Members</th></tr>
<tr><td>1.</td><td>M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366, Sector I-9, Industrial Area, Islamabad.

DML No. 000239 (Formulation)

Period: Commencing on 30-09-2024 ending on 29-09-2029.

Evaluator:- Urooj Fatima (DD-Lic)</td><td>21-11-2024 & 22-11-2024</td><td>Good</td><td>1. Mr. Asad Ullah, Deputy Director, DRAP, Islamabad.
2. Hafiz Sana Ullah Babar, Deputy Director, DRAP, Islamabad.
3. Ms. Mehwish Tanveer, Deputy Director, DRAP, Islamabad.</td></tr>
<tr><td></td><td>QC Incharge</td><td colspan="3">Mr. Gulzar Khan (B. Pharm)</td></tr>
<tr><td></td><td>Production Incharge</td><td colspan="3">Mr. Tipu Sultan Akram (B. Pharm)</td></tr>
<tr><td></td><td colspan="4">The inspection was conducted with the mandate of verification of renewal status of Drug Manufacturing License of M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366, Sector I-9/3, Industrial Area, Islamabad. Based on findings of the inspection, review of documents and records, system, utilities, physical inspection of areas in the manufacturing facility mentioned above, and interview of personnel, it is concluded that the establishment meets the minimum requirements for the renewal of the Drug Manufacturing License, as prescribed under the Drug Act, 1976, the DRAP Act, 2012, and the rules framed thereunder. Moreover, the firm is required to fulfill the requirements as mentioned in Part 02 of this report in accordance with the requirements of cGMP. The panel recommends the renewal of the Drug Manufacturing License of the below mentioned sections along with Quality Control Laboratory and approved stores (Raw material store, Packaging Material store & Finished goods store):
<table>
<tr><td>i.</td><td>Tablet Section (General)</td><td>vi.</td><td>Ointment/Cream/Gel Section (General)</td></tr>
<tr><td>ii.</td><td>Capsule Section (General)</td><td>vii.</td><td>Dry Powder Inhaler Capsule Section (General)</td></tr>
<tr><td>iii.</td><td>Oral Dry Powder for Suspension Section (General)</td><td>viii.</td><td>Soft Gel Capsule Section (General)</td></tr>
<tr><td>iv.</td><td>Oral Liquid Section (General)</td><td>ix.</td><td>Tablet Section (Psychotropic)</td></tr>
<tr><td>v.</td><td>Sachet Section (General)</td><td>x.</td><td>R&D facility</td></tr>
</table>
</td></tr>
</table>

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000239, by way of Formulation, in the name of M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366, Sector I-9, Industrial Area, Islamabad, for the period commencing on 30-09-2024 ending on 29-09-2029, for the following sections:

i.	Tablet Section (General)	vi.	Ointment/Cream/Gel Section (General)
ii.	Capsule Section (General)	vii.	Dry Powder Inhaler Capsule Section (General)
iii.	Oral Dry Powder for Suspension Section (General)	viii.	Soft Gel Capsule Section (General)
iv.	Oral Liquid Section (General)	ix.	R&D facility
v.	Sachet Section (General)		

2. Approved renewal of following section, subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:

1. Tablet Section (Psychotropic)

2.	M/s Islam Pharmaceuticals, 7-Km, Pasrur Road, Sialkot. **DML No. 000885 (Formulation)** **Period:** Commencing on 29-08-2023 ending on 28-08-2028. Evaluator:- Zunaira Faryad (DD-Lic)	**04-11-2024**	**Good**	1. Mr. Muhammad Shamoon Chaudhary, Expert Member. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Abdul Rashid Shaikh, FID, DRAP, Lahore.
	QC Incharge	Mr. Muhammad Nadir Khan (M-Phil-Chemistry)		
	Production Incharge	Mr. Arif Khan (Pharm-D)		

Recommendations of the panel:

Keeping in view the manufacturing facility like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment plant, testing facilities, technical personnel, documentation, the panel of inspector's is of the opinion to recommend the grant of renewal of Drug Manufacturing License by way of formulation (vide letter Tracking ID RH7-QIQ-HNB2 date 23-09-2024) to M/s Islam Pharmaceuticals, 7-Km, Pasrur Road, Sialkot for the following sections:

1. Tablet Section (General)
2. Capsule Section (General)
3. Sachet Section (General)

	4. Dry Powder Section (General) 5. Liquid Ampoule (SVP) Section (General) **<u>Decision of the Central Licensing Board in its 305th meeting:</u>** The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000885, by way of Formulation, in the name of M/s Islam Pharmaceuticals, 7-Km, Pasrur Road, Sialkot, for the period commencing on 29-08-2023 ending on 28-08-2028, for the following sections:- 1. Tablet Section (General) 2. Capsule Section (General) 3. Sachet Section (General) 4. Dry Powder Section (General) 5. Liquid Ampoule (SVP) Section (General)			
3.	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Tringale, Kahuta Road, Islamabad. **DML No. 000432 (Formulation)** **Period:** Commencing on 15-06-2024 & ending on 14-06-2029. Evaluator:- Urooj Fatima (DD-Lic)	**13-11-2024 & 14-11-2024**	**Good**	1. Mr. Mehwish Tanveer, Deputy Director, DRAP, Islamabad. 2. Mr. Ziaullah, Deputy Director, DRAP, Islamabad. 3. Hafiz Sanaullah Babar, Deputy Director, DRAP, Islamabad.
	QC Incharge	Mr. Aamir Shahzad (M.Sc Chemistry)		
	Production Incharge	Mr. Amir Badshah (B. Pharm)		

Recommendations of the panel:

In conclusion, after reviewing the documentation submitted by the firm, inspecting the premises, noting the positive attitude and intent of the management, the panel is of the view that the establishment is operating at the minimum acceptable cGMP level and meets the requirements for the renewal of the Drug Manufacturing License, as prescribed under the Drug Act, 1976, the DRAP Act, 2012, and the rules framed thereunder and **recommends** the renewal of the Drug Manufacturing License of the below mentioned sections along with Quality Control Laboratory and approved stores (Raw material store, Packaging Material store & Finished goods store) of M/s Davis Pharmaceutical Laboratories, Plot No.121, Industrial Tringale Area, Kahuta Road, Islamabad:

Sr. No.	Formulation(s)	Pharmacological Category(ies)
1.	Tablet Section	General
2.	Capsule Section	General
3.	Cream/Ointment/Gel Section	General
4.	Sachet Section	General
5.	Liquid Section	General
6.	Capsule Section	Cephalosporin
7.	Dry Powder Suspension	Cephalosporin

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000432, by way of Formulation, in the name of M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Tringale, Kahuta Road, Islamabad, for the period commencing on 15-06-2024 & ending on 14-06-2029, for the following sections:-

Sr. No.	Formulation(s)	Pharmacological Category(ies)
1.	Tablet Section	General
2.	Capsule Section	General
3.	Cream/Ointment/Gel Section	General
4.	Sachet Section	General
5.	Liquid Section	General
6.	Capsule Section	Cephalosporin
7.	Dry Powder Suspension	Cephalosporin

4.	M/s Welmark Pharmaceuticals, Plot No.122, Block-B, Phase-V, Industrial Estate, Hattar. **DML No. 000614 (Formulation)** **Period:** Commencing on 11-04-2022 ending on 10-04-2027.	**19-09-2024**	**Good**	1. Hafiz Sanaullah Babar, Deputy Director, DRAP, Islamabad. 2. Mr. Asad Ullah, Deputy Director, DRAP, Islamabad. 1. Mr. Muhammad Ashfaq, Deputy Director, DRAP, Islamabad.

	Evaluator:- Urooj Fatima (DD-Lic)			
	QC Incharge	Mr. Muhammad Imran (Msc-Chemistry)		
	Production Incharge	Mr. Ashfaq Ur Rehman (B-Pharm)		

Recommendations of the panel:

Keeping in view the comprehensive inspection conducted by the panel including a detailed review of documentation at the time of inspection, and taking in account the positive attitude cooperative intent of the management towards the suggestions made by the panel, the panel unanimously **recommends** the renewal of the Drug Manufacturing License of M/s Welmark Pharmaceuticals (Pt) Ltd., Plot No.122, Block-B, Phase-V, Industrial Estate, Hattar for the following sections, along with the Quality Control Laboratory and approved stores (Raw Material Store, Packaging Material Store, and Finished Goods Store).

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

Furthermore, the recommendation may please be considered subject to the regularization and approval of changes in the layout plan applied by M/s Welmark Pharmaceuticals (Pt) Ltd., Hattar from the Division of Drugs Licensing DRAP, Islamabad.

It is submitted that revised layout plan of the firm is under consideration and is not approved yet.

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000614, by way of Formulation, in the name of M/s Welmark Pharmaceuticals, Plot No.122, Block-B, Phase-V, Industrial Estate, Hattar, for the period commencing on 11-04-2022 ending on 10-04-2027, for the following sections, subject to the regularization and approval of changes in the layout plan applied by the firm:

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

	II. Approved renewal of following section, subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020: 1. Tablet Section (Psychotropic)			
5.	M/s Hawk Bio (Pvt.) Ltd., Plot No.10, Street S-6, National Industrial Estate RCCI, Rawat. **DML No. 000798 (Formulation)** **Period:** Commencing on 03-07-2024 & ending 02-07-2029. Evaluator:- Zunaira Faryad (DD-Lic)	**29-10-2024**	**Satisfactory / Average**	1. Hafiz Muhammad Ahsan, Deputy Director (QA&LT), DRAP, Islamabad. 2. Mr. Adil Saeed, Deputy Director (PE&R), DRAP, Islamabad. 3. Mr. Shafqat Hussain Danish, Assistant Director (PS), DRAP, Islamabad.
	QC Incharge	Mr. Ajmal Zaman (M. Sc Chemistry)		
	Production Incharge	Mr. Zia Hussain (B-Pharm)		

Recommendations of the panel:

Based on the inspection conducted by the panel including the review of the submitted documentation, keeping in view the positive attitude and intent of the management and review of CAPA report the panel **recommend** the renewal of the Drug Manufacturing License No.000798 of M/s Hawk Bio Pharma (Pvt.) Ltd., Plot No.10, Street S-6, National Industrial Estate RCCI, Rawat for the following sections, along with the Quality Control Laboratory and approved stores (Raw Material Store, Packaging Material Store, and Finished Goods Store):

i. Veterinary Oral Powder (General)
ii. Veterinary Oral Powder (Antibiotic)
iii. Veterinary Oral Liquid (General)
iv. Veterinary Oral Liquid (Antibiotic)

Panel has informed that firm has made the contract testing agreement with M/s. Bio-Labs for testing on FTIR.

Decision of the Central Licensing Board in its 305th meeting:

The Board on the basis of **Satisfactory / Average** remarks of the panel of experts deferred the application for grant of renewal for re-inspection by all three members of the panel of inspectors along with the directions to the firm for purchase of FTIR and its verification by field office of DRAP.

6.	M/s Perfect Pharma (Pvt) Ltd., 5-Km, Manga Road, Raiwind, Lahore. **DML No. 000469 (Formulation)** **Period:** Commencing on 01-03-2020 & ending on 28-02-2025. Evaluator:- Abdullah (DD-Lic)	**20-09-2024**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 1. Mr. Azhar Jamal Saleemi, Chief Drug Controller Punjab, Lahore.
	QC Incharge	Mr. Muhammad Umar Nisar (Pharm-D)		
	Production Incharge	Ms. Mubashra Javid (Pharm-D).		

Recommendations of the panel:

Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and microbiology laboratory, testing facilities, technical personnel met and documentation reviewed, the panel of inspectors is of the opinion to recommend the renewal of Drug Manufacturing License by way formulation (vide DRAP, **Islamabad** letter No.F.1-15/98-Lic (Vol-III), dated 19-04-2023), for the following sections, to M/s Perfect Pharma (Pvt) Ltd., 5-Km, Manga Road, Raiwind, Lahore:

1. Tablet Section (General)
2. Capsule Section (General)
3. External Preparation Section (Repacking)
4. Cream/Ointment Section (General) First Floor
5. Liquid Section (General) Ground Floor

The panel has informed that Tablet (Psychotropic) Section is not yet ready due to ongoing upgradation.

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000469, by way of Formulation, in the name of M/s Perfect Pharma (Pvt) Ltd., 5-Km, Manga Road, Raiwind, Lahore, for the period commencing on 01-03-2020 & ending on 28-02-2025, for the following sections:-

1. Tablet Section (General)
2. Capsule Section (General)
3. External Preparation Section (Repacking)
4. Cream/Ointment Section (General) First Floor
5. Liquid Section (General) Ground Floor

II. As the panel did not recommend the renewal of **Tablet (Psychotropic) Section**, therefore, the Board decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and

	Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000469**,** by way of Formulation, in the name of M/s Perfect Pharma (Pvt) Ltd., 5-Km, Manga Road, Raiwind, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the the Drugs (Licensing, Registering and Advertising) Rules, 1976 for the following section: i. **Tablet (Psychotropic) Section**			
7	M/s AGP Limited, Plot No. D-109, S.I.T.E., Karachi. DML No. 000044 (Formulation). **Period:** Commencing on 15.07.2024 ending on 14.07.2029 Evaluator: - Akbar Ali (DD-Lic)	**20.12.2024**	**Good**	1. Additional Director, DRAP, Karachi. 2. Mr. Awais Ahmed, DD, DRAP, Karachi 3. Mrs. Sanum Kausar, DD, DRAP.
	QC In-charge	Ms. Seema Zohra (Msc-Chemistry)		
	Production In-charge	Ms. Shafqat Fatima (B. Pharm)		
	<u>Recommendations of the panel:</u> In compliance to DRAP Islamabad Licensing Division Letter No.F.2-49/84-Lic (Vol-I) Dated 23rd October, 2024, the panel of experts visited the M/s AGP Limited, Karachi, D-109, S.I.T.E., Karachi on 20th December. The Panel visited for the purpose of renewal of DML No.000044, Panel verified that facility was constructed as per approved layout plan and HVAC installation and qualification was found satisfactory. During audit of QC section, all relevant equipment like HPLC, FTIR, UV, Spectrometer, Stability Chambers, PH Meter, Conductivity meter, analytical balances etc., were available. The firm was advised to further improve QMS and Pharmacovigilance reporting system reporting system. Some suggestions were also given regarding cleaning validation, which were agreed by the firm. In the light of the inspection conducted by the panel and based on the findings given above, it is **recommended** that the case of the firm M/s AGP Limited, D-109, S.I.T.E., Karachi may be considered for the renewal of DML No.000044 as per relevant rules/laws. As per available record of Licensing Division the detail of section is as under: 1. Tablet (Cephalosporin) 2. Capsule (Cephalosporin) 3. Dry Powder Suspension (Cephalosporin) 4. Warehouse 5. QC Laboratory **<u>Decision of the Central Licensing Board in its 305th meeting:</u>** The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000044, by way of Formulation, in the name of M/s AGP Limited, Plot No. D-			

109, S.I.T.E., Karachi., for the period commencing on 15.07.2024 ending on 14.07.2029, for the following sections:-

1. Tablet (Cephalosporin)
2. Capsule (Cephalosporin)
3. Dry Powder Suspension (Cephalosporin)

The Board further decided that the firm shall ensure improvements in the cleaning validation as suggested by the panel of experts and report to the relevant field office.

8.	M/s Medwell Pharmaceuticals, 1-Km, Terbella Road, Lawrencepur Faqirabad. DML No. 000699 (Formulation). **Period:** Commencing on 05-01-2021 & ending on 04-01-2026. Evaluator: - Zunaira Faryad (DD-Lic)	1-01-2025	**Good**	1. Mr. Shoaib, Deputy Director NCLB, DRAP, Islamabad. 2. Mrs. Gulnaz Yaqoob, Deputy Director, DRAP, Islamabad. 1. Mr. Umar Latif, Deputy Director, DRAP, Islamabad.
	QC In-charge	Mr. Muhammad Yaseen (M.Sc Chemistry)		
	Production In-charge	Mr. Ahmed Usman (B. Pharm)		

Recommendations of the panel:

In view of the inspection conducted, reviewing the documents, interview of technical team, intent of the management and verification of manufacturing and testing facility such as FTIR, HPLC, UV Spectrometer, Dissolution apparatus, Karl Fisher, Polarimetry and other QC equipment along with stability chambers (list already attached) the panel unanimously **recommends** the Grant of renewal of Drug Manufacturing License (000699) for following sections:

Sr No.	Sections
1.	Topical Liquid Preparation
2.	Liquid Repacking

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000699, by way of Formulation, in the name of M/s Medwell Pharmaceuticals, 1-Km, Terbella Road, Lawrencepur Faqirabad, for the period commencing on 05-01-2021 & ending on 04-01-2026, for the following sections:-

1. Topical Liquid Preparation
2. Liquid Repacking

9.	M/s Vetec Laboratories, Plot No. 20, St. No, S-5, Rawat Industrial Estate, Rawat. DML No. 000893 (Formulation). **Period:** Commencing on 05-03-2024 & ending on 04-03-2029 Evaluator: - Abdullah (DD-Lic)	22-11-2024	**Good**	1. Dr. Haseeb Tariq, Deputy Director (PE&R), DRAP, Islamabad. 2. Mr. Adil Saeed, Deputy Director (PE&R), DRAP, Islamabad. 2. Ms. Gulnaz Yaqoob, Deputy Director (I&E), DRAP, Islamabad.
	QC In-charge	Mr. Muhammad Shahid (Pharm-D)		
	Production In-charge	Mr. Mubashir Iqbal (Pharm-D)		
	Recommendations of the panel: Based on the inspection conducted by the panel including the review of the submitted documentation, keeping in view the positive attitude and intent of the management and review of CAPA report the panel **recommends** the renewal of the Drug Manufacturing License No.000893 of M/s Vetec Laboratories, Plot No.20, St. No. S-5, National Industrial Estate RCCI, Rawat for the following sections, along with the Quality Control Laboratory and approved stores (Raw Material Store, Packaging Material Store, and Finished Goods Store): i. Oral Powder (General) (Veterinary) ii. Oral Liquid (General) (Veterinary) **Decision of the Central Licensing Board in its 305th meeting:** The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000893, by way of Formulation, in the name of M/s Vetec Laboratories, Plot No. 20, St. No, S-5, Rawat Industrial Estate, Rawat, for the period commencing on 05-03-2024 & ending on 04-03-2029, for the following sections:- i. Oral Powder (General) (Veterinary) ii. Oral Liquid (General) (Veterinary)			
10.	M/s Carryfor Pharmaceutical (Pvt) Ltd., Plot No. E-81, North Western Industrial Zone, Port Qasim, Karachi. **DML No. 000901 (Semi-Basic)** **Period:** Commencing on 05-03-2024 ending on 04-03-2029.	**21-11-2024**	**Good**	1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Sindh. 2. Dr. Awais Ahmed, Assistant Director, DRAP, Karachi. 1. Mrs. Hira Bhutto, Assistant Director, DRAP, Karachi.

	Evaluator:- Abdullah (DD-Lic)			
	QC Incharge	Mr. Naseer Ahmed (M. Sc Chemistry)		
	Production Incharge	Mr. Wasi Ahmed (M. Sc Chemistry)		

Recommendations of the panel:

In compliance to DRAP Islamabad Licensing division letter No.F.1-3/2011-Lic (Vol-I) dated 19th September, 2024, following panel visited the M/s Carryfor Pharmaceuticals (Pvt) Ltd., Pakistan on 21st November, 2024. The panel visited for the purpose of renewal of DML No.000901 (Semi Basic Manufacture). It was found that area was constructed as existing approved layout plan and no irregularities were found. Furthermore, the panel also verified the HVAC installation and qualification and found satisfactory. During audit of QC section, all required equipments were available, furthermore firm is in process of purchase of other lab equipments for further improvement and R&D purpose.

The firm was advised to further improve working environment in General Production area, which was agreed by the firm.

In the light of the inspection conducted by the panel and based on the findings given above, panel **recommends** renewal of following sections:

1. API General
2. API Cephalosporin (Oral)
3. API Steroids
4. API Vitamins

However, Panel **does not recommend** renewal of Sterile section, as renovation/up-gradation work in sterile section was underway as firm was also working on already approved revised layout; therefore, firm is advised to update the status of sterile section after completion of renovation work to the Licensing division for consideration of the section.

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. **000901**, by way of Formulation, in the name of M/s Carryfor Pharmaceutical (Pvt) Ltd., Plot No. E-81, North Western Industrial Zone, Port Qasim, Karachi, for the period commencing on 05-03-2024 ending on 04-03-2029, for the following sections, subject to submission of NOC from Ministry of Narcotics, in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:-

1. API General
2. API Cephalosporin (Oral)
3. API Steroids
4. API Vitamins

	III. As the panel did not recommend the renewal of **Sterile section**, therefore, the Board decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. **000901,** by way of Semi-Basic, in the name of M/s Carryfor Pharmaceutical (Pvt) Ltd., Plot No. E-81, North Western Industrial Zone, Port Qasim, Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the the Drugs (Licensing, Registering and Advertising) Rules, 1976 for the following section along with the APIs granted in this section: i. **Cephalosporin Sterile section**			
11.	M/s Wenovo Pharmaceuticals, Plot No.31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **DML No. 000790 (Formulation)** **Period:** Commencing on 03-02-2024 ending on 02-02-2029. Evaluator:- Abdullah (DD-Lic)	**12-12-2024 & 13-12-2024**	**Good**	1. Mr. Umar Latif, Deputy Director, DRAP, Islamabad. 2. Mr. Abdul Mateen, Deputy Director, DRAP, Islamabad. 1. Mr. Nouman Yousuf, Deputy Director, DRAP, Islamabad.
	QC Incharge	Mrs. Faiqa Ashfaq (M. Sc Analytical Chemistry)		
	Production Incharge	Mr. Saqib Yaqub Awan (B. Pharm)		

Recommendations of the panel:

In view of above of the inspection conducted, reviewing the documents, interview of technical tem, intent of the management and verification of manufacturing and testing facility such as FTIR, HPLC, Spectrometer, Dissolution Apparatus, LFC, TOC, Liquid Particle Counter, polarimetry, ultrasonic bath, and other QC equipment along with stability chambers (list already attached) the panel unanimously recommends the Grant of renewal of Drug manufacturing License by way of formulation (000790) for following section;

In the light of the inspection conducted by the panel and based on the findings given above, panel **recommends** renewal of following sections:

Sr no.	Sections:	Category
1.	Tablet	(General)
2.	Capsule	(General)
3.	Oral Dry Powder for Suspension	(General)
4.	Sachet	(General)
5.	Capsule	(Cephalosporin)
6.	Dry Powder for Injectable	(Cephalosporin)

7.	Dry Powder Sachet	(Cephalosporin)
8.	Dry Powder Injectable Vial	(General)
9.	Liquid Injectable-SVP Ampoule	(General)
10.	Dry Powder for Injectable	Steroidal
11.	Oral Dry Powder for Suspension	(Cephalosporin)

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. **000790**, by way of Formulation, in the name of M/s Wenovo Pharmaceuticals, Plot No.31 & 32, Punjab Small Industrial Estate, Taxila, Rawalpindi, for the period commencing on 03-02-2024 ending on 02-02-2029, for the following sections:-

Sr no.	Sections:	Category
1.	Tablet	(General)
2.	Capsule	(General)
3.	Oral Dry Powder for Suspension	(General)
4.	Sachet	(General)
5.	Capsule	(Cephalosporin)
6.	Dry Powder for Injectable	(Cephalosporin)
7.	Dry Powder Sachet	(Cephalosporin)
8.	Dry Powder Injectable Vial	(General)
9.	Liquid Injectable-SVP Ampoule	(General)
10.	Dry Powder for Injectable	Steroidal
11.	Oral Dry Powder for Suspension	(Cephalosporin)

12.	M/s Metro Pharmaceuticals, Plot No.14, Street No. SS-2, National Industrial Zone, RCCI, Rawat. **DML No. 000772 (Formulation)** **Period:** Commencing on 08-03-2023 ending on 07-03-2028. Evaluator:- Zunaira Faryad (DD-Lic)	**03-12-2024 & 04-12-2024**	**Good**	1. Mr. Salateen Philips, Deputy Director, DRAP, Islamabad. 2. Mr. Abdullah, Deputy Director, DRAP, Islamabad. 1. Mr. Umar Latif, Deputy Director, DRAP, Islamabad.
	QC Incharge	Mr. Muhammad Akram (M. Sc Chemistry)		
	Production Incharge	Syed Nasim ul Hassan (Pharm-D)		
	Recommendations of the panel: In view of above of the inspection conducted, reviewing the documents, interview of technical tem, intent of the management and verification of manufacturing and testing facility			

such as FTIR, HPLC, Spectrometer, Dissolution Apparatus, Karl Fisher, Liquid Particle Counter, Total Organic Carbon Analyzer, Polarimetry, Atomic Absorption Spectrometer and other QC equipment along with stability chambers (list attached) the **panel unanimously recommends the Grant of renewal of** Drug manufacturing License by way of formulation (000772) of M/s Metro Pharmaceuticals, Plot # 14, Street # SS-2, (RCCI) Industrial Estate, Rawat Islamabad for following sections;

Sr no.	Sections:
1.	Tablet (General)
2.	Dry Suspension (General)
3.	Oral Liquid (General)
4.	Sachet (General)
5.	Cream, Ointment, Gel, Lotion (Non-Steroidal)
6.	Capsule (General)
7.	Capsule (Cephalosporin)
8.	Dry Suspension (Cephalosporin)
9.	Dry Vial (Cephalosporin)
10.	Sachet (Cephalosporin)
11.	Liquid Injection (Vial)(General)
12.	Liquid Ampoule (General)
13.	Sterile Dry Powder Injection (Pre-Lyophilized ready to fill)(General)

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. **000772**, by way of Formulation, in the name of M/s Metro Pharmaceuticals, Plot No.14, Street No. SS-2, National Industrial Zone, RCCI, Rawat, for the period commencing on 08-03-2023 ending on 07-03-2028, for the following sections:-

Sr no.	Sections:
1.	Tablet (General)
2.	Dry Suspension (General)
3.	Oral Liquid (General)
4.	Sachet (General)
5.	Cream, Ointment, Gel, Lotion (Non-Steroidal)
6.	Capsule (General)
7.	Capsule (Cephalosporin)
8.	Dry Suspension (Cephalosporin)
9.	Dry Vial (Cephalosporin)
10.	Sachet (Cephalosporin)
11.	Liquid Injection (Vial)(General)
12.	Liquid Ampoule (General)
13.	Sterile Dry Powder Injection (Pre-Lyophilized ready to fill)(General)

13.	M/s Aamster Laboratories, Plot No.18, Street No. SS-2, RCCI Industrial Estate, Rawat. **DML No. 000908 (Formulation)** **Period:** Commencing on 26-09-2024 ending on 25-09-2029. Evaluator:- Zunaira Faryad (DD-Lic)	**14-01-2025**	**Good**	1. Ms. Mehwish Tanveer, Deputy Director, DRAP, Islamabad. 2. Mr. Muhammad Zubair, Deputy Director, DRAP, Islamabad. 1. Mrs. Gulnaz Yaqoob, Deputy Director, DRAP, Islamabad.
	QC Incharge	Mr. Muhammad Ayaz (M. Sc Chemistry)		
	Production Incharge	Mr. Khalid Usman (B. Pharm)		

Recommendations of the panel:

Based on the findings of the inspection, review of documents and records, systems, utilities, physical inspection of the facility and interview of personnel, it is concluded that the establishment meets the minimum requirements for the renewal of the Drug Manufacturing License. Moreover, the firm is required to upgrade the systems and practices as mentioned in Part 02 of this report in accordance with the requirements of cGMP which can be reviewed by area FID in the routine inspection. The panel **recommends** the renewal of the Drug Manufacturing License of the below mentioned sections along with Quality Control Laboratory and approved stores (Raw material store, Packaging Material store & Finished goods store);

i. Oral Powder Section-I (General) Veterinary
ii. Oral Powder Section-II (General) Veterinary
iii. Oral Liquid Section-I (General) Veterinary
iv. Oral Liquid Section-II (General) Veterinary
v. Liquid Injectable Section (General) Veterinary
vi. Oral Powder Section (Penicillin) Veterinary

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. **000908**, by way of Formulation, in the name of M/s Aamster Laboratories, Plot No.18, Street No. SS-2, RCCI Industrial Estate, Rawat, for the period commencing on 26-09-2024 ending on 25-09-2029, for the following sections:-

i. Oral Powder Section-I (General) Veterinary
ii. Oral Powder Section-II (General) Veterinary
iii. Oral Liquid Section-I (General) Veterinary
iv. Oral Liquid Section-II (General) Veterinary
v. Liquid Injectable Section (General) Veterinary

	vi. Oral Powder Section (Penicillin) Veterinary			
14.	M/s Hilton Pharma (Pvt.) Ltd, Plot No.13-14 & 43, Sector 15, Korangi Industrial Area, Karachi DML No. 000136 (Formulation). **Period:** Commencing on 23.10.2024 & ending on 22.10.2029 Evaluator: - Akbar Ali (DD-Lic)	09.12.2024 & 10.12.2024	**Good**	1. Dr. Affan Ali, DD, DRAP, Karachi 2. Dr. Mahrukh Mughal, DD, DRAP, Karachi 3. Dr. Asfandyar Ajab Khan, DD, DRAP, Karachi
	QC In-charge	Mr. Waqas Ahmed (M.Sc. Chemistry)		
	Production In-charge	Mr. Muhammad Shahzad (Pharm-D)		

Recommendations of the panel:

The inspection team observed that the management demonstrated a commitment to quality assurance and several improvements were made. Overall, a well maintained facility with adequate ventilation and lighting, good plant machinery, effective HVAC system, comprehensive document control, effective traceability systems, well trained staff demonstrating good hygiene practices and a quality control laboratory equipped with well complaint instruments.

The firm was advised to improve training system to include trainings on advanced concepts of Quality Management System, leadership and risk management.

Considering the management's proactive approach in maintain quality standards, and the facility's overall operations to ensure the production of safe, effective and quality medicines the panel **recommends** the renewal of the firm's manufacturing license for the next five years.

Detail of the sections given as under:

Sr.#	Sections	Sr.#	Sections
1	Tablet (General)	2.	Capsule (General)
3.	Sachet (General)	4.	Oral Liquid (General)
5.	Liquid Injection (SVP)	6.	Capsule (Ceph.)
7.	Dry Powder Injection (Ceph)	8.	Dry Suspension (Ceph)
9.	Dry Powder (Vet)	10.	Liquid Syrup (Vet)
11.	Tablet (Psychotropic)	12.	Tablet (Biotech)
13.	Liquid Injection (Biotech)-Regularization	14.	Sachet (Probiotic)
15.	Oral Dry Powder Suspension (General) Section		

Decision of the Central Licensing Board in its 305th meeting:

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000136, by way of Formulation, in the name of M/s Hilton Pharma (Pvt.) Ltd, Plot No.13-14 & 43, Sector 15, Korangi Industrial Area, Karachi, for the period commencing on 23.10.2024 & ending on 22.10.2029, for the following sections:-

Sr.#	Sections	Sr.#	Sections
1	Tablet (General)	2.	Capsule (General)
3.	Sachet (General)	4.	Oral Liquid (General)
5.	Liquid Injection (SVP)	6.	Capsule (Ceph.)
7.	Dry Powder Injection (Ceph)	8.	Dry Suspension (Ceph)
9.	Dry Powder (Vet)	10.	Liquid Syrup (Vet)
11.	Tablet (Biotech)	12.	Liquid Injection (Biotech)-Regularization
13.	Sachet (Probiotic)	14.	Oral Dry Powder Suspension (General) Section

2. Approved renewal of following section, subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:

1. Tablet (Psychotropic)

15.	M/s Jaens Pharmaceutical Industries (Pvt) Ltd., 28-Km, Lahore-Sheikhupura Road, Lahore. **DML No. 000532 (Formulation)** **Period:** Commencing on 26-01-2024 ending on 25-01-2029. Evaluator:- Zunaira Faryad (DD-Lic)	**17-12-2024**	**Good**	3. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 4. Mr. Azhar Jamal Saleemi, Chief Drugs Controller Punjab, Lahore. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	QC Incharge	Syed Shahbaz Ali (M.Sc. Chemistry)		
	Production Incharge	Mr. Anjum Saeed (B. Pharm)		
	<u>Recommendations of the panel:</u> Keeping in view the manufacturing facility, like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment plant, testing facilities, technical personnel, documentation, on the day of inspection, the panel of inspector's in of the opinion to **recommend** the grant of renewal of Drug manufacturing			

	License (by way of formulation) vide DRAP, Islamabad letter Tracking ID No.SLY-B5E-AZL7 dated 19-08-2024, to M/s Jaens Pharmaceutical Industries (Pvt) Ltd., 28-Km, Lahore-Sheikhupura Road, Sheikhupura, for following sections; 1. Tablet Section (General) 2. Tablet Section (Non-Penicillin Antibiotic) 3. Capsule Section 4. Liquid Injectable Section 5. Eye Drops Section 6. Eye/Ear Drops Section (Steroidal) 7. Topical Preparations Section 8. Ophthalmic Ointment Section **Decision of the Central Licensing Board in its 305th meeting:** The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. **000532**, by way of Formulation, in the name of M/s Jaens Pharmaceutical Industries (Pvt) Ltd., 28-Km, Lahore-Sheikhupura Road, Lahore, for the period commencing on 26-01-2024 ending on 25-01-2029, for the following sections:- 1. Tablet Section (General) 2. Tablet Section (Non-Penicillin Antibiotic) 3. Capsule Section 4. Liquid Injectable Section 5. Eye Drops Section 6. Eye/Ear Drops Section (Steroidal) 7. Topical Preparations Section 8. Ophthalmic Ointment Section			
16.	M/s Unison Chemical Works, Post Office Araian, 15-Km Raiwind Road Lahore. **DML No. 000174 (Formulation)** **Period:** Commencing ending on 31-05-2024 to 30-05-2029 Evaluator:- Abdullah (DD-Lic)	08-01-2025	**Good**	4. Mr. Faisal Shahzad, Additional Director (E&M), DRAP, Lahore. 5. Mr. Abdul Rasheed Shaikh, FID, DRAP, Lahore. 1. Mr. Ishtaiq Shafiq, Deputy Director, DRAP, Lahore.
	Production Incharge	Mr. Hafeez Tahseen (B. Pharm)		
	Quality Control Incharge	Mr. Tariq Mahmood (MSc. Chemistry)		

	RECOMMENDATION Keeping in view the manufacturing facility, like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment plant, testing facilities, technical personnel, documentation, on the day of inspection, the panel of inspector's in of the opinion to **recommend** the grant of renewal of Drug manufacturing License (by way of formulation) vide DRAP, Islamabad letter No. 1-35/2007-Lic (Vol.II) dated 18-12-2024, to M/s. Unison Chemical Works., Post Office Araian, 15-Km Raiwind Road, Lahore for the following sections. 1. Liquid Injection Ampoule Section (Steroidal). 2. Liquid Injection Ampoule Section (General). 3. Capsule Section (General). 4. Tablet Section (General). 5. Tablet Section (Psychotropic). 6. Liquid Syrup Section (General). **Decision of the Central Licensing Board in its 305th meeting:** The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. **000174**, by way of Formulation, in the name of M/s Unison Chemical Works, Post Office Araian, 15-Km Raiwind Road Lahore, for the period commencing on 31-05-2024 to 30-05-2029, for the following sections:- 1. Liquid Injection Ampoule Section (Steroidal). 2. Liquid Injection Ampoule Section (General). 3. Capsule Section (General). 4. Tablet Section (General). 5. Liquid Syrup Section (General). II. Approved renewal of following section, subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020: 1. Tablet Section (Psychotropic).			
17.	M/s. Zam Zam Pharma, Plot No. 5, Street No. SS-4, N.I.Z., Rawat. **DML No. 000833 (Formulation)**	**01-01-2025**	**Not Recommended**	1. Mr. Zain-ul-Abidin, Deputy Director, DRAP Islamabad 2. Mr. Abdul Mughees Mudassir, Deputy Director, DRAP Islamabad 1. Hafiz Sanaullah Babar, Deputy Director, DRAP Islamabad

	Period: Commencing on 23-08-2021 ending on 22-08-2026. Evaluator:- Abdullah (DD-Lic)			
	QC Incharge	Mr. Majid		
	Production Incharge	Mr. Azam Khan		
	Recommendations of the panel: Keeping in view the above mentioned details and current situation of the firm, the panel unanimously decided **not to recommend DML renewal** of M/s. Zam Zam Pharma, Plot No. 5, No. SS-4, N.I.Z., RCCI, Rawat. **Decision of the Central Licensing Board in its 305th meeting:** The Board, on the recommendations of the panel of experts, decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16, Rule 19 and Rule 20 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. **000833,** by way of Formulation, in the name of M/s. Zam Zam Pharma, Plot No. 5, Street No. SS-4, N.I.Z., Rawat may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the the Drugs (Licensing, Registering and Advertising) Rules, 1976 on following grounds:- i. Conduction of manufacturing activities without any approved qualified staff. ii. Poor compliance of Good Manufacturing Practices. iii. Stocking of huge expired stock without any proper justification and documentation. iv. Manufacturing and marketing of Moncep (Ciprofloxacin) Tablets 250mg and 500mg bath No. 331, without any proper documentation and pharmacopoeial testing. v. Un-availiblity of proof of procurment of Active Pharmraceutical Ingredients. The Board also advised QA&LT Division to initiate necessary action in light of the findings of the panel.			
18.	M/s. Fynk Pharmaceuticals, 19-Km, G.T Road, Kala Shah Kaku, Lahore. **DML No. 000494 (Formulation)** **Period:** Commencing on 11-10-2023 ending on 10-10-2028. Evaluator:- Zunaira Faryad (DD-Lic)	**30-08-2024 & 30-09-2024**	**Good**	3. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 4. Mr. Abdul Rasool Shaikh, FID, DRAP, Lahore. 1. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	QC Incharge	Mr. Muhammad Omer Kaleem Malik (M.Sc Chemistry)		
	Production Incharge	Mr. Abdul Rauf (Pharm-D)		
	Recommendations of the panel:			

	Keeping in view the manufacturing facility, like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment plant, testing facilities, technical personnel and documentation, the panel of inspector's is of the opinion to **recommend the grant of renewal of Drug manufacturing License** vide DRAP Islamabad letter no.1-61/84-Lic (Vol-IV), dated 28-02-2024 to M/s. Fynk Pharmaceuticals, 9-Km, G.T Road, Kala Shah Kaku, Tehsil Ferozwala, District Sheikhupura for the following sections: 1. Liquid Syrup/Suspension Section (General) 2. Liquid Injectable (Ampoule) Section (General) 3. Dry Powder Injection Section (Cephalosporin) 4. Dry Powder Suspension Section (Cephalosporin) 5. Capsule Section (Cephalosporin) 6. Cream. Ointment Section (General) 7. Cream. Ointment Section (Steroidal) 8. Tablet Section (General) 9. Capsule Section (General) 10. Oral Dry Powder Suspension Section (General) 11. Sachet Section (General) 12. Dry Powder Injection Section (General) 13. Capsule Section (Penicillin) 14. Dry Powder Injection Section (Penicillin) 15. Dry Powder Suspension Section (Penicillin) 16. Dry Powder Injection Section (Carbapenem) 17. Research and Development Facility 18. **Liquid Injectable-II (Ampoule) (General) Section (New)** in place of licensed Liquid Injectable (Ampoule) (Psychotropic) Section. **<u>Decision of the Central Licensing Board in its 305th meeting:</u>** The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. **000494**, by way of Formulation, in the name of M/s Fynk Pharmaceuticals, 19-Km, G.T Road, Kala Shah Kaku, Lahore, for the period commencing on 11-10-2023 ending on 10-10-2028, for the following sections:- 2. Liquid Syrup/Suspension Section (General) 3. Liquid Injectable (Ampoule) Section (General) 4. Dry Powder Injection Section (Cephalosporin) 5. Dry Powder Suspension Section (Cephalosporin) 6. Capsule Section (Cephalosporin) 7. Cream. Ointment Section (General) 8. Cream. Ointment Section (Steroidal) 9. Tablet Section (General) 10. Capsule Section (General) 11. Oral Dry Powder Suspension Section (General) 12. Sachet Section (General) 13. Dry Powder Injection Section (General) 14. Capsule Section (Penicillin) 15. Dry Powder Injection Section (Penicillin) 16. Dry Powder Suspension Section (Penicillin)

<table>
<tr><td></td><td colspan="4">17. Dry Powder Injection Section (Carbapenem)
18. Research and Development Facility</td></tr>
<tr><td>19.</td><td>M/s Arsons Pharmaceutical Industries (Pvt.) Ltd, 22-Km, Multan Road, Off 2.5-Km, Defence Road, Lahore.

DML No. 000514 (Formulation).

Period: Commencing on 23.06.2023 ending on 22.06.2028

Evaluator: - Zunaira Faryad (DD-Lic)</td><td>15.11.2024</td><td>Good</td><td>1. Faisal Shahzad, Additional Director, DRAP, Lahore.
2. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab, Lahore.
3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td>QC In-charge</td><td colspan="3">Mr. Muhammad Nawaz (M.Sc. Chemistry)</td></tr>
<tr><td></td><td>Production In-charge</td><td colspan="3">Mr. Rashid Bilal (Pharm.D)</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>

Keeping In view manufacturing facility, Like building, HVAC system, Production machinery, equipment in quality control and microbiology laboratory, water treatment plant, testing facilities, technical personnel, documentation, the panel of inspector’s is of the opinion to recommended the grant of renewal of Drug Manufacturing License by way pf formulation of the following sections vide DRAP, Islamabad letter No.F.1-9/2011-Lic (Vol-II) dated 10.05.2024 to M/s Arsons Pharmaceutical Industries (Pvt.) Ltd, 22-Km, Multan Road, Off 2.5-Km, Defence Road, Lahore.
i. Tablet Section (General) (Renewal)
ii. Capsule Section (Renewal)
iii. Cream/Ointment/Gel Section (Renewal)
iv. Tablet Section (Psychotropic)

<u>Decision of the Central Licensing Board in its 305th meeting:</u>

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000514, by way of Formulation, in the name of M/s Arsons Pharmaceutical Industries (Pvt.) Ltd, 22-Km, Multan Road, Off 2.5-Km, Defence Road, Lahore, for the period commencing on 23.06.2023 & ending on 22.06.2028, for the following sections:-
i. Tablet Section (General)
ii. Capsule Section
iii. Cream/Ointment/Gel Section

2. Approved renewal of following section, subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad’s letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad’s Letter No.5-4/2020-CD dated 10/11/2020:</td></tr>
</table>

	i. Tablet Section (Psychotropic)

Case No. 20 <u>RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000838 (FORMULATION) OF M/S JUPITER PHARMA, RAWAT.</u>

<u>Case Background:</u>

13	M/s. Jupiter Pharma, Plot No. 25, Street No. S-6, National Industrial Zone, RCCI, Rawat. DML No. 000838 (Formulation) Period: Commencing on 01-06-2021 & ending on 31-05-2026.	**14-11-2022**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad. 2. Mr. Abdullah, Deputy Director, DRAP, Islamabad (Could not join the panel due to official engagements) 3. Ms. Zunaira Faryad, Assistant Director, DRAP, Islamabad.
	<u>Recommendations of the panel:</u> The panel is of the opinion that the establishment meets the requirements of renewal of license as laid down in Drug Act, 1976, DRAP Act, 2012 and the Rules framed their under. Moreover, seeing the positive attitude and intent of the management, reviewing the documents and inspecting the premises, the panel recommends the establishment for renewal Drug Manufacturing License w.e.f 01-06-2021 with following sections. i. Tablet Section (General). ii. Capsule Section (General) iii. Dry Powder Suspension Section (General) iv. Capsule Section (Cephalosporin) v. Dry Suspension Section (Cephalosporin) *vi.* Dry Injection Vial (Cephalosporin). <u>Decision of the Central Licensing Board in 289th meeting</u> The Board considered and deferred the application for grant of renewal for re-inspection by all three members of the panel of inspectors.			

The panel of experts/Inspectors was reconstituted on 03-09-2024 by Chairman, CLB. The detail is as under:

M/s Jupiter Pharma, Plot No.25, Street No. S-6, National Industrial Zone (RCCI), Rawat. **DML No. 000838 (Formulation)** **Period:** Commencing on 01-06-2021 & ending on 31-05-2026. (Evaluator: - Zunaira Faryad (DD-Lic)	**02-10-2024 & 03-10-2024**	-	1. Mrs. Tehreem Sara, FID-IV, Islamabad. 2. Mr. Zain Ul Abidin, Deputy Director (NCLB), DRAP, Islamabad. 3. Mr. Zia Ullah, Assistant Director (QA/LT), DRAP, Islamabad.
QC Incharge	Mr. Naveed Khan (B. Pharm)		
Production Incharge	Ms. Asmaa Jabeen (Pharm-D)		

Recommendations of the panel:

The panel is of the view that the establishment meets the minimum requirements for the renewal of Drug Manufacturing License, as prescribed under the Drug Act, 1976, the DRAP Act, 2012 and the Rules framed their under. Furthermore, after reviewing the submitted documentations, inspecting the premises, noting the positive attitude and intent of the management, the panel recommends the renewal of the Drug Manufacturing License subject to the requalification of the Water Treatment Plant and provision of Liquid Particle Counter and TOC (Which the firm submitted that they will comply in shortest period of time copy attached). The renewal will be effective from 01-06-2021, with the following sections:

S. No.	Name of Sections
1.	Tablet Section (General)
2.	Capsule Section (General)
3.	Dry Powder Suspension section (General)
4.	Capsule Section (Cephalosporin)
5.	Dry Powder Suspension section (Cephalosporin)
6.	Dry Powder injection section (Vial) (Cephalosporin)

Decision of the Central Licensing Board in 302nd meeting

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000838 by way of Formulation in the name of M/s Jupiter Pharma, Plot No.25, Street No. S-6, National Industrial Zone (RCCI), Rawat, for the period commencing on 01-06-2021 & ending on 31-05-2026, for the following sections, subject to verification of necessary testing equipments, requalification of the Water Treatment Plant and provision of TOC:

1. Tablet Section (General)
2. Capsule Section (General)
3. Dry Powder Suspension section (General)

Furthermore, the Board authorized Chairman CLB to issue the renewal of the following Cephalosporin Sections after receiving the undertaking for establishing a segregated dedicated facility within 2 years:

1. Capsule Section (Cephalosporin)

2.	Dry Powder Suspension section (Cephalosporin)
3.	Dry Powder injection section (Vial) (Cephalosporin)

Proceedings of Licensing Division in Compliance to Decision of Central Licensing Board:

A letter dated 16th December, 2024 was issued to the firm to submit undertaking for establishing a segregated dedicated facility within 2 years.

The Additional Director (E & M), DRAP, Islamabad was requested vide letter dated 16th December, 2024 to depute an officer for verification of necessary testing equipments of the firm.

The firm has responded through e-App with tracking ID: MDJ-NS8-SBEP which is reproduced as under:

"We, Jupiter Pharma, located at Plot No. 25, Street No. S-6, National Industrial Zone, Rawat Islamabad-Pakistan, and our DML renewal was conducted from October 2nd to October 3rd 2024 by panel members. The panel suggested FTIR and TOC analyzer. Further our DML was approved in 302nd meeting of Central Licensing board with recommendation of FTIR and TOC analyzer purchase. We are outsourcing TOC tests from BIOLABS and FTIR test from KARSONS Pharma. We are requesting to grant us permission for contract analysis. These equipments are expensive to buy at the moment. We humbly request to give us timeline of one year for the purchase of own FTIR & TOC. Kindly permit us to outsource for contract analysis till purchase of our own instruments."

Decision of the Central Licensing Board in its 305th meeting:

The Board, deliberated that both the instruments are required for the routine mandatory testing of raw materials and water. Out sourcing of such routine activities is not a practicable approach and will lead to numerous requests from pharmaceutical firms for such permission, therefore, the Board decided not to accede the request of the firm.

Case No. 21 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MIRACLE PHARMACEUTICALS (PVT) LTD, RAWAT.

Case Background:

M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street S-5, National Industrial Zone, Rawat had applied for renewal of DML No. 000593 by way of Formulation for the period of 29-06-2021 to 28-06-2026 on 28-06-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 02-08-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing due certificate regarding CRF from STO.
iii. Detail of management, if any change, apply for change of management.
iv. Duly attested CNIC copies of Directors.
v. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original).

vi. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.
vii. Approval letters of technical staff.

The firm did not reply and reminder letter was issued on 18-10-2021 to the firm for completion of application for renewal of DML:

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing due certificate regarding CRF from STO.
iii. Application for change of management along with prescribed fee of Rs. 75,000/-.
iv. Duly attested CNIC copies of Directors.
v. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original).
vi. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.
vii. Approval letters of technical staff.

The firm has not yet reply and application for renewal of DML is not complete.

Decision of the Central Licensing Board in 288th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No000593 by way of formulation of M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street S-5, National Industrial Zone, Rawat, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street S-5, National Industrial Zone, Rawat on 22nd November, 2022.

The firm has replied to Show Cause Notice on 28-12-2022 and application for renewal of DML is still deficient of following documents:

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing due certificate regarding CRF from STO.
iii. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original). (The firm has submitted digital certified copy)
iv. Duly attested appointment letter, job acceptance letter, academic degree, undertaking as whole time employee on stamp paper and resignation of appointee from previous firm (Production Incharge).
v. Duly attested appointment letter, job acceptance letter, undertaking as whole time employee on stamp paper and resignation of appointee from previous firm (Quality Control Incharge).

vi. Duly attested resignation of earlier Quality Control Incharge and Production Incharge.

A letter of personal hearing has been issued to the firm on 17th January, 2023.

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

Mr. Muhammad Naveed and Shumaila Rani of the firm appeared before the Board. They contended that they will provide/submit all requisite documents at the earliest. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration.

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

The decision of CLB was conveyed to the firm vide letter dated 16-03-2023. The firm did not reply and the application for renewal of DML is still incomplete.

Moreover, the proposed Production Incharge Mr, Khalid Mehmood and proposed QC Incharge Mr. Muhammad Ibrahim had resigned from the firm. The firm have neither applied for approval of new qualified staff nor intimated to CLB despite issuance of letter dated 21-07-2023, final reminder dated 25-09-2023 and show Cause notice dated 01-03-2024.

Decision of the Central Licensing Board in 302nd meeting:

The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000593, by way of Formulation, of M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street S-5, National Industrial Zone, Rawat till fulfilment of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Accordingly, the decision of the Central Licensing Board was conveyed to the firm vide letter dated 16-12-2024.

Now the firm has submitted all shortcoming documents and completed all codal formalities. The case is hereby placed before the Board for revocation of suspension order.

Decision of the Central Licensing Board in its 305th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of suspension of Drug Manufacturing License No 000593, by way of Formulation, of M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street S-5, National Industrial Zone, Rawat.

ITEM NO. V. **CHANGE OF MANAGEMENT CASES.**

Case No. 01. CHANGE OF TITLE & MANAGEMENT OF M/S. FORTUNE PHARMA (PVT) LTD, KARACHI.

M/s Fortune Pharma (Pvt) Ltd, Plot No.20/K, S.I.T.E., Super Highway Phase-II, Karachi under DML No. 000924 (By way of formulation) has submitted request for change in title and management of the firm as per Form 9 and Form A along with prescribed Fee Challan of 93,000/-. The detail of title & management is as under:-

Change of Title:

Previous Title	New Title
M/s Fortune Pharmaceuticals	M/s Fortune Pharma (Pvt.) Ltd

Change of Management:

Previous Management (As per Partnership Deed)	New Management (As per Form-9 dated 4th April, 2024)
1. Muhammad Talib S/o Muhammad Sikandar CNIC No.42201-2790408-5. 2. Muhammad Shemeer Imtiaz S/o Imtiaz Ahmed CNIC No.44103-4535598-9.	1. Muhammad Shehmeer Imtiaz S/o Imtiaz Ahmed CNIC No.44103-4535598-9. **2. Muhammad Sikander S/o Muhammad Usman CNIC No.42201-3841893-5.** **3. Akber Ali S/o Khan Muhammad Babbar CNIC No.41304-2384539-1.**

Decision of the Central Licensing Board in 305th meeting

Based on Form-9 dated **4th April, 2024** issued by SECP, the Board considered and accepted for record the change of title and management as below of M/s Fortune Pharma (Pvt) Ltd, Plot No.20/K, S.I.T.E., Super Highway Phase-II, Karachi under DML No. **000924** (**Formulation**), subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of title and management shall be effective from the change of title and management in SECP / Registrar of firms / sale deed.

Change of Title:

Previous Title	New Title
M/s Fortune Pharmaceuticals	M/s Fortune Pharma (Pvt.) Ltd

Change of Management:

Previous Management (As per Partnership Deed)	New Management (As per Form-9 dated 4th April, 2024)

1. Muhammad Talib S/o Muhammad Sikandar CNIC No.42201-2790408-5. 2. Muhammad Shemeer Imtiaz S/o Imtiaz Ahmed CNIC No.44103-4535598-9.	1. Muhammad Shehmeer Imtiaz S/o Imtiaz Ahmed CNIC No.44103-4535598-9. **2. Muhammad Sikander S/o Muhammad Usman CNIC No.42201-3841893-5.** **3. Akber Ali S/o Khan Muhammad Babbar CNIC No.41304-2384539-1.**

Case No. 2 **CHANGE OF MANAGEMENT OF M/S BOSCH PHARMACEUTICALS (PVT) LTD, PLOT NO 209, SECTOR 23, KORANGI INDUSTRIAL AREA KARACHI UNDER DML NO.000707 (FORMULATION)**

M/s Bosch Pharmaceuticals (Pvt) Limited, Plot No. 209, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. 000707 (Formulation)) has submitted request for change in management of the firm as per Form-29 & Form 9 along with prescribed Fee Challan of 93,000/- as under: -

Existing Management	New Management (As per Form-29 dated 25th October, 2023)
1. Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7 2. Mr. Farhan Chawla S/o Mohiuddin Chawla CNIC NO. 42201-8008212-1 3. Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3 4. Mr. Zakariya Nasib S/o Mr. Ahmed Nasib CNIC NO. 42201-2340655-3 5. Mr. Ambia Nasib S/o Mr. Ahmed Nasib CNIC No. 42201-2245655-3	1. Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7 2. Mr. Farhan Chawla S/o Mohiuddin Chawla CNIC NO. 42201-8008212-1 3. Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3 4. Mr. Zakariya Nasib S/o Ahmed Nasib CNIC NO. 42201-2340655-3 **5.** Mr. Ambia Nasib S/o Ahmed Nasib CNIC No. 42201-2245655-3 **6. Mr. Taha Farhan S/o Sheikh Farhan Chawla CNIC No.42201-8836797-9.**

Decision of the Central Licensing Board in 305th meeting

Based on Form-29 dated **25th October, 2023** issued by SECP, the Board considered and accepted for record the change of management as below of M/S Bosch Pharmaceuticals (Pvt) Limited, Plot No. 209, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. **000707** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Existing Management	New Management (As per Form-29 dated 25th October, 2023)
1. Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7 2. Mr. Farhan Chawla S/o Mohiuddin Chawla CNIC NO. 42201-8008212-1 3. Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3 4. Mr. Zakariya Nasib S/o Mr. Ahmed Nasib CNIC NO. 42201-2340655-3 5. Mr. Ambia Nasib S/o Mr. Ahmed Nasib CNIC No. 42201-2245655-3	1. Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7 2. Mr. Farhan Chawla S/o Mohiuddin Chawla CNIC NO. 42201-8008212-1 3. Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3 4. Mr. Zakariya Nasib S/o Ahmed Nasib CNIC NO. 42201-2340655-3 **5.** Mr. Ambia Nasib S/o Ahmed Nasib CNIC No. 42201-2245655-3 **6. Mr. Taha Farhan S/o Sheikh Farhan Chawla CNIC No.42201-8836797-9.**

Case No. 3 **CHANGE OF MANAGEMENT OF M/S DYSON RESEARCH LABORATORIES (PVT) LTD LAHORE UNDER DML NO. 000559 (FORMULATION).**

M/s Dyson Research Laboratories (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore under DML No. 000559 by way of formulation has submitted request for change in management of the firm as per digital certified copy of Form-9 with prescribed Fee Challan of Rs. 93,000/-. The detail of management of the firm is as under;

Previous Management	New Management as per Form-9 dated 11th December, 2024
1. Mr. Mahmood Ahmad Virk S/o Muhammad Younas CNIC No. 90403-0110978-7. 2. Mr. Faisal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3. 3. Mr. Aftab Ahmad Virk S/o Muhammad Younas CNIC No. 352010-499026-7. 4. Mr. Tahir Sharif S/o Muhammad Sharif CNIC No. 35202-8557574-1. 5. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 6. Mr. Jehanzeb Rauf Kahlon S/o Ajmal Rauf Kahlon CNIC No. 35201-7891435-7.	1. Mr. Mahmood Ahmad Virk S/o Muhammad Younas CNIC No. 90403-0110978-7. 2. Mr. Faisal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3. 3. Mr. Aftab Ahmad Virk S/o Muhammad Younas CNIC No. 352010-499026-7. 4. Mr. Tahir Sharif S/o Muhammad Sharif CNIC No. 35202-8557574-1. 5. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 6. Mr. Jehanzeb Rauf Kahlon S/o Ajmal Rauf Kahlon CNIC No. 35201-7891435-7.

7. Mr. Mubashar Javed S/o Muhammad Tufail CNIC No. 35201-1514183-3. 8. Mrs. Tahira Khatoon W/o Muhammad Sharif CNIC No. 35202-2574072-0. 9. Mr. Shahzad Shafique S/o Shafique Ahmed CNIC No. 35202-3030292-5. 10. Mr. Iqbal Ahmad Choudhry S/o Shah Muhammad Shahi CNIC No. 352006-814242-9.	7. Mr. Mubashar Javed S/o Muhammad Tufail CNIC No. 35201-1514183-3. 8. Mrs. Tahira Khatoon W/o Muhammad Shahrif CNIC No. 35202-2574072-0.

Decision of the Central Licensing Board in 305th meeting

Based on Form-9 dated **11th December, 2024** issued by SECP, the Board considered and accepted for record the change of management as below of M/s Dyson Research Laboratories (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore under DML No. **000559** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New Management as per Form-9 dated 11th December, 2024
1. Mr. Mahmood Ahmad Virk S/o Muhammad Younas CNIC No. 90403-0110978-7. 2. Mr. Faisal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3. 3. Mr. Aftab Ahmad Virk S/o Muhammad Younas CNIC No. 352010-499026-7. 4. Mr. Tahir Sharif S/o Muhammad Sharif CNIC No. 35202-8557574-1. 5. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 6. Mr. Jehanzeb Rauf Kahlon S/o Ajmal Rauf Kahlon CNIC No. 35201-7891435-7. 7. Mr. Mubashar Javed S/o Muhammad Tufail CNIC No. 35201-1514183-3. 8. Mrs. Tahira Khatoon W/o Muhammad Sharif CNIC No. 35202-2574072-0. 9. Mr. Shahzad Shafique S/o Shafique Ahmed CNIC No. 35202-3030292-5. 10. Mr. Iqbal Ahmad Choudhry S/o Shah Muhammad Shahi CNIC No. 352006-814242-9.	1. Mr. Mahmood Ahmad Virk S/o Muhammad Younas CNIC No. 90403-0110978-7. 2. Mr. Faisal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3. 3. Mr. Aftab Ahmad Virk S/o Muhammad Younas CNIC No. 352010-499026-7. 4. Mr. Tahir Sharif S/o Muhammad Sharif CNIC No. 35202-8557574-1. 5. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 6. Mr. Jehanzeb Rauf Kahlon S/o Ajmal Rauf Kahlon CNIC No. 35201-7891435-7. 7. Mr. Mubashar Javed S/o Muhammad Tufail CNIC No. 35201-1514183-3. 8. Mrs. Tahira Khatoon W/o Muhammad Shahrif CNIC No. 35202-2574072-0.

Case No. 4 **CHANGE OF MANAGEMENT OF M/S ETHICAL LABORATORIES (PVT) LTD, LAHORE UNDER DML NO. 000100 (FORMULATION).**

M/s Ethical Laboratories (Pvt) Ltd, 14-Km, Thokar Niaz Baig, Multan Road, Lahore under DML No. 000100 by way of formulation has submitted request for change in management of the firm as per digital certified copy of Form-29 with prescribed Fee Challan of Rs. 93,000/-. The detail of management of the firm is as under;

Previous Management	New Management as per Form-29 dated 2nd November, 2023
1. Mr. Abdul Waheed Sheikh S/o Sheikh Hafeezudin CNIC No. 35202-2864953-3. 2. Mr. Sheikh Mughisudin S/o Hafiz Sheikh Samiuddin CNIC No. 35202-2448979-9. 3. Mr. Iftikhar Alam Chaudhary S/o Ch. Muhammad Saeed CNIC No. 35202-7220664-5. 4. Mr. Sheikh Azizuddin S/o Haj S. Ameer Din CNIC No. 35202-5871736-3 5. Mr. Sheikh Laiquddin S/o Sheikh Moinuddin CNIC No. 37405-2309789-5 6. Mr. Fasihuddin S/o Sheikh Aliuddin CNIC No.35201-8936993-1 7. Mr. Atif Altaf S/o Shahid Altaf CNIC No. 35202-2847873-9. 8. Hafiz Sheikh Aminuddin S/o Haji S. Ameer Din CNIC No.35202-2972218-9	1. Mr. Abdul Waheed Sheikh S/o Sheikh Hafeezudin CNIC No. 35202-2864953-3. 2. Mr. Sheikh Mughisudin S/o Hafiz Sheikh Samiuddin CNIC No. 35202-2448979-9. 3. Mr. Iftikhar Alam Chaudhary S/o Ch. Muhammad Saeed CNIC No. 35202-7220664-5 4. **Mr. Waseem ud Din Sheikh S/o Hafiz Sheikh Aminuddin CNIC No. 35202-2972215-1.** 5. **Mr. Shehzad Aziz Sheikh S/o Sheikh Aziz ud Din CNIC No. 35202-5881331-3.** 6. **Mr. Muhammad Usama Waheed S/o Abdul Waheed Sheikh CNIC No. 35202-8437766-1.** 7. **Ms. Naghmana Waheed W/o Abdul Waheed Sheikh CNIC No. 35202-2667483-6.**

Decision of the Central Licensing Board in 305th meeting

Based on Form-29 dated **2nd November, 2023** issued by SECP, the Board considered and accepted for record the change of management as below of M/S Ethical Laboratories (Pvt) Ltd, 14-Km, Thokar Niaz Baig, Multan Road, Lahore under DML No. **000100** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New Management as per Form-29 dated 2nd November, 2023
1. Mr. Abdul Waheed Sheikh S/o Sheikh Hafeezudin CNIC No. 35202-2864953-3.	1. Mr. Abdul Waheed Sheikh S/o Sheikh Hafeezudin CNIC No. 35202-2864953-3.

2. Mr. Sheikh Mughisudin S/o Hafiz Sheikh Samiuddin CNIC No. 35202-2448979-9. 3. Mr. Iftikhar Alam Chaudhary S/o Ch. Muhammad Saeed CNIC No. 35202-7220664-5. 4. Mr. Sheikh Azizuddin S/o Haj S. Ameer Din CNIC No. 35202-5871736-3 5. Mr. Sheikh Laiquddin S/o Sheikh Moinuddin CNIC No. 37405-2309789-5 6. Mr. Fasihuddin S/o Sheikh Aliuddin CNIC No.35201-8936993-1 7. Mr. Atif Altaf S/o Shahid Altaf CNIC No. 35202-2847873-9. 8. Hafiz Sheikh Aminuddin S/o Haji S. Ameer Din CNIC No.35202-2972218-9	2. Mr. Sheikh Mughisudin S/o Hafiz Sheikh Samiuddin CNIC No. 35202-2448979-9. 3. Mr. Iftikhar Alam Chaudhary S/o Ch. Muhammad Saeed CNIC No. 35202-7220664-5 4. **Mr. Waseem ud Din Sheikh S/o Hafiz Sheikh Aminuddin CNIC No. 35202-2972215-1.** 5. **Mr. Shehzad Aziz Sheikh S/o Sheikh Aziz ud Din CNIC No. 35202-5881331-3.** 6. **Mr. Muhammad Usama Waheed S/o Abdul Waheed Sheikh CNIC No. 35202-8437766-1.** 7. **Ms. Naghmana Waheed W/o Abdul Waheed Sheikh CNIC No. 35202-2667483-6.**

Case No. 5 **CHANGE OF MANAGEMENT OF M/S MCOLSON RESEARCH LABORATORIES (PVT) LTD, SHEIKHUPURA UNDER DML NO. 000664 (FORMULATION).**

M/s McOLSON Research Laboratories (Pvt) Ltd, 26-Km, Lahore Sharikpur Road, Sheikhupura under DML No. 000664 has submitted request for change in management of the firm as per digital certified copy of Form-A with prescribed fee. The detail of management of the firm is as under;

Previous Management	New Management as per Form-A dated 8th November, 2023
1. Mr. Ghulam Mustafa Jajjah S/o Muhammad Sadiq CNIC No. 34101-2601504-3. 2. Mr. Qaisar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-6554673-1. 3. Mr. Zafar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 35202-1546650-7. 4. Mr. Muhammad Faisal Mushtaq S/o Mushtaq Ahmad CNIC No. 35202-7491903-9. 5. Mr. Faysal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3.	1. Mr. Ghulam Mustafa Jajjah S/o Muhammad Sadiq CNIC No. 34101-2601504-3. 2. Mr. Qaisar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-6554673-1. 3. Mr. Zafar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 35202-1546650-7. 4. Mr. Muhammad Faisal Mushtaq S/o Mushtaq Ahmad CNIC No. 35202-7491903-9.

6. Ms. Tahira Khatoon W/o Mian Muhammad Sharif CNIC No. 35202-2574072-0.	

Decision of the Central Licensing Board in 305th meeting

Based on Form-A dated **8th November, 2023** issued by SECP, the Board considered and accepted for record the change of management as below of M/S McOLSON Research Laboratories (Pvt) Ltd, 26-Km, Lahore Sharikpur Road, Sheikhupura under DML No. **000664** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New Management as per Form-A dated 8th November, 2023
1. Mr. Ghulam Mustafa Jajjah S/o Muhammad Sadiq CNIC No. 34101-2601504-3. 2. Mr. Qaisar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-6554673-1. 3. Mr. Zafar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 35202-1546650-7. 4. Mr. Muhammad Faisal Mushtaq S/o Mushtaq Ahmad CNIC No. 35202-7491903-9. 5. Mr. Faysal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3. 6. Ms. Tahira Khatoon W/o Mian Muhammad Sharif CNIC No. 35202-2574072-0.	1. Mr. Ghulam Mustafa Jajjah S/o Muhammad Sadiq CNIC No. 34101-2601504-3. 2. Mr. Qaisar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-6554673-1. 3. Mr. Zafar Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 35202-1546650-7. 4. Mr. Muhammad Faisal Mushtaq S/o Mushtaq Ahmad CNIC No. 35202-7491903-9.

Case No. 6 CHANGE OF MANAGEMENT OF M/S HOOVER PHARMACEUTICALS (PVT) LTD LAHORE UNDER DML NO. 000676 (FORMULATION).

M/s Hoover Pharmaceuticals (Pvt.) Ltd, Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore under DML No. 000676 by way of formulation has submitted request for change in management of the firm as per digital certified copy of Form-9 with prescribed Fee Challan of Rs. 93,000/-. The detail of management of the firm is as under;

Previous Management	New Management as per Form-9 dated 27th November, 2024

1. Mr. Mir Anjum Ishaque S/o Mir Muhammad Ishaque CNIC No: 35202-9968914-1. 2. Mr. Azhar Mahmood S/o Abdul Majeed CNIC No. 35202-2187045-5. 3. Mrs. Sumera Ahmad W/o Imtiaz Abdullah CNIC No: 35202-4322091-6	1. Mr. Mir Anjum Ishaque S/o Mir Muhammad Ishaque CNIC No: 35202-9968914-1. 2. Mr. Azhar Mahmood S/o Abdul Majeed CNIC No. 35202-2187045-5. **3. Mrs. Salma Jamil W/o Jamil Anwer CNIC No. 35202-1166596-2.**

Decision of the Central Licensing Board in 305th meeting

Based on Form-9 dated **27th November, 2024** issued by SECP, the Board considered and accepted for record the change of management as below of M/S Hoover Pharmaceuticals (Pvt.) Ltd, Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore under DML No. **000676** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New Management as per Form-9 dated 27th November, 2024
1. Mr. Mir Anjum Ishaque S/o Mir Muhammad Ishaque CNIC No: 35202-9968914-1. 2. Mr. Azhar Mahmood S/o Abdul Majeed CNIC No. 35202-2187045-5. 3. Mrs. Sumera Ahmad W/o Imtiaz Abdullah CNIC No: 35202-4322091-6	1. Mr. Mir Anjum Ishaque S/o Mir Muhammad Ishaque CNIC No: 35202-9968914-1. 2. Mr. Azhar Mahmood S/o Abdul Majeed CNIC No. 35202-2187045-5. **3. Mrs. Salma Jamil W/o Jamil Anwer CNIC No. 35202-1166596-2.**

Case No. 7 CHANGE OF TITLE OF M/S AXIS PHARMACEUTICALS, FAISALABAD UNDER DML NO. 000667 (FORMULATION).

M/s Axis Pharmaceuticals, 3-B Value Addition City, 1.5 Km, Khurrianwala - Sahianwala Road, Faisalabad under DML No. 000667 by way of formulation has submitted request for change in title of the firm as per digital certified copy of Certificate of Incorporation with SECP with prescribed Fee Challan of Rs. 93,000/-. The detail is as under;

Previous Title	New Title as per Certificate of Incorporation with SECP dated 29th July, 2024
M/s Axis Pharmaceuticals	M/s Axis Pharmaceuticals (Pvt) Ltd

Decision of the Central Licensing Board in 305th meeting

Based on Certificate of Incorporation dated **29th July, 2024** issued by SECP, the Board considered and accepted for record the change of title as below of M/S Axis Pharmaceuticals, 3-B Value Addition City, 1.5 Km, Khurrianwala - Sahianwala Road, Faisalabad under DML No. **000667** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of

whatsoever nature. The change of title shall be effective from the change of title in SECP / Registrar of firms / sale deed.

Previous Title	New Title as per Certificate of Incorporation with SECP dated 29th July, 2024
M/s Axis Pharmaceuticals	M/s Axis Pharmaceuticals (Pvt) Ltd

Case No. 8 **CHANGE OF MANAGEMENT OF M/S WILSON'S PHARMACEUTICALS, PLOT NO. 387-388 & 366 SECTOR I-9 INDUSTRIAL AREA, ISLAMABAD UNDER DRUG MANUFACTURING LICENSE NO. 000239 (FORMULATION).**

M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366 Sector I-9 Industrial Area, Islamabad under DML No. 000239 (By way of Formulation) has submitted request for change in management of the firm along with prescribed Fee. The detail of management is as under:-

Previous Management	New Management as per partnership deed dated 03-07-2023 (effective from 01-07-2023)
1. Mr. Muhammad Saeed S/o Muhammad Shafi CNIC 61101-6934512-5 2. Mr. Muddassar Habib Sheikh S/o Muhammad Yousaf, CNIC 37405-2777117-3 3. Mr. Ali Ameen Sheikh S/o Noor-Ul-Amin, CNIC 61101-0909202-7 4. Mr. Muhammad Bilal S/o Tahir Hameed, CNIC 61101-1856273-3 5. Mr. Farooq Owais S/o Muhammad Awais, CNIC 61101-1929057-5	1. Mr. Ali Ameen Sheikh S/o Noor-Ul-Amin, CNIC 61101-0909202-7 2. Mr. Farooq Owais S/o Muhammad Awais, CNIC 61101-1929057-5 **3. Mr. Hashim Habibullah Sheikh S/o Muddassar Habib Sheikh CNIC 37405-5991727-5**

Decision of the Central Licensing Board in 305th meeting

Based on partnership deed **dated 03-07-2023 (effective from 01-07-2023)**, the Board considered and accepted for record the change of management as below of M/S Wilson's Pharmaceuticals, Plot No. 387-388 & 366 Sector I-9 Industrial Area, Islamabad under DML No. **000239** (**Formulation**) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New Management as per partnership deed dated 03-07-2023 (effective from 01-07-2023)
1. Mr. Muhammad Saeed S/o Muhammad Shafi CNIC 61101-6934512-5	1. Mr. Ali Ameen Sheikh S/o Noor-Ul-Amin, CNIC 61101-0909202-7

2. Mr. Muddassar Habib Sheikh S/o Muhammad Yousaf, CNIC 37405-2777117-3 3. Mr. Ali Ameen Sheikh S/o Noor-Ul-Amin, CNIC 61101-0909202-7 4. Mr. Muhammad Bilal S/o Tahir Hameed, CNIC 61101-1856273-3 5. Mr. Farooq Owais S/o Muhammad Awais, CNIC 61101-1929057-5	2. Mr. Farooq Owais S/o Muhammad Awais, CNIC 61101-1929057-5 **3. Mr. Hashim Habibullah Sheikh S/o Muddassar Habib Sheikh CNIC 37405-5991727-5**

Case No. 9 **CHANGE OF MANAGEMENT OF M/S WERRICK PHARMACEUTICALS, PLOT NO. 216-217, I-10/3, INDUSTRIAL AREA, ISLAMABAD UNDER DRUG MANUFACTURING LICENSE NO. 000340 (FORMULATION).**

M/s Werrick Pharmaceuticals, Plot No. 216-217, I-10/3, Industrial Area, Islamabad under Drug Manufacturing License No. 000340 has submitted request for change in management of the firm along with prescribed Fee. The detail of management is as under:-

Previous Management	New Management as per partnership deed dated 03-07-2023 (effective from 01-07-2023)
1. Mr. Ali Ameen Sheikh S/o Noor-Ul-Amin, CNIC 61101-0909202-7 2. Mr. Muhammad Bilal S/o Tahir Hameed, CNIC 61101-1856273-3 3. Mr. Muhammad Umair S/o Tahir Hameed CNIC 61101-7964040-9 4. Mr. Farooq Owais S/o Muhammad Awais, CNIC 61101-1929057-5	1. Mr. Muhammad Bilal S/o Tahir Hameed, CNIC 61101-1856273-3 2. Mr. Muhammad Umair S/o Tahir Hameed CNIC 61101-7964040-9 **3. Mr. Ghulam Mustafa Saeed S/o Muhammad Saeed CNIC 61101-7329839-9**

Decision of the Central Licensing Board in 305th meeting

Based on partnership deed **dated 03-07-2023 (effective from 01-07-2023)**, the Board considered and accepted for record the change of management as below of M/S Werrick Pharmaceuticals, Plot No. 216-217, I-10/3, Industrial Area, Islamabad under Drug Manufacturing License No. **000340** (**Formulation**) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New Management as per partnership deed dated 03-07-2023 (effective from 01-07-2023)

1. Mr. Ali Ameen Sheikh S/o Noor-Ul-Amin, CNIC 61101-0909202-7 2. Mr. Muhammad Bilal S/o Tahir Hameed, CNIC 61101-1856273-3 3. Mr. Muhammad Umair S/o Tahir Hameed CNIC 61101-7964040-9 4. Mr. Farooq Owais S/o Muhammad Awais, CNIC 61101-1929057-5	1. Mr. Muhammad Bilal S/o Tahir Hameed, CNIC 61101-1856273-3 2. Mr. Muhammad Umair S/o Tahir Hameed CNIC 61101-7964040-9 **3. Mr. Ghulam Mustafa Saeed S/o Muhammad Saeed CNIC 61101-7329839-9**

Case No. 10 CHANGE OF MANAGEMENT OF M/S SHAZAL'S PHARMACEUTICALS, PLOT NO. 41/1-A, PHASE-I, INDUSTRIAL ESTATE, HATTAR UNDER DRUG MANUFACTURING LICENSE NO. 000592 (FORMULATION).

M/s Shazal's Pharmaceuticals, Plot No. 41/1-A, Phase-I, Industrial Estate, Hattar under Drug Manufacturing License No. 000592 (formulation) has submitted request for change in management of the firm along with prescribed fee. The detail of management is as under:-

Previous Management	New Management as per undertaking And firm's submission dated 05-11-2024
1. Mr. Rafi Ul Mulk S/o Kamran Khan, CNIC 15602-3332129-1	1. Mr. Mustafa Bashir S/o Muhammad Bashir, CNIC 61101-7725236-5

Decision of the Central Licensing Board in 305th meeting

Based on **undertaking and firm's submission dated 05-11-2024**, the Board considered and accepted for record the change of management as below of M/S Shazal's Pharmaceuticals, Plot No. 41/1-A, Phase-I, Industrial Estate, Hattar under Drug Manufacturing License No. **000592** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New Management as per undertaking And firm's submission dated 05-11-2024
1. Mr. Rafi Ul Mulk S/o Kamran Khan, CNIC 15602-3332129-1	1. Mr. Mustafa Bashir S/o Muhammad Bashir, CNIC 61101-7725236-5

Case No. 11 CHANGE OF MANAGEMENT OF M/S. SEARLE PAKISTAN LTD., PLOT NO.C-14, MANGHOPIR ROAD, S.I.T.E., KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000012 (FORMULATION).

M/s. Searle Pakistan Ltd., Plot No.C-14, Manghopir Road, S.I.T.E., Karachi submitted application for change of management under Drug Manufacturing License No. 000012 by way of (Formulation) along with prescribed fee. The detail of management is as under:-

Previous management	New management as per Form-29 dated 22-11-2023
1. Mr. Mufti Zia Ul Islam S/o Mr. Taus Khan, CNIC No.42000-0467228-3. 2. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala, CNIC No.42201-5080780-3. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No.42301-0859989-9. 4. Mr. Mobin Alam S/o Muhammad Aziz Alam, CNIC No.42301-4675803-3. 5. Ms. Fareen Naz Qureshi D/o Muhammad Hassan Azwar CNIC No.42301-0763444-4. 6. Mr. Tahir Ahmed S/o Maqbool Ahmed, CNIC No.42201-0169711-5. 7. **Mr. Muhammad Zubair Haider Shaikh S/o Haider Buksh Shaikh, CNIC No.42301-9578130-3.**	1. Mr. Mufti Zia Ul Islam S/o Mr. Taus Khan, CNIC No.42000-0467228-3. 2. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala, CNIC No.42201-5080780-3. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No.42301-0859989-9. 4. Mr. Mobin Alam S/o Muhammad Aziz Alam, CNIC No.42301-4675803-3. 5. Ms. Fareen Naz Qureshi D/o Muhammad Hassan Azwar CNIC No.42301-0763444-4. 6. Mr. Tahir Ahmed S/o Maqbool Ahmed, CNIC No.42201-0169711-5. 7. **Mr. Munis Abdullah S/o Rashid Abdullah, CNIC No.42201-9982517-1.**

Decision of the Central Licensing Board in 305th meeting

Based on Form-29 **dated 22-11-2023** issued by SECP, the Board considered and accepted for record the change of management as below of M/S Searle Pakistan Ltd., Plot No.C-14, Manghopir Road, S.I.T.E., Karachi under Drug Manufacturing License No. **000012** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous management	New management as per Form-29 dated 22-11-2023
1. Mr. Mufti Zia Ul Islam S/o Mr. Taus Khan, CNIC No.42000-0467228-3. 2. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala, CNIC No.42201-5080780-3. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No.42301-0859989-9. 4. Mr. Mobin Alam S/o Muhammad Aziz Alam, CNIC No.42301-4675803-3. 5. Ms. Fareen Naz Qureshi D/o Muhammad Hassan Azwar CNIC No.42301-0763444-4.	1. Mr. Mufti Zia Ul Islam S/o Mr. Taus Khan, CNIC No.42000-0467228-3. 2. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala, CNIC No.42201-5080780-3. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No.42301-0859989-9. 4. Mr. Mobin Alam S/o Muhammad Aziz Alam, CNIC No.42301-4675803-3. 5. Ms. Fareen Naz Qureshi D/o Muhammad Hassan Azwar CNIC No.42301-0763444-4.

6. Mr. Tahir Ahmed S/o Maqbool Ahmed, CNIC No.42201-0169711-5. 7. **Mr. Muhammad Zubair Haider Shaikh S/o Haider Buksh Shaikh, CNIC No.42301-9578130-3.**	6. Mr. Tahir Ahmed S/o Maqbool Ahmed, CNIC No.42201-0169711-5. 7. **Mr. Munis Abdullah S/o Rashid Abdullah, CNIC No.42201-9982517-1.**

Case No. 12 **CHANGE OF MANAGEMENT OF M/S. WNSFIELD PHARMACEUTICALS, PLOT NO.122, BLOCK-A, PHASE-V, INDUSTRIAL ESTATE, HATTAR, KPK UNDER DRUG MANUFACTURING LICENSE NO. 000610 (FORMULATION).**

M/s. Wnsfield Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate, Hattar, KPK under drug manufacturing license no. 000610 (Formulation) has submitted an application for change of management along with prescribed fee. The detail of management is as under:-

Previous management	New management as per Partnership deed dated 30-08-2016
1. Mr. Arshad Mehmood S/o Khushi Muhammad, CNIC No. 61101-6927558-3 2. Mrs. Almas W/o Arshad Mehmood, CNIC No. 61101-3811152-4. 3. Mr. Zafar Mehmood Khan S/o Talib Hussain khan CNIC No. 37405-4617280-7 4. Mr. Iftikhar Hussain Abbasi S/o Maqsood hussain Abbasi, CNIC No. 61101-8156540-7 5. Mr. Muhammad Tahir S/o Malik Muhammad Yaqoob CNIC No. 34101-2367288-9 6. Mr. Muhammad Shahid S/o Malik Muhammad Yaqoob, CNIC No. 34101-7007738-5	1. Mr. Arshad Mehmood S/o Khushi Muhammad, CNIC No. 61101-6927558-3 2. Mrs. Almas W/o Arshad Mehmood, CNIC No. 61101-3811152-4. 3. Mr. Zafar Mehmood Khan S/o Talib Hussain khan CNIC No. 37405-4617280-7 4. Mr. Iftikhar Hussain Abbasi S/o Maqsood Hussain Abbasi, CNIC No. 61101-8156540-7 5. Mr. Muhammad Tahir S/o Malik Muhammad Yaqoob CNIC No. 34101-2367288-9 6. Mr. Muhammad Shahid S/o Malik Muhammad Yaqoob, CNIC No. 34101-7007738-5 7. **Mrs. Shazadi Neelum Zafar W/o Zafar Mehmood Khan, CNIC No 37405-6117651-0**

Decision of the Central Licensing Board in 305th meeting

Based on Partnership deed **dated 30-08-2016**, the Board considered and accepted for record the change of management as below of M/S Wnsfield Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate, Hattar, KPK under Drug Manufacturing License No. **000610** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous management	New management as per Partnership deed dated 30-08-2016

1. Mr. Arshad Mehmood S/o Khushi Muhammad, CNIC No. 61101-6927558-3 2. Mrs. Almas W/o Arshad Mehmood, CNIC No. 61101-3811152-4. 3. Mr. Zafar Mehmood Khan S/o Talib Hussain khan CNIC No. 37405-4617280-7 4. Mr. Iftikhar Hussain Abbasi S/o Maqsood hussain Abbasi, CNIC No. 61101-8156540-7 5. Mr. Muhammad Tahir S/o Malik Muhammad Yaqoob CNIC No. 34101-2367288-9 6. Mr. Muhammad Shahid S/o Malik Muhammad Yaqoob, CNIC No. 34101-7007738-5	1. Mr. Arshad Mehmood S/o Khushi Muhammad, CNIC No. 61101-6927558-3 2. Mrs. Almas W/o Arshad Mehmood, CNIC No. 61101-3811152-4. 3. Mr. Zafar Mehmood Khan S/o Talib Hussain khan CNIC No. 37405-4617280-7 4. Mr. Iftikhar Hussain Abbasi S/o Maqsood Hussain Abbasi, CNIC No. 61101-8156540-7 5. Mr. Muhammad Tahir S/o Malik Muhammad Yaqoob CNIC No. 34101-2367288-9 6. Mr. Muhammad Shahid S/o Malik Muhammad Yaqoob, CNIC No. 34101-7007738-5 7. **Mrs. Shazadi Neelum Zafar W/o Zafar Mehmood Khan, CNIC No 37405-6117651-0**

Case No. 13 **CHANGE OF MANAGEMENT M/S TRISON RESEARCH LABORATORIES (PVT.) LTD., 27-A, PUNJAB SMALL INDUSTRIAL ESTATE, SARGODHA.**

The firm, M/s Trison Laboratories (Pvt.) Ltd., 27-A, Punjab Small Industrial Estate, Sargodha wherein the firm has submitted application for change of management with relevant fee of Rs. 93,000/. The detail of management is as under;

Previous Management	**New Management as per Form-A dated 5th June, 2024**
1. Mubashar Javed S/o Muhammad TufailCNIC No.35201-1514163-3. 2. Mr. Irfan Gulzar Ahmad S/o Gulzar Ahmad CNIC No.38403-2956767-5.	**1. Mr. Muhammad Tabish Waleed S/o Irfan Gulzar Anjum CNIC No. 38403-2408627-9.** 2. Mr. Irfan Gulzar Anjum S/o Gulzar Ahmad CNIC No. 38403-2956767-5.

Decision of the Central Licensing Board in 305th meeting

Based on Form-A dated **5th June, 2024**, the Board considered and accepted for record the change of management as below of M/S Trison Research Laboratories (Pvt.) Ltd., 27-A, Punjab Small Industrial Estate, Sargodha under Drug Manufacturing License No. **000529** (**Formulation**). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	**New Management as per Form-A dated 5th June, 2024**

1. Mubashar Javed S/o Muhammad TufailCNIC No.35201-1514163-3. 2. Mr. Irfan Gulzar Ahmad S/o Gulzar Ahmad CNIC No.38403-2956767-5.	**1. Mr. Muhammad Tabish Waleed S/o Irfan Gulzar Anjum CNIC No. 38403-2408627-9.** 2. Mr. Irfan Gulzar Anjum S/o Gulzar Ahmad CNIC No. 38403-2956767-5.

Case No. 14. <u>CHANGE OF MANAGEMENT OF M/S TRIGON PHARMACEUTICALS (PVT) LTD., 8-KM, THOKAR RAIWIND ROAD, LAHORE.</u>

M/s Trigon Pharmaceuticals (Pvt) Ltd., 8-Km, Thokar Raiwind Road, Lahore has submitted request for change in management of the firm as per Form-29 with the prescribed fee. The detail of the management of the firm is as under:

Previous Management as per form 29	**New Management as per Form-A dated 28th October, 2022**
1. Shahida Safdar W/o Muhammad Safdar CNIC No. 35202-2688806-4. 2. Mr. Muhammad Safdar S/o Chaudhary Muhammad Shafi CNIC 36501-3646813-9.	1. Mr. Muhammad Safdar S/o Chaudhary Muhammad Shafi CNIC 36501-3646813-9. **2. Mr. Haddi Hassan Qureshi S/o Muhammad Din Qureshi CNIC No.35202-5353860-7.** 3. **Mr. Hashim Tareen Khan S/o Muhammad Asghar Khan Tareen CNIC No.36302-5286384-7.**

<u>Decision of the Central Licensing Board in 305th meeting</u>

Based on Form-A dated **28th October, 2022**, the Board considered and accepted for record the change of management as below of M/S Trigon Pharmaceuticals (Pvt) Ltd., 8-Km, Thokar Raiwind Road, Lahore under Drug Manufacturing License No. **000342** (**Formulation**) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per form 29	**New Management as per Form-A dated 28th October, 2022**
1. Shahida Safdar W/o Muhammad Safdar CNIC No. 35202-2688806-4. 2. Mr. Muhammad Safdar S/o Chaudhary Muhammad Shafi CNIC 36501-3646813-9.	1. Mr. Muhammad Safdar S/o Chaudhary Muhammad Shafi CNIC 36501-3646813-9. **2. Mr. Haddi Hassan Qureshi S/o Muhammad Din Qureshi CNIC No.35202-5353860-7.** 3. **Mr. Hashim Tareen Khan S/o Muhammad Asghar Khan Tareen CNIC No.36302-5286384-7.**

ITEM NO. VI. MISCELLANEOUS CASES

Case No. 1 STATUS OF DML OF M/S MUNAWAR PHARMA (PVT) LTD, 31-KM, FEROZEPUR ROAD, LAHORE.

The Drug Manufacturing License No. 000379 by way of Formulation was issued to M/s Munawar Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore and due date of renewal of License was 11-01-2024. The firm did not file application for renewal of DML for the period of 12-01-2024 to 11-01-2029.

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule 5(3) states that "If the application for renewal of the License is made after the expiry of the period of the validity of the License, it shall be treated as a fresh application for the grant of a License.

Accordingly, a Show Cause notice was issued to the firm on 1st November, 2024. The firm did not reply.

Therefore, Drug Manufacturing License No. 000379 (Formulation) of M/s Munawar Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore is invalid and stands cancelled. The letter of expiration of validity was issued on 16th December, 2024.

Decision of the Central Licensing Board in its 305th meeting:

The Board noted the information.

Case No. 2 STATUS OF DML OF M/S BIO FINE PHARMACEUTICALS (PVT) LTD, 74-INDUSTRIAL ESTATE, MULTAN.

The Drug Manufacturing License No. 000334 by way of Formulation was issued to M/s Bio Fine Pharmaceuticals (Pvt) Ltd, 74-Industrial Estate, Multan. The renewal of Drug Manufacturing License was due on 18-07-2024. Application for renewal of DML for the period of 19-07-2024 to 18-07-2029 was received on 08-10-2024 through e-App with tracing ID: B99-QNU-H8L9.

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule

5(3) states that "If the application for renewal of the License is made after the expiry of the period of the validity of the License, it shall be treated as a fresh application for the grant of a License.

Accordingly, a Show Cause notice was issued to the firm on 1st November, 2024. The firm replied on 7th November, 2024 which is reproduced as under:

"We want to state that:

Our Company has always submitted DML renewal applications on time in previous history. Our current DML renewal was due on 18-07-2024 and we deposited fee voucher on 30-07-2024 & appeared in person at DRAP office to submit the hard copies of application as per previous method. We were informed; our application can only be submitted online for which we created our company's online page with DRAP website after putting in efforts which took time. Our documents were not being uploaded online due to technical issue and sorting the problem took more time. We are ready to pay any penalty, if required."

Furthermore, the firm through case Management with tracking ID: VYM-QX3-RBT2 uploaded another reply of Show Cause Notice which is reproduced as under:

"With reference to the letter tracking ID: B99-QNU-H8L9 dated 1st November, 2024 we receive the show cause notice regarding our submitted file for the renewal of Drugs Manufacturing License (000334) in which the late renewal submission was the reason of the notice.

*Sir we submitted the balance late fee of (11) days @ 15000 per day *****165000/- under the ABL challan No.034988706338 dated 14-11-2024 requested to please consider the submission and process the renewal application on early bases. On the same day a letter under the Tracking ID: B99-QNU-H8L9 dated 1st November 2024 move to the Director (QA&LT) to direct the field officer to stop the manufacturing activities on the premises of the company M/s Bio Fine Pharmaceuticals (Pvt.) Ltd, 74-Industrial Estate, Multan. Sir it is requested to please to please pass the order of production resumption because the staff working the plant will be jobless because of this act, on humanitarian ground, we submit the late fee and we apologies and we will be very careful in future regarding the renewal submission.*

Prayer:

Request to please consider our of renewal of Drugs Manufacturing License and constitute a panel to inspect the premises for the same, also pass the resumption of production orders we will be very grateful to the respected and competent authority on this act of kindness, if the department require any clarification regarding late renewal submission we are available to present in person."

The Drug Manufacturing License No. 000334 (Formulation) of M/s Bio Fine Pharmaceuticals (Pvt) Ltd, 74-Industrial Estate, Multan is invalid and stands cancelled. The letter of expiration of validity was issued on 9th December, 2024.

Decision of the Central Licensing Board in its 305th meeting:

The Board noted the information.

Case No. 3 GRANT OF RE-PACKING PRODUCTS TO M/S INTERVAC (PVT) LTD., 18-KM, LAHORE-SHEIKHUPURA ROAD, SHEIKHUPURA.

The firm, M/s Intervac (Pvt) Ltd., 18-Km, Lahore-Sheikhupura Road, Sheikhupura under Drug Manufacturing Licence No. 000623 by way of Formulation has submitted application for Grant of following Re-packing products as per Schedule-D. The firm has submitted challan Fee of Rs. 7500/ per product.

i. Boric Acid
ii. Calcium Gluconate
iii. Castor Oil
iv. Glycerin
v. Kaolin
vi. Liquid Paraffin Heavy
vii. Magnesium Sulphate
viii. Sodium Salicylate
ix. Sodium Bicarbonate
x. Soft Yellow Paraffin
xi. Zinc Oxide

Decision of the Central Licensing Board in its 305th meeting:

The Board considered and approved the grant of following repacking products to M/s Intervac (Pvt) Ltd., 18-Km, Lahore-Sheikhupura Road, Sheikhupura under Drug Manufacturing Licence No. 000623 by way of formulation;

i. Boric Acid
ii. Calcium Gluconate
iii. Castor Oil
iv. Glycerin
v. Kaolin
vi. Liquid Paraffin Heavy
vii. Magnesium Sulphate
viii. Sodium Salicylate
ix. Sodium Bicarbonate
x. Soft Yellow Paraffin
xi. Zinc Oxide

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

Case No.4 REQUEST FOR WITHDRAWAL OF LICENSED SECTIONS OF M/S A.J MIRZA PHARAM (PVT.) LTD, KARACHI.

M/s A.J Mirza Pharma (Pvt.) Ltd, Plot No.44, Sector 27, Korangi Industrial Area, Karachi under DML No.000234 by way of Formulation has submitted request for withdrawal of following licensed sections:

1. Liquid Syrup (General) Section-Ground Floor

Liquid Syrup Section is replaced with "Dry Powder Inhaler (Capsule).

Decision of the Central Licensing Board in its 305th meeting:

The Board approved the withdrawal of following Section of M/s A.J Mirza Pharma (Pvt.) Ltd, Plot No.44, Sector 27, Korangi Industrial Area, Karachi under DML No.000234 by way of Formulation and decided to notify the Drug Registration Board to take the necessary action;

1. Liquid Syrup (General) Section-Ground Floor

Case No.5 REQUEST FOR WITHDRAWAL OF LICENSED SECTIONS OF M/S ABBOTT LABORATORIES (PAKISTAN) LTD, KARACHI UNDER DML NO.000001 (FORMULATION) .

M/s Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre Hyderabad Road, Landhi, Karachi under DML No.000001 by way of Formulation has submitted request for withdrawal of following licensed sections:

1. Capsule Section (General)

Decision of the Central Licensing Board in its 305th meeting:

The Board approved the withdrawal of following Section of M/s Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre Hyderabad Road, Landhi, Karachi under DML No.000001 by way of Formulation and decided to notify the Drug Registration Board to take the necessary action;

1. Capsule Section (General)

Case No. 6 REQUEST FOR WITHDRAWAL OF LICENSED SECTIONS OF M/S IRZA PHARMA (PVT) LTD, 10.2 KM, SHEIKHUPURA ROAD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000108 (FORMULATION)

M/s Irza Pharma (Pvt) Ltd, 10.2 Km, Sheikhupura Road, Lahore under Drug Manufacturing License No. 000108 (Formulation) has submitted request for withdrawal of following licensed sections:

1. Liquid Repacking Section.
2. Ointment (General) Section.

Decision of the Central Licensing Board in its 305th meeting:

The Board approved the withdrawal of following Sections of M/s Irza Pharma (Pvt) Ltd, 10.2 Km, Sheikhupura Road, Lahore under Drug Manufacturing License No. 000108 by way of Formulation and decided to notify the Drug Registration Board to take the necessary action;

1. Liquid Repacking Section.
2. Ointment (General) Section.

Case No. 7 **REQUEST FOR WITHDRAWAL OF LICENSED SECTIONS OF M/S FARM AID GROUP, HATTAR.**

M/s Farm Aid Group, Plot No.3/2, Phase-I&II, Hattar Industrial Estate, Haripur DML No. 000298 (Formulation) have applied for the withdrawal of their following three approved sections:

Block C (First Floor)	
Oral Powder-I (General-Veterinary-)	Oral Liquid-I (General-Veterinary)
Oral Bolus -I (General-Veterinary)	

The abovementioned sections were already suspended by Central Licensing Board Meeting in its in 286th held on 11th May,2022. The decision of the CLB is reproduced as under:

"The secretariat of the Board informed that mandate for renewal of following section was inadvertently missed and subsequently panel of expert did not give any recommendation regarding renewal. The Board after consideration of the facts and perusal of record decided to not approve the grant of renewal of DML No. 000298 by way of Formulation in the name of M/s. Farm Aid Group, Plot No.3/2, Phase-I&II, Hattar Industrial Estate, Haripur, for following sections. The Board further decided to ask the firm for further utilization of the following sections. The production shall remain suspended till decision by the Board.

Block C	
Oral Powder-I (General-Veterinary-)	*Oral Liquid-I (General-Veterinary)*
Oral Bolus -I (General-Veterinary)	

The firm has submitted the requisite fee of Rs.7500 on 02-01-2024.

Decision of the Central Licensing Board in its 305th meeting:

The Board approved the withdrawal of following Sections of M/s Farm Aid Group, Plot No.3/2, Phase-I&II, Hattar Industrial Estate, Haripur DML No. 000298 by way of Formulation and decided to notify the Drug Registration Board to take the necessary action;

Block C

Oral Powder-I (General-Veterinary)	*Oral Liquid-I (General-Veterinary)*
Oral Bolus -I (General-Veterinary)	

Case No. 8 SITE VERIFICATION OF M/S MEDIWAVES (PVT) LTD, PLOT NO. 106-D, QUAID-E-AZAM BUSINESS PARK, SHEIKHUPURA.

M/s Mediwaves (Pvt) Ltd has applied for verification of site located at Plot No. 106-D, Quaid-e-Azam Business Park, Sheikhupura for establishment of pharmaceutical unit. The firm was advised to choose a different name as *'Mediwaves'* closely resembles the name of an already licensed firm, *'Mediways,'* which was cancelled by the CLB in its 277th meeting held on 15th and 16th October, 2020. In response, the firm has stated that they have registered as a Private Limited Company under the name 'Mediwaves (Pvt) Ltd' and are already operating under this name. Therefore, they have requested that their firm name, 'Mediwaves (Pvt) Ltd, may be considered for site verification

Decision of the Central Licensing Board in its 305th meeting:

The Board acceded to the request of the firm on the grounds that license of "Mediways" was cancelled by the CLB in its 277th meeting held on 15th and 16th October, 2020.

Case No. 9 PANEL INSPECTION FOR GRANT OF ADDITIONAL SECTIONS OF M/S CITI PHARMA LTD, LAHORE UNDER DML NO. 000512 (FORMULATION).

M/s Citi Pharma Ltd, 3 Km, Head Balloki Road, Phool Nagar, District Kasur under DML No. 000512 (Formulation) got approval of layout plan on 29-10-2020 for the following sections:

1. Tablet (Penicillin) Section unlicensed (Revised).
2. Capsule (Penicillin) Section unlicensed (Revised).
3. Dry Powder Suspension (Penicillin) Section unlicensed (Revised).
4. Dry Powder Injection (Penicillin) Section unlicensed (Revised).
5. Oral Liquid (General) Section (New).
6. Quality Control Laboratory (Cephalosporin) Block (New).

It is pertinent to mention that, as per the practice in vogue, firms were advised in paragraph 3 of the LOP approval letter that:

"*This approval is valid for a period of one year only, unless construction of the main building is started within this period and a progress report, duly verified by the area Federal Inspector of Drugs, is submitted to the Central Licensing Board. This approval shall be further subject to the rules that may be framed from time to time under the Drugs Act, 1976."*

However, the CLB considered the matter in its 302nd meeting held on 20th November, 2024 and decided as under:

Decision of the Central Licensing Board in 302nd meeting:

The Board considered the request of the firm and decided to extend validity period of approved layout plan to two years for additional sections and to three years for new units, unless construction of the main building is started within this period and a progress report, duly verified by the area Federal

Inspector of Drugs, is submitted to the Central Licensing Board. This approval shall be further subject to the rules that may be framed from time to time under the Drugs Act, 1976.

The Board further decided to delegate the power for extension in the validity period for one year in both case to Chairman, CLB.

In the instant case, the layout plan was approved on 29-10-2020; however, no progress report was submitted by the firm. The firm has now requested to constitute a panel for the inspection of their facility, as the building construction has been completed. Since the validity period has already expired, the matter is submitted to the CLB for consideration.

Decision of the Central Licensing Board in its 305th meeting:

The Board decided that following practice shall be adopted to deal with cases of already approved layout plans prior to its decision taken in the 302nd meeting dated 20th November, 2024: -

i. If the applicant applies for panel inspection within 5 years of approval of layout plan, Chairman, CLB shall proceed for constitution of panel subject to fullfiilment of other codal formalities.
ii. In case, panel inspection is requested after 5 years of approval of layout plan, the case shall be placed in the CLB, alongwith the justification by the firm, for its decision by the Board.

Case No. 10 **CORRECTION IN SECTIONS APPROVAL AND ADDRESS OF M/S. PHARMAWISE LABS (PVT) LTD, 25-M, KOT LAKHPAT INDUSTRIAL ESTATE, LAHORE UNDER DML NO. 000182 (FORMULATION)**

M/s. Pharmawise Labs (Pvt) Ltd, **25-M**, Kot Lakhpat Industrial Estate, Lahore submitted it requested wherin the firm has requested for correction in address of the firm and addition of following sections in the section approval letter:

1. Tablet (General) Section
2. Capsule (General) Section

The firm LOP was approved for regularization and panel letter was issued for renewal and regularization of following sections. Subsequently, the Board in its 290th meeting held on 28th April, 2023 has considered and approved the grant of renewal of DML No. **000182** and Regularization of Layout Plan for the following sections and letter was issued, accordingly.

Ground Floor		First Floor	
S. No	**Name of Section**	**S. No**	**Name of Section**
1.	Syrup (General).	1.	Capsule (Penicillin)
2.	External Application (Antiseptic Liquid)	2.	Tablet (General/Antibiotic)
3.	Cream/Ointment/Gel (General)	3.	Dry Powder (General/Antibiotic)
4.	Packing	4.	Tablet (Steroid)
5.	Sachet ORS (General)	5.	Quality Control Laboratory

6.	Microbiology Laboratory	6.	Packing material Store
7.	Finished Goods Store		
8.	Liquid Repacking Section		
9.	Raw Material Store.		

However, the firm has already following sections approved vide this Division letter No. 1-7/85-Lic(Vol-II) dated 24th November, 2008

1. Tablet (General) Section
2. Capsule (General) Section

Furthermore, the approved LOP for regularization / revision of sections also contains abovementioned sections, however, covering letter NO. same as above dated 18th December, 2017 does not contain these sections.

The panel of experts in their renewal inspection report dated 21-03-2023 clearly mentioning above two sections, however, the CLB in its 290th meeting didn't approve these sections. Both of these sections are also reported in the panel inspection report conducted by five-member panel on the directions of Appellate Board (150th meeting held on 04-04-2018). (Report placed at Page No. 485-492 of Volume-II of F. No. 1-7/85-Lic.)

Moreover, the correction in the address requested in the DML is also inadvertently recorded in the minutes of the CLB as M/s. Pharmawise Labs (Pvt) Ltd, **25-Km**, Kot Lakhpat Industrial Estate, Lahore instead of M/s. Pharmawise Labs (Pvt) Ltd, **25-M**, Kot Lakhpat Industrial Estate, Lahore

The case is placed before the CLB for consideration for approval of the two missing sections and the correct address of the firm.

Decision of the Central Licensing Board in its 305th meeting:

The Board made the following decisions:-

i. Correction in the address of M/s. Pharmawise Labs (Pvt) Ltd, **25-Km**, Kot Lakhpat Industrial Estate, Lahore to M/s. Pharmawise Labs (Pvt) Ltd, **25-M**, Kot Lakhpat Industrial Estate, Lahore in the renewal letter and Form-2 issued on 22nd June, 2023 in light of 290th meeting of CLB held on 28th April, 2023.

ii. Addition of following sections in the renewal letter issued on 22nd June, 2023 in light of 290th meeting of CLB held on 28th April, 2023:-

    i. Tablet (General) Section
    ii. Capsule (General) Section i.e. Capsule (Penicillin) mentioned in the renewal letter dated 22nd June, 2023 shall be considered as Capsule (General) Section.
    iii. As the firm has the registration of Ampicillin capsule, therefore, same will be referred to the PE&R Division for further necessary action.

Case No. 11 **ENLISTMENT OF SODIUM BICARBONATE COATED GRANULES OF M/S SURGE LABORATORIES (PVT) LTD., 10-KM FAISALABAD ROAD**

BHIKHI DISTT SHEIKHUPURA (000649 SEMI BASIC MANUFACTURE) WITH TRADE NAME FOR EXPORT PURPOSE

The Firm M/s Surge Laboratories (Pvt) Ltd., 10-Km Faisalabad Road Bhikhi Distt Sheikhupura (000649 Semi Basic Manufacture) submitted that they are the manufacturer and exporter of Microencapsulation products in Coated Granules/Pellets form by way of semi basic manufacturer. They further submitted that are exporting Sodium Bicarbonate Coated Granules Powder 85% to Brazil and their costumer (in the importing country) want to import this product with brand name "Effer-Soda Coated Granules".

It is submitted that the CLB in 234th meeting held on 27/02/2014 approved Sodium Bicarbonate Coated Granules.

Decision of the Central Licensing Board in its 305th meeting:

The Board acceded to the request of the firm for export purpose only subject to the opinion from the Legal Affairs Division of the DRAP that whether the resemblance of applied brand name i.e. "Effer-Soda Coated Granules" with the brand name of any foreign company not registered with DRAP/Pakistan, will create any legal complications.

Case No. 12 **CORRECTION IN CONDITION OF LETTER OF M/S STANDPHARM PAKISTAN (PVT) LTD., 20- KM FEROZEPUR ROAD LAHORE UNDER DML NO. 000051 (FORMULATION)**

The Central Licensing Board in its 302nd meeting held on 20th November, 2024 considered the case of M/s Standpharm Pakistan (Pvt) Ltd., 20- Km Ferozepur Road Lahore under DML No. 000051 (Formulation) and decided as under;

> *"The Board approved the withdrawal of following Section of M/s Standpharm Pakistan (Pvt) Ltd., 20- Km Ferozepur Road Lahore under DML No. 000051 (Formulation) and decided to notify the Drug Registration Board to take the necessary action;*
>
> 1. *Injectable Liquid ampoule (General)*
> 2. *Injectable Liquid infusion (General)*

Accordingly, in the light of above decision of CLB in said meeting, letter No. 1-51/84-Lic (Vol-II) dated 18/12/2024 for withdrawal of was issued where Division of PE&R, DRAP was requested to take necessary action for the cancelation of registered products against above mentioned section" of the referred letter.

It is submitted that CLB in its 287th meeting held on held on 24th June, 2022 approved following section and letter was issued on 04th July, 2022, accordingly.

1. *Liquid Injectable Ampoule (General) Section (New)*
2. *Liquid Injectable Vial LVP (General) Section (New)*

The firm submitted that all products have been shifted to their approved Injectable Section and requested for re-issuance of letter without mentioning the cancelation of registered products, (as

mentioned vide Copy to:- (iii)", "the request to take necessary action for the cancelation of registered products against above mentioned section" of the referred letter.)

Therefore, corrigendum letter was issued as requested by the firm vide letter No. 1-51/84-Lic (Vol-II) dated 31/12/2024

Decision of the Central Licensing Board in its 305th meeting:

The Board ratified the issuance of corrigendum vide letter No. 1-51/84-Lic (Vol-II) dated 31/12/2024 being in line with the record of the Division of Drug Licensing.

Case No. 13 **STATUS OF RENEWAL OF DML OF M/S ZAMKO PHARMACEUTICALS (PVT) LTD., PLOT NO. 641-A, SUNDER INDUSTRIAL ESTATE, LAHORE UNDER THE DRUG MANUFACTURING LICENSE NO. 000890 (FORMULATION).**

The firm M/s Zamko Pharmaceuticals (Pvt) Ltd., Plot No. 641-A, Sunder Industrial Estate, Lahore under the Drug Manufacturing License No. 000890 (formulation) submit application for renewal of DML from 08-01-2024 to 07-01-2029 on 07-06-2024. Moreover, the firm also request for panel constitution for renewal of DML vide application No. PXN-LS7-8M9J on 14-03- 2024.

It is submitted that upon evaluation it was noticed that application for renewal of DML was submitted after sixty days of the expiry of the period of validity of license. Accordingly, Showcause Notice was issued to the firm on 06/11/2024 where they were advice to submit evidence/prof for submission of renewal of DML.

In continuation to Showcause Notice issued vide letter of even number dated 6th November, 2024 the only document provided by firm as evidence of submission of application for renewal of Drug Manufacturing License for duration 08-01-2024 to 07-01-2029 was a photocopy of a general request/application for the constitution of a panel for the renewal of both Good Manufacturing Practice (GMP) Renewal of Drug Manufacturing License. Moreover, E-APP was implemented since October, 2023 while it was compulsory since January, 2024. Only those application could be submitted in hard form which were permitted by the Director-Licensing. Hence you they did not provide reliable evidence of submission of application for renewal of Drug Manufacturing License No. 000890 (Formulation) of the firm M/s Zamko Pharmaceuticals (Pvt) Ltd., Plot No. 641-A, Sunder Industrial Estate, Lahore for duration 08-01-2024 to 07-01-2029.

In the light of above and as per available record in the Licensing Division, DRAP, application for renewal of Drug Manufacturing License No. 000890 (Formulation) of M/s Zamko Pharmaceuticals (Pvt) Ltd., Plot No. 641-A, Sunder Industrial Estate, Lahore for the duration of 08-01-2024 to 07-01-2029 has been received on **07-06-2024** i.e., after 60 (sixty) days of the period of validity of License as per Drugs (Licensing, Registering and Advertising) Rules, 1976 and **stands invalid**. Letter of invalidity was issued vide letter No.F. 1-62/2011-Lic on 02/01/2025.

The firm submitted application for grant of afresh DML along with requisite documents and panel for following sections was constituted and letter was issued, accordingly;

i. Tablet–(General)
ii. Capsule–(General)

iii. Oral Dry Suspension –(General)

Decision of the Central Licensing Board in its 305th meeting:

The information was noted by the Board.

Case No. 14 **SUSPENSION OF LICENSES OF M/S LISKO PAKISTAN (PVT) LTD. L-10-D, BLOCK 21 F.B INDUSTRIAL AREA, KARACHI AND M/S. THERAMED PHARMACEUTICAL 45 KM, MULTAN ROAD, LAHORE**

A Marasla/letter is received from Honorable Chairman Drug Court Gujranwala Division vide reference No. DC/GRW/282 dated 15/01/2025 addressed to CEO DRAP, which is reproduced under

"Without reference to the Subject Cited above, it is brought into your notice that the case titled " The State Vs. M/S Lisko Pakistan (PVT) LTD. etc" vide judicial No. 452/2022 is pending adjudication before this court for summoning/ appearance of accused company and its employees. The details of which are as under:

- ***i. M/S Lisko Pakistan (Pvt) Ltd. L-10-D, Block 21 F.B Industrial Area, Karachi Through its Nazar Talib.***
- ***ii. Nazar Talib Chief Executive Officer of M/S Lisko Pakistan (Pvt) Ltd. L-10-D, Block 21 F.B Industrial Area, Karachi.***
- ***iii. Muhammad Muzamil Nazar, Director of M/S Lisko Pakistan (Pvt) Ltd. L-10-D, Block 21 F.B Industrial Area, Karachi.***
- ***iv. Naeema Khanam, Quality Control Manager of M/S Lisko Pakistan (Pvt) Ltd.. L-10-D, Block 21 F.B Industrial Area, Karachi.***

The summons as well as non- bailable warrants of arrest of the accused persons have been issued for numerous times but the service of the above said accused persons have not been effected yet which reflect that the said accused persons have deliberately concealed their presence in order to avoid the process of the law.

In view of the supra, you are hereby directed to suspend the drug manufacturing license of M/s Lisko Pakistan (Pvt) Ltd. L-10-D, Block 21 F.B Industrial Area, Karachi, due to non-appearance to face the trial before this court. You are further directed to submit compliance report in this regard before this court till next date of hearing i.e 29.01.2025."

2. Similarly, another marasla/letter is received from Honorable Chairman Drug Court Gujranwala Division vide reference No. DC/GRW/181 dated 15/01/2025 Addressed to CEO, DRAP, which is reproduced as under

"Without reference to the Subject Cited above, it is brought into your notice that the case titled " The State Vs. M/S Theramed Pharmaceutical etc" vide judicial No. 365/2022 is pending adjudication before this court for summoning/ appearance of accused company and its employees. The details of which are as under:

i. ***Theramed Pharmaceutical 45 KM, Multan Road, Lahore, Through its Director, Kauser Jaben.***
ii. ***Kauser Jabeen Director of M/S Theramed Pharmaceutical 45 KM,Multan Road, Lahore.***
iii. ***Abdul Ghaffar, Chief Executive Office of M/S Theramed Pharmaceutical, 45 KM, Multan Road, Lahore.***
iv. ***Attique, Production Incharge of M/S Theramed Pharmaceutical 45 KM, Multan Road, Lahore.***
v. ***Muhammad Asif, Quality Control Incharge/ Warrantor of M/S Theramed pharmaceutical 45 KM, Multan Road, Lahore.***

The summons as well as non- bailable warrants of arrest of the accused persons have been issued for numerous times but the service of the above said accused persons have not been effected yet which reflect that the said accused persons have deliberately concealed their presence in order to avoid the process of the the law

In view of the supra, you are hereby directed to suspend the drug manufacturing license of M/s Theramed Pharmaceutical 45 KM, Multan Road, Lahore. due to non-appearance to face the trial before this court. You are further directed to submit compliance report in this regard before this court till next date of hearing i.e. 29.01.2025.

3. It is pertinent to mention that case of similar nature, case No. 35/2021 regarding suspension of DML of M/s EPharm Laboratories North Karachi, was received form Honorable Chairman Drug Court of Balochistan, Quetta, which was considered in 287th meeting of the Central Licensing Board (CLB), held on 24th June, 2022 and CLB decided as under:

> ***"The Board considering the case and observed that there is no express provision undr the Drugs Act, 1976 and rules framed there under to suspend the Drug Manufacturing Licence of M/S Epharm Laboraotories A-40 Road No.01, Site, Super Highway Industrial Area North Karachi on the basis of Marasla of the Chairman, Drug Court Balochistan, Quetta. The Board further observed that Drug Court Balochistan, Quetta may seek attendance of the accused through Law Enforcement Departments. The Board therefore decided to forward Marasla of the Chairman, Drug Court Balochistan, Quetta to of M/S Epharm Laboratories A-40 Road No.01, Site, Super Highway Industrial Area North Karachi for compliance under intimation to the Board."***

Decision of the Central Licensing Board in its 305th meeting:

The Board in light of its stance already taken in its 287th meeting held on 24th June, 2022 decided that there is no express provision undr the Drugs Act, 1976 and rules framed there under to suspend the Drug Manufacturing Licence of firms on the basis of Marasla of the Chairman, Drug Courts. The Board further observed that Chairman of the Drug Courts may seek attendance of the accused through Law Enforcement Departments.

The Board also decided to forward the Marasla of the Chairman, Drug Court to the Incharge of relevant field office / FID to ensure appearance of the firm before the relevant Court.

Case No. 15 **MANUFACTURING OF CEPHALOSPORIN, PENCILLINS, PENEMS AND HORMONAL PRODUCTS;**

The CLB while confirming the minutes of 297th meeting of the Board in its 298th meeting held on 26th July, 2024 made the following decisions:-

“

- **Manufacturing requirements for Cephalosporin products**

The Board discussed that the operations related to the manufacture, processing, and packing of cephalosporin should be performed in facilities segregated / separate from those used for other drug products for human use. This is due to their potential for causing allergic reactions. Earlier, the Board in its 296th meeting held on 2nd April, 2024 decided that penicillin, carbapenems, and monobactams shall only be manufactured, processed, and packed in segregated / separate and dedicated facilities.

Therefore, regarding new facilities, the Board also decides that cephalosporin shall only be manufactured, processed, and packed in separate and dedicated facilities. A separate manufacturing facility is a design that has, Separate manufacturing area from the main plant for manufacturing of other products, separate HVAC System, Separate Equipment, Separate Workforce, Separate Laundry, Separate Canteen and Separate Washrooms.

The Board Authorized Chairman CLB to issue the renewal of the Cephalosporin / Penicillin/ Penem Sections after receiving the undertaking for establishing a separate dedicated facility for Penicillin/ cephalosporin/Carbapenem injectable within 2 years.

Manufacture of veterinary medicinal products containing penicillin

Based on the explanations provided online by the USFDA and European Union, the Board approved the use of veterinary penicillin in designated areas.

“Animal penicillin and cephalosporin drugs can be manufactured in the same facility as non-penicillin and non-cephalosporin animal drugs. Operations should be performed in dedicated production areas, which can include separate facilities, separate air handling equipment and/or separate process equipment, unless cleaning procedures are established, implemented, and maintained to prevent cross-contamination. Dedicated manufacturing lines within the facility reduce the risk of cross contamination. Risks for cross-contamination are assessed during preapproval inspections (when

applicable) and during routine surveillance current good manufacturing practice (CGMP) inspections of the facility (https://www.fda.gov/animal-veterinary/resources-you/manufacturing-considerations-penicillin-or-cephalosporin-animal-drugs).

"The use of penicillin in veterinary medicine does not present the same risks of hypersensitivity in animals as in humans. Although incidents of hypersensitivity have been recorded in horses and dogs, there are other materials which are toxic to certain species, e.g. the ionophore antibiotics in horses. Although desirable, the requirements that such products be manufactured in dedicated, self-contained facilities (point 3.6) may be dispensed with in the case of facilities dedicated to the manufacture of veterinary medicinal products only. However, all necessary measures should be taken to avoid cross contamination and any risk to operator safety in accordance with the guide. In such circumstances, penicillin-containing products should be manufactured on a campaign basis and should be followed by appropriate, validated decontamination and cleaning procedures". (https://health.ec.europa.eu/document/download/940ed86d-0537-46aa-b43e-1b8f32bc7418_en?filename=anx04en200408_en.pdf)

2. One of the other major decision also taken in the 298th meeting is as under:-

Decision of the Central Licensing Board in 298th meeting:

After careful consideration of the facts on record and a thorough deliberation, the Board has come to the following decision:

1. Products containing androgens, contraceptives shall be manufactured in the segregated dedicated facilities (Separate building).
2. Products containing hormonal substances (other than androgens and contraceptives) may be manufactured in the same building, provided certain conditions are met. Separate entries, HVAC systems, and other precautions should be taken to ensure complete segregation.

In the future, the Board will closely monitor any updates published by any relevant reference regulatory authorities or the World Health Organization (WHO). These updates may warrant further decisions by the Board, depending on the nature and content of the information. By adhering to these guidelines, the Board aims to ensure the safety and integrity of products containing hormonal substances while allowing for their manufacture in the same building. The decision takes into account the specific circumstances and risks associated with such products. It is important to emphasize that the Board will continue to review and reassess the situation as new information becomes available. Any updates to the regulatory framework or scientific discoveries may require adjustments to the Board's decision.

In the Light of above decision, the also decided to approved the grant of renewal of DML of following firm for following sections

S. No.	Manufacturer	Section
1	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi. DML No. 000327 (Formulation).	1. Dedicated Sterile Liquid Injectable Veterinary (Hormone/Steroid)
2	M/s. Hansel Pharmaceuticals (Pvt) Ltd, Plot No.2, Pharma City, 30-Km Multan Road, Lahore. DML No.000581 (Formulation).	1. Tablet Section (Hormone) 2. Liquid Injectable Section (Hormone)
3	M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar. DML No. 000610 (Formulation)	1. Tablet (Steroidal Hormone) Section
4	M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabad. DML No.000616 (Formulation).	1. Tablet Section (Steroidal-Hormone)

Accordingly, in light of the aforesaid decision of the CLB, the Division is performing following functions:-

i. Issuance of renewal letters of pharmaceutical firms having Cephalosporin, Penicillin and Penem Section on submission of undertaking that they will construct separate building for these sections within two years.

ii. No new layout plan or alteration is approved for pharmaceutical firms applying or having Cephalosporin, Penicillin and Penem Sections where separate building as per decision of the CLB is not present.

However, while practicing in light of aforesaid decisions of the CLB, it has been noted that:-

i. Timeline will be different for various companies which may extend upto seven years for those, who have recently got renewals before the decision was taken by the Board in its 298th meeting.

ii. Those pharmaceutical firms, who try to avoid renewal inspections, will have an advantage over others.

iii. Compliance of two years undertaking will be a big issue after completion of two years, which will vary for each and every company.

Therefore, it is necessitated that a fixed cut-off date for Cephalosporin, Penicillin, Penem and Hormones (Androgens and contraceptive) sections, be decided and notified to all pharmaceutical industry and their associations across the board, so that a uniform and harmonized decision is practiced and meanwhile, new layout plan approval of above sections, without separate building shall be stopped and same shall also be notified.

Decision of the Central Licensing Board in its 305th meeting:

The Board, in order to harmonize the applicability of decision as well as to provide the sufficient timeline to the pharmaceutical industry to shift their operations to separate dedicated manufacturing facilities for GMP compliance as per best international practices, made the following decisions:

i. Fix the cut off date to 31st December, 2027 (date was fixed on the special request of representative of PPMA during Meeting) for shifting of operations of existing manufacturing facilities having Cephalosporin, Penicillin, Penem, Oncology (Anticancer) and Hormones (Androgens and contraceptive) sections to a separate, open to sky from all sides, dedicated and self contained building with allied facilities for each class of drugs for above section separately.

ii. From now on, new layout plans will not be processed and approved without separate, open to sky from all sides, dedicated and self contained buildings with allied facilities for each class of drugs for following sections separately for Cephalosporin, Penicillin, Penem, Oncology (Anticancer) and Hormones (Androgens and contraceptive) section.

iii. Meanwhile amendments / revisions in the already approved Layout Plans and sections for Cephalosporin, Penicillin, Penem, Oncology (Anticancer) and Hormones (Androgens and contraceptive) sections shall be processed by the Division of Drug Licensing for the better GMP compliance subject to submission of undertaking for compliance of cut off date of 31-Dec-2027.

Case No. 16: **SITE VERIFICATION REQUEST OF M/S PINNACLE BIOTECH (PVT.) LTD.KARACHI.**

Back Ground

1. The Division of Licensing DRAP has received an application for site verification of M/s Pinnacle Biotech (Pvt.) Ltd. Karachi at Plot no. WH-01-20-A7-A8_Bin Qasim Industrial Park Karachi, Pakistan for the establishment of Pharmaceutical & Nutraceutical Plant. The plot size as per submitted documents is 10 Acres. The firm has provided following documents:

i. Fee
ii. Article of Association
iii. Memorandum of Association i
v. Form-A and Form-29
v. CNICs of Directors
vi. Certificate of Incorporation
vii. Land Documents with copy of Site Map.

The firm was asked which biotech products they intend to manufacture as the name of the firm could be misleading. As per memorandum of association, they intend to do businesses of non-pharma products, nutraceuticals etc. as well. The firm replied as follows:

"Thank you for your query regarding the biotech products that our firm intends to manufacture and clarification required in our Principal Line of Business. As per our Memorandum of Association, the firm is primarily focused on pharma products. However, we understand the need for clarification and would like to provide further information. While biotech products are indeed part of our future expansion plans, our immediate focus is on establishing a specialized plant for Cephalosporin products.

Moreover, for a comprehensive understanding of our firm's business activities, we would like to draw your attention to the SECP Attested Form-A and Form 29. These documents clearly indicate that Pinnacle Biotech (Pvt.) Ltd.'s principal line of business is in the field of Pharmaceuticals. I have attached the SECP Attested Form-A for your reference and clearance."
The matter is placed before the Central Licensing Board for deliberation and directions.

Decision of the Central Licensing Board in 297th meeting:

Board members discussed the request of the firm and decided that "biotech" title cannot be approved for a company that does not manufacture biotech products. The Board advised the firm to change the firm's name before site verification.

Reply of Firm:

With reference to the 297th Central Licensing Board meeting "Board members discussed the request of our firm and decided that "Biotech" title cannot be approved for a company that does not manufacture biotech products. The Board advised the firm to change the firm's name before site verification" We have already communicated you via official response of query dated April, 2024 that "Biotech products are indeed part of our future expansion plans, our immediate focus is on establishing a specialized plant for Cephalosporin products". We want to further clarify that Pinnacle Biotech (Pvt.) Ltd Intends to Manufacture Biotech Products which will be incorporated in next step which is Layout Plan & Section Approvals, currently we are seeking approval for Site verification only. Therefore, the current decision of the 297th Central Licensing Board meeting does not apply to us in this case, as we will manufacture biotech products as well. As you are already aware of extreme shortages of essentials and life-saving drugs, we aim to address and resolve national market shortages of these critical products in our new facility, which includes Insulins, Vaccines, Antibiotics, Anti-viral & Nutrition for Infants and Adults, which will be designed in compliance with WHO & FDA guidelines. We request you to please facilitate us to overcome national market shortages. Our project falls under Federal Government, Special Economic Zone & Board of Investment, we have huge pressure from Prime Minister Office & Ministry of Industries & Production to Initiate Project as soon as possible.

Decision of the Central Licensing Board in 298th meeting

After detailed deliberation, the Board, considering the facts on record, upheld its decision in the 297th meeting held on 2nd May, 2024 that "biotech" titles cannot be approved for companies that do not manufacture biotech products. The Board advised the firm to change the firm's name

Accordingly the request of firm was rejected on eapp.

Fresh Site Verification Application of Pinnacle Biotech (Pvt.) Ltd.

Now M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. WH-01-20-A7-A8, Bin Qasim Industrial Park has applied and submitted a fresh application for site verification as separate entity (without DML) vide application tracking ID RUX-SGS-GE5S with management comprising of Mr. Abdul Rasheed Chohan and Mr. Saad Rasheed Chohan, having same management of the already licensed company M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi., Karachi having DML 000939 and submitted their request as under;

"We would like to setup a pharmaceutical & Biotech manufacturing unit on subject plots (Plot no. WH-01-20-A7-A8_Bin Qasim Industrial Park Karachi). Therefore, you are requested to kindly arrange a survey for verification at your earliest.

Enclosed.

- ***Challan of fee i.e., Rs.9,000/- (Challan No. 705390441885)***
- ***Disclosure of status of firm: proprietorship, partnership, private limited etc.***
- ***Copies of Certificate of Incorporation with SECP, Memorandum and Article of Association, Form-A, Form-21 and Form-29 duly attested by SECP.***
- ***CNIC of Chief Executive Officer / Managing Director /Directors/ Partners.***
- ***Copy of Certificate of Registration.***
- ***Copy of the Allotment letter of the land and Copy of Site map."***

Decision of the Central Licensing Board in its 305th meeting:

The Board based on the submission of the firm that they want ot establish a pharmaceutical and biotech manufacturing units, allowed the Division to proceed for site verification of the applicant firm subject to the fulfilment of other codal formalities.

Case No. 17 TECHNICAL STAFF/QUALIFIED PERSON FOR SUPERVISION OF MANUFACTURING AS REQUIRED UNDER THE DRUGS (LICENSING, REGISTERING & ADVERTISING) RULES, 1976.

FIRM CASES WITH OBSERVATIONS

As per Rule 15 & 16 of Drugs (Licensing, Registering & Advertising) rules, 1976, the manufacture of Drugs shall be conducted under active directions and personal supervisions of qualified staff. Moreover, under rule 19 of the aforesaid Rules, any change in the technical staff shall be immediately notified to the Central Licensing Board, under intimation to the area Federal Inspector of Drugs.

While evaluating the various applications for change of technical person division of licensing has noted certain serious observations as detailed below:

S. No.	Name of Firm	Application for	Observation(s)

1	M/s Wilshire Laboratories (Pvt) Ltd., 124/1 Industrial Estate Kot Lakhpat Lahore under DML No. 000232 (Formulation)	**Production In-charge** Syeda Anita Marium Mehdi W/o Syed Hassan Mehdi CNIC (B. Pharm).	The firm appointed Mr. Ali Asghar Ali as production In-charge on a temporary basis with effect from March 4th , 2024 to March 18th, 2024, i.e., from the last day of Ms. Samra Farooq's tenure as the previously approved production In-charge to the first day of the proposed production In-charge . The firm stated that to ensure continuity in production oversight during the recruitment process for a permanent replacement, they assigned temporary charge to Mr. Ali Asghar (Pharmacist) effective March 4, 2024 to March 18th, 2024. The firm submitted application for approval of Mr. Ali Asghar. However, as per document submitted by firm, Mr. Ali Asghar does not fulfill the requirement in term of relevant experience.
2	M/s Vetec Laboratories, Plot No. 20, Street No. S-5, RCCI, Rawat under DML No. 000894 (Formulation)	**Production In-charge**. Mr. Mubashir Iqbal S/o. Javid Iqbal (Pharm. D).	The previous production In-charge Mr. Amjad Ikram resigned on March 24, 2022 and the proposed production In-charge commenced duties on May 6, 2022. The firm submitted an **apology** for the delay. The firm reply was unsatisfactory, subsequently in light of power delegated by CLB in its 292nd meeting held on 4th October, 2023, Show cause was issued to the firm for rectification of the said clarification. In response to the show cause notice, the firm acknowledged receiving Show Cause Notice No: -F.1-34/2016-Lic, dated 13th March 2024. They expressed regret for the late submission of documents by their Technical Staff (Production Pharmacist) due to unforeseen circumstances. The firm apologized and requested approval for the documents of their Production In-charge , assuring that such delays would not recur in the future.

3	M/s Unexo Labs (Pvt) Ltd., 9.5-Km Sheikhupura Road Lahore, 000065 Formulation	**Production In-charge.** Mr. Nadeem Ahmad Akhtar s/o Ahmad din (Pharm-D)	The Firm was asked to clarify that the date of death of the previously approved Production In-charge was October 17, 2023, while the proposed production In-charge has been appointed as the new In-charge effective from April 15, 2024. What was the last working day of the deceased production In-charge. Additionally, what was the status of manufacturing activity during the said period? The firm has submitted their response which is reproduced as under: "The last working Date of the previous approved Production In-charge was 14th of October 2023 (Saturday). The new Production In-charge was selected and joined on the 20th of December 2023. The clearance from the current Production In-charge previous employer took till April 2024, hence the stated joining date of 15th April 2024, along-with the supporting documents. The absence of Production In-charge necessitates the temporary delegation of responsibilities to ensure continuous and efficient production operations. These duties are assumed by the individual who has sufficient experience and is well-versed in the production processes, regulatory requirements, and standard operating procedures (SoPs). From 17th October till 19th of December 2023, the production was being supervised by the Plant Manager (Pharmacist with experience of 25+ years) and the assistant Production In-charge (Experience of 09 years in Production)." Accordingly, firm was asked to submit another application with all relevant documents and application processing

			fee for approval of production In-charge (Plant manager) for the intended period. The firm submitted application for approval of Production In-charge Mr. Aqeel Ahmed (Plant manager) for the duration 17-10-2023 to 14-04-2024. The application is complete and the proposed Production In-charge fulfills the requirement of the Rule 16 of Drugs (L,R&A) Rules, 1976 in term of academic qualification and relevant experience
4	M/s Citi Pharma (Pvt) Ltd., 3.5-Km Head Balloki Road Phool Nagar Kasur DML No. 000429 (Semi Basic Manufacture)	**Production In-charge** Khurshid Alam Duri Aman (B. Pharm)	The firm was asked to submit clarification for the gap 05/05/2023 to 02/03/2024 i.e., from last day of previous approved production In-charge and first day of proposed production In-charge. The firm replied that the previous Production In-charge resigned on May 5, 2023. They submitted an application for approval of the proposed Production In-charge Mr. Ahmad Raza S/O. Mr. Talib Hussain CNIC No. 35301-6382056-1 (BS Chemical Engineering) (Semi-Basic) on June 12, 2023, which was subsequently rejected by DRAP on February 29, 2024 (as he does not fulfill the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of relevant experience. The new proposed Production In-charge commenced duty on March 2, 2024. We resubmitted an application for approval of the Proposed Production In-charge on May 3, 2024.
5	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat 000955 Formulation	QC In-charge Shafiullah S/o. Muhammad Atiq (Pharm-D)	The proposed production In-charge was appointment in 1st January, 2023, while the application for approval was made in 1st May, 2024 and firm was ask to submit clarification in this regard.

			The replied that M/s Pine pharmaceuticals is new license facility, they are working in R&D till date, due to their negligence they have applied late for approval of technical staff (QC In-charge). they further submitted that this type of negligence will never happen again. In the light of decision of the Central Licensing Board (CLB) in its 292nd meeting held on 4th October, 2023, show cause was issued to the firm, accordingly. The firm's reply to the show cause notice indicated that the earlier QC In-charge had resigned with only 15 days' notice. Due to the short time frame, hiring a new QC In-charge was challenging. Instead, they assigned additional responsibilities to Fazal Ul Rehman, the Deputy Quality Control Manager with 9 years of experience in the Quality Control department. During the 45-day gap between the resignation and the appointment of the new QC In-charge, all QC work was efficiently managed by the Deputy QCM, ensuring uninterrupted technical staff support. The attachment includes evidence of the Deputy Quality Control Manager's appointment and acceptance letter.
6	M/s Focus & Rulz Pharmaceuticals (Pvt), 44-Industrial Triangle, Kahuta Ltd, Islamabad. DML No. 000628 (Formulation)	<u>QC In-charge</u> Zia Ur Rehman Zia S/o. Khan Sherin (M. Sc. Chemistry)	The proposed technical person fulfills the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience and may be approved. however, it is pertinent to mention that upon initial evaluation of application for approval of QC In-charge, it was observed that proposed QC In-charge was appointment in 01-02-2024, while the previous QC In-charge has resigned on 25-01-2024 and firm was asked to

			submit clarification regarding absence of QC In-charge during the period from 26-01-2024 to 31-01-2024 in this regard. *"From 26-01-2024 to 29-01-2024 Mr. Faisal was available in the office. On the 30th and 31st Mr. Faisal was available on call due to some issues which prevented him from joining the office. On the 30th and 31st our GM of Quality operation (Muhammad Irfan Bhatti) handled office matters"*
7	M/s N.S Pharma, Plot No.576-577, Sundar Industrial State, Lahore. DML No. 000869 (Formulation)	Production In-charge Mr. Naveed Ahmad S/o Abdul Majeed (Pharm-D)	The proposed qualified person fulfills the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience. It is pertinent to mention here that the firm had appointed him w.e.f 18-08-2021 and filed application for his approval on 28-01-2022. Application was incomplete and shortcomings were conveyed to the applicant. Now, the firm has replied and completed the application, however, the firm is manufacturing without approved Production In-charge.
8	M/s N.S Pharma, Plot No.576-577, Sundar Industrial State, Lahore. DML No. 000869 (Formulation)	Quality Control In-charge Ms. Naurina Manzar D/o Manzar Qureshi (M. Sc Chemistry)	The proposed qualified person fulfills the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience. It is pertinent to mention here that the firm had appointed him w.e.f 09-06-2021 and filed application for his approval on 28-01-2022. Application was incomplete and shortcomings were conveyed to the applicant. Now, the firm has replied and completed the application, however, the firm is

			manufacturing without approved Production In-charge .
9	M/s May & Baker (Pvt) Ltd, 43-Km Main Multan Road, Lahore. DML No. 000953 (Formulation)	Quality Control In-charge Mr. Muhammad Aslam S/o Muhammad Faazil (M. SC Analytical Chemistry)	The proposed qualified person fulfills the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience. It is pertinent to mention here that previous QC In-charge Ms. Haniya Hussain resigned on 04-05-2024. The firm appointed Ms. Nadia Saeed on 05-05-2025 but she could not join. Then, Muhammad Aslam joined as QC In-charge w.e.f 07-05-2024.
10	M/s Ambrosia Pharmaceuticals, Plot No. 18, Street No. 9, National Industrial Zone, Rawat. DML No. 000561 (Formulation)	Quality Control In-charge Mr. Malik Zaheer Ahmed.	Previous QC In-charge of the firm resigned w.e.f 16-11-2023. The firm promoted Ms. Isma Akhtar as QC In-charge w.e.f 16-11-2023 and submitted her application to Licensing Division for approval. Ms. Isma Akhtar resigned from the firm on 31-12-2023. However, the firm did not notify to this office of her resignation and appointment of Mr. Malik Zaheer Ahmed on 01-01-2024. The firm has clarified their position which is reproduced as under: "*Our previous QCM before Ms. Isma Akhter, Ms. Nusrat Zaheen submitted her resignation on 15.10.2023 with 1-month notice period. Her resignation was accepted with her last day of working as per notice period on 16.11.2023. Ms. Isma Akhter who was already working with us was promoted as QCM effective 15.11.2023*

			However, Ms. Isma Akhtar got a better opportunity and resigned on 30.11.2023 with 1-month notice period. Her resignation was accepted with her last day of working as per notice period on 31.12.2023. Mr. Malik Zaheer Ahmed was offered employment during this notice period and he joined us as QCM on 01.01.2024. *There was some issue with our online portal on EApp because of which we were not able to file the application online. When this issue was resolved we first filled the application of Ms. Isma Akhter and were awaiting approval of the same so that we could then file the application for Mr. Malik Zaheer Ahmed as QCM so that all records are updated with proper timeline of QCM to DRAP."*
10	M/s S.J & G. Fazul Ellahie (Pvt) limited. E-46, S.I.T.E., Karachi DML No. 000083 (Formulation)	Quality Control In-charge Syed Abbas Haider Rizvi	The previously approved QC Incharge resigned on 29-06-2024 whereas the date of Joining of new appointee is 08-07-2024 The firm has justified that to mitigate the gap created by Ms. Sadia's resignation on June 29, 2024, Mr. Khurram, our Manager of Quality Control, temporarily assumed the responsibilities of the QC In-charge. With the scheduled joining of Mr. Abbas on July 8, 2024, as the new QC In-charge, we have submitted all required documents for his approval, ensuring our manufacturing operations. The firm was asked to provide the copies of degree and experience certificates of Mr. Khurram, Manager Quality Control, who temporarily assumed the responsibilities of the QC In-charge in the gap period. They had submitted the same which shows that Mr. Khurram has a degree of Msc. from

			Karachi University and he has experience in QC department for more than 12 years. The approval of new incumbent was granted by the Secretary CLB. However, regarding working by manager QC in absence of QC Incharge is placed for decision by CLB on such cases.
11	M/s SPL Pharmaceutical Pvt Ltd., Plot No.4, Phase III, Hattar Industrial Estate Hattar DML No. 000605 (Formulation)	Production In-charge Saddam Hussian	The firm has previously applied for change in technical staff on 20-08-2024 which was rejected due to the shortage of experience of newly appointed production Incharge. The firm later applied afresh for approval of newly proposed production Incharge. The application was evaluated, and firm was asked to; "Justify the manufacturing without qualified staff for 1-year time as the previously approved Production Incharge resigned on 30-10-2023 whereas the date of Joining of new appointee is 20-10-2024. Considering your previous application which upon your request have been rejected, the gap period is still 8 months and 20 days' as the previously approved Production Incharge resigned on 30-10-2023 whereas the date of Joining of previously applied Production Incharge was 20-07-2024." Now the firm has submitted that during that time they are not fully functional and were busy with renewal of their DML and they were not doing any production activity during this time period. The approval of new incumbent was granted by the Secretary CLB. However, case regarding absence of

			technical staff during the gap period is placed for decision by CLB.
12	M/s Mediflow Pharmaceutical (Pvt) Ltd. Plot: ID -100, Sector 30 Korangi Industrial Area, Karachi. DML No. 000822 (Formulation)	Quality Control In-charge Mohsin Ali Rind	The previously approved QC Incharge resigned on 25-06-2024 whereas the date of Joining of new appointee is 12-07-2024. The firm has submitted that "In the absence of QC Manager, their Assistant QC Manager (Mr. Babar Rustam) was responsible to authorize the release of any product / batch / material during operation of all function of QC department" as justification for manufacturing without qualified staff for approx. 2 weeks' time. The same has been written in the JD of the Assist QC manager at Point No. 2.24. The firm was then asked to provide attested copies of degree and experience certificates of the Assistant Quality Control Manager who was responsible to authorize the release of any product / batch / material during operation of all function of QC department during the gap period. The firm has provided the copies of degree and experience certificate of their Assistant QCM. He is pharmacist having more than 8 years' experience in Quality Control department. The approval of new incumbent was granted by the Chairman CLB. However, regarding working by Assistant QCM in absence of QC Incharge is placed for decision by CLB on such cases.
13	M/s Bajwa Pharmaceuticals (Pvt.) Ltd, 36-km, Lahore Gujranwala	Production Incharge Mr. Muhammad Faizan Hassan (Pharm-D)	The previous Production Incharge of firm resigned w.e.f 30-09-2024 and appointee joined on 15-11-2024. The firm clarified that during the interim period (1st October to 14th

	Road, Khori, District, Sheikhupura. DML No. 000805 (Formulation)		November 2024), production was managed by Ms. Zubaria Nazir, the Deputy Production Manager. Ms. Zubaria Nazir, who holds a Pharm-D and has been with the company since 2019, was promoted to her current role in January 2023. However, as per experience letters the Deputy Production Manager, who was authorized during the gap period have experience of approx. 5.5 years.
14	M/s Epoch Pharma Plot No. 83-85, Sector 15, Korangi Industrial Area, Karachi DML No. 000425 (Formulation)	Quality Control In-charge Mr. Abdul Jabbar Khaskheli (approved as new QC Incharge)	The newly appointed Quality Control In-charge fulfils the requirement of Rule 16 of Drugs (Licensing, Registering & Advertising) Rules, 1976 in terms of academic qualification and relevant experience. However, the previously approved QC Incharge resigned on 31-08-2023 whereas the date of Joining of new appointee is 18-07-2024 for which the firm has provided following justification: *"It is to inform you that the firm was in process of change of management & under renovation, hence not involved in manufacturing of any registered product during the period mentioned by you without technical staff."* The approval of new incumbent was granted by the Chairman CLB. However, the case regarding gap period of ONE year is placed for decision by CLB on such cases.

It is pertinent to mention that when an approved technical person resigns or terminated by the firm and there is no availability of suitable technical/qualified person to be appointed as permanent/regular

technical person, and the provision for assigning charge to any technical person on **interim** basis is not provided under the Drug (Licensing, Registering and Advertising) Rules-1976.

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation decided that

a. The proposed technical person is approved as they fulfill the requirement of the Rule 16 (or 15) of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience, accordingly from the date of joining.
b. Serve Show Cause Notice to the above firms (those firms to which showcase notice have not been issued) under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 15/16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License of above firms may not be suspended or cancelled by the Central Licensing Board.
c. Refer the case of interim/temporary/alternative appointment of technical person to the DRAP Authority for is recommendations.
d. Refer the case for not complying the provision of Rule, 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 to the Legal affair division for their comments

Decision of the Central Licensing Board in its 305th meeting:

The Board deferred the case for deliberation in the next meeting as the Law member was attending the meeting through virtual link and comprehensive legal deliberations were required in the matter.

QUALITY ASSURACNE AND LABORATORY TESTING DIVISION	
S. No.	**Cast Title**
01	Unregistered Diclocin Forte+ Tablets Mfg By M/S Combitic Global Caplet Pvt Ltd. India)
02	Grant of drug manufacturing license of M/s Glims Pharmaceutical (pvt) Ltd., Risalpur
03	M/s Fassgen Pharmaceutical, Hattar- GMP Non-Compliance- Updated report thereof

Case No. 01: <u>UNREGISTERED DICLOCIN FORTE+ TABLETS MFG BY M/S COMBITIC GLOBAL CAPLET PVT LTD. INDIA)</u>

FID, Karachi visited the premises of M/s. Abdullah Medico & General Store, Minhar Mansion, Ground Floor, Bezoriji Street Fed; iqbal Street near Civil Hospital Emergency Gate Karachi on 01-11-2022 and took the following sample of suspected drug along with other drugs. Detail is as under:

Name of Drug	Reg. No.	Lot No/ Batch No.	Mfg. Date	Exp. Date	Claimed to be Mfg. by
Diclocin Forte + Tablets	Nil	DTF-1199	01 2220	12/2023	MA. Combitic Global M/s. Caplet Pvt Ltd M-15, D-2. D-3, Ind Area Sonepat –

2. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said samples as **"UN-REGISTERD DRUG PRODUCT"** vide their test report No. KQ -11-22-000218 dated 28th November, 2022.

3. FID issued explanation letter to M/s. Abdullah Medicos & General Store, Karachi with subsequent reminder I and II, but no reply received so far.

4. FID concluded that in the light of FGA, CDL, Karachi test report No. KQ -11-22000218 dated 28th, November 2022 M/s. Abdullah Medicos & General Store, Karachi was found involved in selling of un-registered drugs product and violated the section 23(1)(a)(vii), 23(1Xa)(x), 23(1)(b), and 23(1)(i) of the Drugs Act 1976. Punishable under section 27 (1) (a), 27(1) (b) & 27(4) of the Drug Act, 1976.

5. **FID Recommendations:**

FID recommended that following accused persons may be prosecuted in the Drug Court Karachi on violation of section 23(1)(a)(vii), 23(1Xa)(x), 23(1)(b), and 23(1)(i) of the Drugs Act 1976, punishable under section 27 (1) (a), 27(1) (b) & 27(4) of the Drug Act, 1976.

i. M/s. Abdullah Medicco & General Store, Minhar Mension Ground Floor, Bezonji Street near Civil Hospital, Emergency Gate, Karachi.
ii. Sohail Ahmed S/o Nazeer Ahmed (Proprietor) CNIC # 42301-8471356-5
iii. Musheer Ahmed (in charge store) CNIC No # 42301-8627028-7,
iv. Mr. Shamser S/o Abdul Channa (Qualified person)

6. Division of QA&LT issued a Show Cause Notice No. F. 04-26/2022-QC dated 09th July, 2024 under Section 41 of the Drug Act 1976 to the accused persons.

7. M/s. Abdullah Medicco & General Store, Karachi through Channa law Associates, Karachi submitted their reply vide letter No. 125/2024 dated 18th July, 2024 with following points:

1. Lack of Knowledge of Drug Recovery:

It was shocking for our client that some unregistered drug was seized from his establishment as earlier to this show cause notice no letter or explanation was issued to our client as owner/proprietor of the establishment as such it was not within our client's knowledge that any such drug, specifically Diclocin Forte Tablets, was ever recovered from his store by the Federal Inspector of Drugs (FID). Our client were unaware of any inspection or recovery of

this unregistered drug. The notice under reply shows that it was addressed to our client so also Musheer Ahmed (Incharge Store) and Shamsheer (Pharmacy Qualified Person), they both were our client's employees and have left job about two years ago.

2. ***Personnel Changes and Inventory Check:***

The person who was incharge of the store as mentioned in the show-cause notice is no longer employed with our client. Our client have conducted a thorough check of inventory records andfound no evidence that this drug was ever in his/establishment possession. This includes the absence of any invoices, receipts, or other documentation related to Diclocin Forte Tablets.

3. ***Non-Receipt of Previous Communications:***

As the proprietor, this is the first time that our client has received any such notice. Our client has not received any prior explanation letters or subsequent reminders from the Federal Inspector of Drugs (FID) regarding this matter. Although, the show cause notice shows some dates on which the explanations were sent but the notices are silent about the person to whom the said letters were issued. The show-cause notice dated 09th July 2024 is the first and only communication our client have received concerning this issue. Our client assure you that had our client received such communications, our client would have promptly responded and cooperated fully with the investigation.

4. ***Commitment to Compliance:***

Our client has been operating in this business for over 25 years and have consistently adhered to legal and regulatory standards. Throughout his history, our client has never been involved in any illegal or unlawful activities. This is the first instance where our client has received a show cause notice without any prior correspondence or explanations. Had our client received any such letters or explanations, the matter would have been promptly addressed and resolved. Abdullah Medicos & General Store remains committed to adhering to all regulatory requirements. Our client conducts his business with the utmost integrity and are dedicated to maintaining compliance with DRAP regulations. Our client has since reviewed his processes to ensure that such oversights do not occur in the future. Additionally, we are willing to cooperate fully with the DRAP to resolve this matter amicably.

5. ***Request for Consideration:***

Given the circumstances, we kindly request that the Board consider our client's circumstances, we kind position and the fact that this oversight was unintentional. We propose that instead of prosecutorial action, our client be allowed to rectify any procedural lapses under your guidance.

We hope that the above points will be taken into account and the subject show- cause notice may be vacated. Our client is open to any further inquiries or inspections that may be deemed necessary. We also request the opportunity for a personal hearing to present our case in detail if required.

6. Division of QA&LT issued a notice of personal hearing vide letter F.03-44/2024-QALT (302-CLB) dated 13th November, 2024 under Section 41 of the Drug Act 1976, to following accused on violation of section 23(1)(a)(vii), 23(1Xa)(x), 23(1)(b), and 23(1)(i) of the Drugs Act 1976, punishable under section 27 (1) (a), 27(1) (b) & 27(4) of the Drug Act, 1976.

i. M/s. Abdullah Medicco & General Store, Minhar Mension Ground Floor Bezonji Street near Civil Hospital, Emergency Gate, Karachi.
ii. Sohail Ahmed S/o Nazeer Ahmed (Proprietor) CNIC # 42301-8471356-5

iii. Musheer Ahmed (in charge store) CNIC No # 42301-8627028-7,
iv. Mr. Shamser S/o Abdul Channa (Qualified person)

Proceeding and Decision of 302nd Meeting of CLB

8. The case was presented before the Central Licensing Board. It was informed that Show Cause notice and personal hearing letters were issued to the accused persons. The Board deliberated that no seizure was made by the FID. No one appeared before Board neither any written communication from accused persons was received.
9. The Board, after considering the facts of the case and after thorough deliberations, decided as follows:

    i. Final letter for personal hearing will be issued to accused persons.
    ii. Additional Director, DRAP, Karachi will be asked for ensuring the delivery of personal hearing letter to accused.
    iii. Reasons will be asked from the FID for not seizing the recovered un-registered drug.

10. In compliance to the decision of the Board, Area Federal Inspector of Drugs Karachi was communicated the directions of Board vide letter F. No. 3-44/2024-QALT(302-CLB) dated 10-01-2025. Till date no reply has been received from area FID Karachi.

11. Notice of personal hearing as directed by the Board was also issued to the accused as mentioned in para 7 vide letter F. No. 03-44/2024-QALT(302-CLB) dated 16-01-2025 and service of said notices was ensured through Additional Director DRAP Karachi.

Proceedings and Decision of 305th meeting of CLB:

The Board was apprised regarding the compliance of decisions taken in its 302nd meeting. The accused neither by themselves nor through any counsel appeared before the Board. Therefore, keeping in view the aforementioned, the Board decided as under:

1. Provide a final chance of personal hearing to the accused in the forthcoming meeting of the Board.
2. The then Area Federal Inspector of Drugs Karachi will also be once again directed to provide the reason for not seizing the recovered un-registered drug. In case no response is received, FID be called for personal hearing in the next meeting.

Case No. 02: GRANT OF DRUG MANUFACTURING LICENSE OF M/S GLIMS PHARMACEUTICAL (PVT) LTD., RISALPUR.

M/s Glims Pharmaceutical (Pvt) Ltd., Risalpur, through Mr. MoinudDin submitted that they have purchased the said firm in the year 2014. It is further requested for the issuance of Drug Manufacturing License.

2. The case of M/s Glims Pharmaceutical (Pvt) Ltd., Risalpur is summarized as under;

    a. The firm M/s Glims Pharmaceutical (Pvt) Ltd., applied for site verification for establishment of Pharmaceutical Unit situated at Plot No 12 Industrial Estate, Resalpur. Management of the firm was as under;

        i. Arbab Muhammad Iqbal
        ii. Farrukh Mahmood Gilani
        iii Haji. Shib Gul

iv. Mr. Mushtaq Ahmed
v. Haji Noor Gul

b. The said site and LOP for said Unit at said plot was approved, accordingly.
c. The firm applied for the grant of DML as per Form-1 and panel of experts/inspectors was constituted for the said purpose.
d. The constituted panel conducted the inspection of said firm and a panel inspection report was submitted and the case was placed in 225th meeting of CLB held on 22-10-2010. The case presented in 225th meeting "**Grant of Drug Manufacturing License of M/s Glims Pharmaceuticals - Not Recommended** is reproduced as under;

The inspection of M/s Glims Pharmaceuticals, Risalpur was conducted by a panel comprising Prof. Dr. Zafar Iqbal, Member CLB, Dr. Tariq Siddique, FID Peshawar and Mr. Nematullah Khan, ADC Peshawar for grant of drug manufacturing license. The panel has reported as under:

i. Civil work is incomplete which includes installation of aluminum doors, windows, glass walls, concealment of electrical ducts and electrical points.
ii. Connection of electricity has not been acquired. Most of the equipment in quality control laboratory were not available. Requisite tools in raw material store and dispensing area were not provided.
iii. Documentation and SOPs has not been prepared.

The panel has reported that the FIR was launched against all the directors of the firm for their involvement in manufacturing of spurious drugs and the case is under investigation by the police. However, Dr. Azam Khan introduced himself as one of the new owners of the unit and informed that all the previous management has been changed.

Keeping in view the above facts, panel has decided to re-inspect the facility after completion of requisite civil work, installation of equipments / machinery appointment of technical personnel and an uptodate Form-29 issued by Securities and Exchange Commission of Pakistan with the approval of Sarhad Development Authority regarding confirmation of change in management.
The Board discussed the case in detail and decided to pend it.

2. Moreover, Mr. Moinud Din, claims that he is the Chief Executive/Director of M/s Glims Pharmaceutical (Pvt) Ltd., Risalpur and requested for withdrawal of documents. He has requested which is reproduced as under;

"It is stated that due to some unfavorable circumstances we are not in a position to process our case, therefore all members of the company decided to withdraw the documents. In this regard a resolution of the meeting of the board of directors is enclosed herewith for your perusal and necessary action, please."

4. Meanwhile another request was received from Mr. Moinud Din of M/s Glims Pharmaceutical (Pvt) Ltd., Risalpur wherein he has submitted request for legalization of premises and stated as under;

"That with the great reverence and veneration it is submitted that the pharmaceutical request for regularization and clearance of the premises whereby the Pharmaceutical is caring its business activity but in response, the application was not acceded to, for the simple reason, that case has been registered against the directors of the company thereafter the company waited for the result / fate of the said criminal case. The case was finally decided by the competent court vide judgment dated 09/10/2018 and culminated in the acquittal of the accused nominated therein.
That the judgment if the acquittal had gain finality as no appeal etc. was filed by the state and hence the acquittal tantamount to certificate of innocence (Copy of the judgment dates 09/10/2018 is attached)

That in the present scenario the company has the honor to ask for regularization, legalization and clearance of its premises.
It is therefore most humbly requested that this application be considered sympathetically and the needful be done and will be highly obliged."

5. Mr. Moinud Din requested for the further processing in the matter and issuance of Drug Manufacturing License.

7. In light of above, Area FID, DRAP Peshawar was requested to obtain certified true copy of the decision(s) of the Honorable Drug Court, Peshawar about instant case.

7. Additional Director/FID-I, DRAP Peshawar in response to this office letter, submitted certified true copy of the decision(s) of the Honorable Drug Court, Peshawar about instant case vide letter No. 10-46/2009-Glims-DRAP-342 dated 26/01/2022.

8. Decision of Honorable Drug Court, Peshawar passed on 09/10/2018 is reproduce as under;

"Accused Haji Sahib Gul, Mushtaq Ahmad and Haji Noor Gul with their counsel present while rest of the Iram Rehman, Imran Khan and Naveed Iqbal are absconding. PP for State present. Arguments heard and case file/record perused. Vide separate judgment (placed on file), the prosecution has not been able to prove its case/charge against the accused, hence, accused Haji Sahib Gul, Mushtaq Ahmad and Haji Noor Gul are acquitted of the charges leveled against them on the grounds mentioned in the judgment. Their bonds shall stand discharged. Prima facie case exists against the absconding accused Iram Rehman, Imran Khan and Naveed Iqbal, therefore, they are declared proclaimed offenders. Perpetual NBWs of arrest be issued against them with directions to DPO concerned to include their names in the register of Pos. Case property be dealt with by the prosecution according to law. File be consigned to record room after its completion."

9. In light of above, the firm was asked to submit application from grant of DML on prescribed Form-1A duly signed and stamped by the management of the firm along with requisite documents/annexures dully attested/notarized and prescribed fee Rs 150,000/=

Decision of the Central Licensing Board in 285th meeting

10. The Board, after deliberation, considered the facts and decided that FID, DRAP, Peshawar may be asked to provide Memo of recovery and copy of case file for consideration of the Board.

11. In light of above decision of the Board, the FID, DRAP, Peshawar submitted Memo of recovery and copy of case file.

Decision of the Central Licensing Board in 288th meeting

12. The Board observed that a decision had already been taken in 225th meeting of CLB held on 2210-2010.The Board while considering the facts on the record decided to refer the case to QA& LT Division, DRAP, Islamabad for further processing in the matter. The Board further decided that QA& LT, Division, DRAP, Islamabad will seek legal opinion from Legal Affair Division, DRAP on the instant matter and place the case before the Board in its upcoming meeting.

13. In compliance to the decision of 288th meeting of the Board, opinion of legal affairs was sought in the instant matter as the fate of the premises has not been discussed in the said decision.

14. Opinion of the division of Legal Affairs is given as under:

"Reference to preparas, this division evaluated the complete case and judgment of the Drug Court, Peshawar. Three persons have been respectably acquitted and 3 have been declared proclaimed offender. The company i.e M/s Glims Pharmaceutical was not charged with any offense and also automatically acquitted. Therefore, Licensing Division

may process the case for grant of DML afresh to the extent of those management who are acquitted from the case only. "

15. Keeping in view the opinion of the Division of Legal Affairs, DRAP, Islamabad, the matter is placed before the board, in compliance to the decision of 288th meeting of the Board.

Proceedings and Decision of 305th meeting of CLB:

The Board keeping in view the details of the case and opinion of the Legal Affairs Division decided that the application for grant of DML to M/s. Glims Pharmaceuticals (Pvt.) Ltd., Risalpur shall be processed as a new application by the Division of Drugs Licensing, DRAP, Islamabad.

Case No. 03: INSPECTION OF M/S FASSGEN PHARMACEUTICAL, HATTAR.

I. BACKGROUND

Inspection of the firm. A surprise inspection of M/s. Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar was conducted on 08.02.2021 in order to evaluate adherence of the firm toward cGMP. The FID during inspection, noticed following observations: -

Change Rooms: -

i. Overall maintenance of change rooms is required with reference to smooth flooring, walls, cupboards and ceiling.
ii. Washing areas in change rooms needs to be closed permanently or removed to avoid contamination.
iii. Implementation of SOPs for entry / exit by personnel needs to be implemented strictly. It was observed that staff / workers do not follow change room protocols. Training of staff is also required in this context.
iv. Air curtains / doors of change rooms need cleaning / maintenance.
v. Re-organization of change rooms to better fulfill their purpose.

Storage Areas: -

i. Proper receiving bay with necessary equipment to remove dust / dirt from the incoming materials outer packing.
ii. Proper sampling booth as well as dispensing booth for raw material sampling / dispensing with LFH to avoid any contamination.
iii. Segregated Rejection / Recall area needs to be designated with entry from outside the warehouse with proper lock and key and authorized entry system.
iv. Storage conditions of primary packing materials need to be improved i.e., properly packed to avoid dust / dirt / moisture and properly labeled.
v. Materials flow process needs to be improved in stores with reference to quarantine / approved areas. Necessary steps need to be ensured to avoid mix-ups.

Tablet (General Section): -

i. Tools of compression machines needs to be placed in SS boxes with proper cleaning procedure and storage.

ii. Cleaning SOPs needs to be revised with defined timelines for equipment to be cleaned and re-cleaning time if the cleaned equipment is not used for several days.
iii. Fluidized bed dryer is provided, however, only single bag is being used. The firm is advised to provide at least molecule wise FBD bag with proper washing / cleaning SOP for avoiding cross contamination.
iv. Overall area maintenance is required w.r.t. floor, walls, ceiling, electrical panels etc.

Capsule and Dry Suspension (Ceph Section): -

i. In capsule area, general maintenance of the area for smooth surfaces, electric panels and proper storage of filled capsules in SS containers.
ii. Bottle blowing procedure in dry suspension area needs to be improved with reference to quality of blowing air, visual checking of bottle and staging / transfer of cleaned bottles to filling area.
iii. Nitrogen purging procedure needs to be improved and clean Nitrogen supply through filtration is required.
iv. Optical checking counter needs to be provided for bottles after blowing for detection of any contamination / glass particles / broken glass bottles etc.
v. Moisture control measures need to be improved considering the moisture sensitivity of Ceph products.

"Common observations of above four oral dosage form sections which also need to be addressed;"

a) Temperature / humidity monitoring with proper record keeping in all areas.
b) Fulfilling Class-D air requirement via documented / implemented HVAC system.
c) General cleanliness and maintenance of areas / equipment and allied facilities.

Capsule and Dry Suspension (Ceph Sections): -

i. Validation of HVAC system in the area.
ii. Sterilization process validation of vials after washing.
iii. The firm has provided R.O. water for vial washing, however, final rinsing with distil water is recommended.
iv. The firm has provided vial cool down area after sterilization through double door sterilizer. The cool down area is of class B as per firm's information. The product is not terminally sterilized and placing sterile vials in class B without validation data poses risk to the product. Hence, the firm was advised to review their process flow. After sterilization, vials only be exposed in class A area. Option of laminar flow hood or duly designed transfer trolley having laminar flow with continuous power supply up to class A vial filling / stoppering area was discussed by the firm for rectifying the issue.

Quality Control: -

i. The firm has operational HPLC but testing methods of registered products have not been shifted on HPLC method provided in latest pharmacopeia(s). The firm is advised to immediately take action for shifting their testing methods to latest pharmacopeial methods.

ii. The firm has two stability chambers. Stability studies are being performed but protocol for study design in not properly prepared. Stability studies protocol needs to be devised in light of ICH guidelines and according studies should be conducted for the reliability of data.
iii. Separate electricity backup must be provided for all the sensitive equipment in QC along with UPS backup.
iv. Stepwise purchase of Reference Standards from authentic source is also recommended.
v. Authenticity of data must be ensured through data loggers / software based systems.

Quality Assurance: -

"The firm has appointed one QA personnel working in the QC department but not share qualification of QA person. The firm is advised to;"

i. Establish separate QA department independent of QC.
ii. Strengthen QA department with well experienced staff to develop proper Quality Management System and validation / qualification purpose.
iii. QA department must be assigned the task of master validation plan. Cleaning validation and validation of HVAC system especially in dry vial Injectable needs to be started immediately to avoid contamination / cross contamination of pharmaceutical products.
iv. System of self-inspection needs to be strengthened.

Personnel: -

i. Training of staff needs to be done for better understanding of cGMP guidelines. Trainings on firefighting system / emergency situation may also be performed.

Conclusion: -

"*Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection, the firm is considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under. Further, section wise observations need to be addressed for improvement in their manufacturing unit.*"

In view the observations noticed by the FID, the firm was issued **explanation letter** for and directed to present their reasons serious violations and to submit compliance report of the rectification of the observations.

M/s. Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar, with reference to this office letter of even No. dated 18.03.2021, submitted plan for rectification of the observations which were observed in GMP inspection of their firm conducted on 08.02.2021.

It was observed during the evaluation of compliance report submitted by the firm that they are not familiar with the Pharmaceutical Quality System (PQS) as the submitted documents lack the basic components i.e. the CAPA is not as per standard format as both corrective action and preventive actions are placed in one head. Secondly Risk assessment and mitigation has not been done to ascertain the impact of changes done. Root Cause Analysis also not preformed. Furthermore, the compliance report does not have any evidence to support whether or not the rectifications have been made.

In view the reply of the firm, the Additional Director, DRAP, Peshawar was requested to direct the area FID to guide the manufacturer on the subject matter and conduct an inspection to verify the status of the rectification

II. Initial Seizure and Request for Safe Custody

On 28.11.2022, Mr. Faisal Shehzad, Additional Director/FID-I, DRAP, Peshawar, issued a letter (No. 10-166/2021-Fassgen-DRAP) regarding the seizure of drugs under Section 18(1)(f) of the Drugs Act 1976. The letter detailed the non-compliance issues discovered during the inspection, which included significant deviations from Good Manufacturing Practices (GMP). These deviations posed potential risks to product quality and patient safety. Additionally, the letter requested the safe custody of the seized drugs and an extension of the "Not to dispose of" period for three months under Section 18(1)(i) of the Drugs Act 1976 to allow for further investigation and resolution of the issues. The request for grant of extension in not to dispose of period was acceded in light of the Decision of 273rd meeting of CLB.

In the above report GMP non-compliance including lapses in documentation, inadequate quality control procedures, improper handling and storage of raw materials, and failure to maintain a clean and hygienic production environment were also reported. These violations necessitated immediate corrective measures to prevent any adverse impact on product quality and patient safety It underscored the importance of maintaining control over potentially unsafe drug stocks until compliance could be assured. The firm was issued the following letters dated 17.01.2023: -

i. Seizure of Drugs under DRAP Act 2012, permission for safe custody of seized drugs.
ii. Extension in period of not to dispose of.
iii. Explanation letter/ Suspension of production in injectable section.

III. Firm's 1st Response

On 31.05.2024, the firm responded to the FID inspection report dated 08.02.2021, but the response was found lacking in critical aspects. The firm's response failed to adequately address essential elements of Corrective and Preventive Actions (CAPA). Specifically, it did not include a thorough Root Cause Analysis, which is fundamental for identifying the underlying reasons for the non-compliance issues. Furthermore, the response lacked a clear Correction plan and Methodology for Corrective Action, both of which are necessary to rectify the identified deficiencies. The firm also did not outline a robust Preventive Action strategy to ensure that such issues do not recur in the future. Additionally, the response was deficient in providing a Validation process through Quality Risk Management, which is crucial for ensuring that the corrective measures are effective and sustainable. Overall, the response lacked specific details on how the firm planned to rectify the deficiencies and prevent their recurrence, thus failing to meet the regulatory requirements for a comprehensive CAPA.

IV. Show Cause Notice by FID

On March 7, 2023, the office of FID, Peshawar issued an **unprecedented Show Cause Notice** to M/s Fassgen Pharmaceuticals. The Notice underscored the severity of the firm's non-compliance with Good Manufacturing Practices (GMP) and demanded a detailed explanation for the observed deficiencies. It explicitly warned of potential consequences, such as suspension of production

activities, if prompt corrective actions were not taken. This measure was aimed at compelling the firm to address the identified GMP issues urgently and to ensure strict adherence to regulatory standards.

V. Action by QA&LT Division:

The firm's response being inadequate and the seriousness of the GMP non-compliance issues identified, several critical actions were already taken including ensuring the;

i. safe custody of seized drugs to mitigate potential risks to public health,
ii. temporarily suspending production activities in the affected sections until full GMP compliance is achieved,
iii. issuing a formal Show Cause Notice

to prompt immediate corrective actions, and preparing the case for discussion at the Central Licensing Board (CLB) to address the firm's non-compliance at a strategic regulatory level.

VI. Firm's 2nd Response

On 28.056.2024, the firm responded to this office letter, the firm's response was acceptable as it had provided a brief Root Cause Analysis, CA/PA, Timeline and Status of the observations to adequately address essential elements. However, it lacked the validation through QRM.

RECOMMENDATION FROM QA&LT

In view of the scenario detailed above since the firm had claimed to have made rectifications and ample time for the same was given to the firm; the QA&LT Division recommends that prior to the initiation of any punitive action against the firm, it may be given an audience before the esteemed Board and if deemed appropriate the CLB may constitute a panel of investigate the matter pertaining to Seizure & Not to Dispose of and submit the report to the Director of QA&LT for further processing the case and subsequently the developments thereon be placed before the CLB in its upcoming meeting.

Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 10.07.2024

PROCEEDINGS OF CLB 298TH MEETING

The representative of the firm Mr. Zeeshan Fasih (Director), Mr. Hameed Ullah Khan (QC In Charge) and Mr. Waqar Shah (Production In-Charge) appeared before the board in response to the Show Cause Letter.

DECISION OF CLB 298th MEETING

Pursuant to the personal hearing of the firm's aforementioned representative before the Board, and subsequent to thorough deliberations and due diligence, the Central Licensing Board has resolved to constitute the following panel:

i. Mr. Yunus Khattak, Chief Drug Inspector of KPK
ii. Mr. Atiq Ul Bari, Federal Inspector of Drugs (FID), DRAP Peshawar

iii. A nominee of the Director QA&LT

This panel is entrusted with the mandate to conduct an exhaustive review of the firm's compliance status with Good Manufacturing Practice (GMP) guidelines as delineated in the Drugs Act, 1976, and the corresponding regulations. Specifically, the panel shall:

i. Scrutinize the areas inspected, personnel interviewed, and documents reviewed during the initial inspection.
ii. Rigorously verify the firm's submitted compliance report, with particular emphasis on the adequacy and implementation of Corrective and Preventive Actions (CAPA), including Root Cause Analysis and risk mitigation strategies.

The panel is required to compile a comprehensive report based on the findings from their review and follow-up inspection. This report shall be submitted to the Director of QA&LT for further processing and shall include clear and candid recommendations for the Board's consideration.

UPDATED STATUS-PANEL INSPECTION REPORT

The panel has inspected the premises on 13-12-2024 & 24-12-2024. The panel verified the CAPA against following observations raised in previous inspection reports:-

Findings/Observation	**CAPA by the firm.**	**Remarks by the panel**
Overall maintenance of change rooms is required with reference to smooth flooring, walls, cupboards and ceiling.	The firm has Provided proper tools and paints etc for smooth flooring, walls, cupboards and ceiling. Overall maintenance of change rooms with reference to smooth flooring, walls, cupboards and ceiling work has been completed. The firm has developed SOP to monitor defects on the weekly basis.	Satisfactory
Washing areas in change rooms needs to be closed permanently or removed to avoid contamination.	To avoid contamination washing areas in change rooms permanently closed. Wash basin, water supply had been removed, however the panel advised to install the wash basins outside the change rooms which was complied and verified in 2nd visit.	Satisfactory

Implementation of SOPs for entry/exit by personnel needs to be implemented strictly. It was observed that staff/ workers do not follow change room protocols. Training of staff is also required in this context.	Properly prepared standard operating procedure for entry/exit were developed. Training session was conducted for staff.	Satisfactory
Air curtains/ doors of change rooms need cleaning/ maintenance.	Observation related air curtains/door of change rooms maintenance has been rectified.	Satisfactory
Re-organization of change rooms to better fulfill their purpose.	Change rooms properly re-organized, with new paint. Insect killers were Installed in all change rooms. Training on SOP for cleaning done.	Satisfactory
Proper receiving bay with necessary equipment to remove dust/ dirt from the incoming materials outer packing.	Receiving bay area for both sides (Ceph & General) were Constructed properly. Necessary equipment (Blower) to remove dust/dirt from the materials were arranged.	Satisfactory
Proper sampling booth as well as dispensing booth for raw material sampling/dispensing with LFH to avoid any contamination.	Purchased & provided.	Satisfactory
Segregated Rejection/ Recall area needs to be designated with proper lock and key and authorized entry system.	Area for Rejection/Recall with proper maintained lock and key with authorized entry system allocated.	Satisfactory
Storage conditions of primary packing materials need to be improved i.e., properly packed to avoid dust/dirt/moisture and properly labeled.	Proper racks and pallets for primary packaging materials Provided. Primary packaging materials were	Satisfactory

	properly packed to avoid dust/dirt and moistures etc and labeled.	
Materials flow process needs to be improved in stores with reference to quarantine/ approved areas. Necessary steps need to be ensured to avoid mix-ups.	Materials flow process was improved.	Satisfactory
Tools of compression machines needs to be placed in SS boxes with proper cleaning procedure and storage.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Cleaning SOPs needs to be revised with defined timelines for equipment to be cleaned and re-cleaning time if the cleaned equipment is not used for several days.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Fluidized bed dryer is provided, however, only single bag is being used. The firm is advised to provide at least molecule wise FBD bag with proper washing/ cleaning SOP for avoiding cross contamination.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Overall area maintenance is required w.r.t. floor, walls, ceiling, electrical panels *etc.*	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
In capsule area, general maintenance of the area for smooth surfaces, electric panels and proper storage of filled capsules in SS containers.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Bottle blowing procedure in dry suspension area needs to be improved with reference to quality of blowing air, visual checking of bottles and staging/ transfer of cleaned bottles to filling area.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Nitrogen purging procedure needs to be improved and clean Nitrogen supply through filtration is required.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory.
Optical checking counter needs to be provided for bottles after blowing for detection of any contamination/ glass particles/ broken glass bottles *etc.*	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory

Moisture control measures need to be improved considering the moisture sensitivity of Ceph products. Common observations of above four oral dosage form sections which also need to be addressed; *a. Temperature/ humidity monitoring with proper record keeping in all areas.* *b. Fulfilling Class-D air requirement via documented/ implemented HVAC system.* *c. General cleanliness and maintenance of areas/ equipment and allied facilities.*	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Validation of HVAC system in the area.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Sterilization process validation of vials after washing.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
The firm has provided R.O. water for vial washing, however, final rinsing with distil water is recommended.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
The firm has provided vial cool down area after sterilization through double door sterilizer. The cool down area is of class B as per firm's information. The product is not terminally sterilized and placing sterile vials in class B without validation data poses risk to the product. Hence, the firm was advised to review their process flow. After sterilization, vials only be exposed in class A area. Option of laminar flow hood or duly designed transfer trolley having laminar flow with continuous power supply up to class A vial filling/stoppering area was discussed by the firm for rectifying the issue.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024. However, the firm has provided SS transfer trolley having laminar flow with continuous power supply up to class A. The firm was advised to adjust their batch size according to capacity of the LFH trolley.	Satisfactory

The firm has operational HPLC but testing methods of registered products have not been shifted on HPLC method provided in latest pharmacopeia(s). The firm is advised to immediately take action for shifting their testing methods to latest pharmacopeial methods.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
The firm has two stability chambers. Stability studies are being performed but protocol for study design in not properly prepared. Stability studies protocol needs to be devised in light of ICH guidelines and according studies should be conducted for the reliability of data.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Separate electricity backup must be provided for all the sensitive equipment in QC along with UPS backup.	Separate UPS backup supply given to Sensitive equipment to ensure the compliance and safety of quality data. The firm was advised to provide UPS backup supply to both the incubators in microbiology which was compiled by the firm and verified in second visit.	Satisfactory
Stepwise purchase of Reference Standards from authentic source is also recommended.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Authenticity of data must be ensured through data loggers/ software based systems.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Establish separate QA department independent of QC.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
Strengthen QA department with well experienced staff to develop proper Quality Management system and validation/ qualification purpose.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
QA department must be assigned the task of master validation plan. Cleaning validation and validation of HVAC system especially in dry vial injectable needs to be started	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory

immediately to avoid contamination/ cross contamination of pharmaceutical products.		
System of self-inspection needs to be strengthened.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory
The firm has hired necessary staff for production/ QC department with defined roles and responsibilities. However, further training of staff needs to be done for better understanding of cGMP guidelines. Trainings on firefighting system/ emergency situation may also be performed.	Verified as the firm submitted vide their CAPA report dated 26th June, 2024	Satisfactory

Conclusion of the Panel:

Based on the areas inspected, the people met, documents reviewed, the intention towards further improvements and the corrective and preventive action taken; it is verified that that the firm has rectified most of the observations raised satisfactorily. The panel recommends the resumption of production in Cephalosporin Dry Powder injection as requested by the firm.

Recommendation of the panel for resumption of production in Cephalosporin Dry Powder injection of the firm M/s. Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar, in compliance with decision of 298th meeting of Central Licensing Board is submitted for consideration of the Board. Furthermore, comprehensive GMP report is also submitted for perusal of the Board.

Proceedings and Decision of 305th meeting of CLB:

The Board after thorough deliberation, considering the facts and recommendations of panel of experts in its report dated 13-12-2024 & 24-12-2024 decided to allow M/s. Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar to resume the production in the "Cephalosporin Dry Powder for Injection Section".

Meeting ended with vote of thanks to and from the Chair.