MINUTES OF 302ND MEETING OF CENTRAL LICENSING BOARD HELD ON 20TH NOVEMBER, 2024

302nd meeting of the Central Licensing Board (CLB) was held on 20th November, 2024 in the Committee Room, Ground Floor, NCLB, Drug Regulatory Authority of Pakistan (DRAP) National Institute of Health (NIH), 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. Mohammad Younas Khattak, Chief Inspector of Drugs, 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
6.	Mr. Abid Ali, Deputy Draftsman, Ministry of Law & Justice Division, Islamabad	Member
7.	Ch. Zeeshan Nazir Bajar, Director (QA& LT) DRAP	Member

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

Item-I **CONFIRMATION OF THE MINUTES OF 298th, 299th, 300th, 301st MEETING**

All members of the Central Licensing Board (CLB) formally confirmed the minutes of 298th held on 26th July, 2024, 299th meeting held on 23rd August, 2024, 300th meeting held on 26th September, 2024 and 301st meeting held on 2nd October, 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 Starways Pharmaceuticals (Pvt.) Ltd., Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, KPK. (New License) (Evaluator: - Urooj Fatima (DD-Lic)	**12-08-2024**	**Good**	1. Mr. Muhammad Younas Khattak, Chief Drug Inspector, Peshawar. 2. Mr. Atiq-ul-Bari, Federal Inspector of Drugs, DRAP, Peshawar. 3. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.
	QC Incharge	Mr. Adil Ghaffar (Pharm-D)		
	Production Incharge	Syed Yasar Jamal Bacha (Pharm-D)		

Recommendations of the panel: -

As per manufacturing / testing equipment installed in the production, quality control & microbiology lab, utilities, engineering of the firm, the panel unanimously **recommended** the grant of DML by way of formulation to the firm for below mentioned sections.

1. Capsule (General) Section
2. Tablet (General) Section
3. Capsule (Cephalosporin) Section
4. Oral Dry Powder (Cephalosporin) Section
5. Warehouse (Cephalosporin)
6. Warehouse (General)
7. QC Lab / Microbiology

Decision of the Central Licensing Board in 302nd 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 Starways Pharmaceuticals (Pvt.) Ltd., Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, KPK, for the following sections:

1. Capsule (General) Section
2. Tablet (General) Section
3. Warehouse (General)
4. QC Lab / Microbiology.

	Furthermore, the Board authorized Chairman CLB to issue the grant of the following Cephalosporin Sections after receiving the undertaking for establishing a segregated dedicated facility within 2 years: 1. Capsule (Cephalosporin) Section 2. Oral Dry Powder (Cephalosporin) Section 3. Warehouse (Cephalosporin)			
2.	M/s Ruth Pharmaceutical, 1.5-Km, Bhatti Mansoor Road, Ghakhar Tehsil Wazirabad, Gujranwala. (New License) (Evaluator: - Abdullah (AD-Lic)	**03-07-2024**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.
	QC Incharge	Ms. Fazilat Mehboob Ahmed (Pharm. D)		
	Production Incharge	Ms. Tayyiba Zaib (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 to M/s Ruth Pharmaceutical, 1.5-Km, Bhatti Mansoor Road, Ghakhar Tehsil Wazirabad, Gujranwala for the following sections. i. Oral Powder (Veterinary) Section (General) ii. Oral Liquid (Veterinary) Section (General) **Decision of the Central Licensing Board in 302nd 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 Ruth Pharmaceutical, 1.5-Km, Bhatti Mansoor Road, Ghakhar Tehsil Wazirabad, Gujranwala, for the following sections: i. Oral Powder (Veterinary) Section (General) ii. Oral Liquid (Veterinary) Section (General)			
3.	M/s Hinucon (Pvt.) Ltd, Plot No.IT-03-A3 & IT-04-A3, KCIP, Karachi. New License *Evaluator: - Akbar Ali (DD-Lic)*	07.11.2024	Good	1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Sindh. 2. Mrs. Mahrukh Mughal, DD, CDL, DRAP, Karachi. 3. Mr. Asfandyar Khan, DD, DRAP, Karachi.

	QC In-charge	Mr. Ammad Nazar Butt S/o Nazar Hussain Butt (M.Sc. Chemistry)		
	Production In-charge	Mr. Qasim Raza S/o Muhammad Arif (Pharm-D)		
	Recommendations of the panel: - M/s Hinucon (Pvt.) Ltd, situated at Plot #IT-03-A3 & IT-04-A3, KCIP, Karachi was visited and inspected in compliance to the DRAP's letter No.F.2-11/21-Lic dated 30th October, 2024. In the light of areas visited, documents reviewed and meeting with technical persons, the panel unanimously **recommend** the grant of Drug Manufacturing License of following sections: 1. Capsule Section (General) 2. R&D Lab 3. QC Lab 4. Warehouse **Decision of the Central Licensing Board in 302nd 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 Hinucon (Pvt.) Ltd, Plot No.IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park, Karachi for the following sections: 1. Capsule Section (General) 2. R&D Lab 3. QC Lab 4. Warehouse			
4.	M/s RSK Pharmaceutical Plot No.13-N, Street No. N-5, RCCI Industrial Estate, Rawat New License *Evaluator: - Abdullah (AD-Lic)*	14.11.2024 & 18.11.2024	**Good**	1. Mrs. Tehreem Sara DD/FID, DRAP, Islamabad. 2. Area FID, DRAP Islamabad. 3. Hafiz Muhammad Umair, DD, DRAP Islamabad.
	QC In-charge	Mr. Saddam Hussain (M.Phil Chemistry)		
	Production In-charge	Mr. Umar Wadahya (B.Pharm)		
	Recommendations of the panel: - Keeping in view the above stated facts, panel of inspectors are of view that **GMP compliance of the firm found Good as of inspection day** 14.11.2024 and 18.11.2024 some useful suggestions given for improvements and suggestions have been well accepted by the management with very positive intent. The cGMP is continuous process of upgradation and firm's executive management has very good intent.			

	The firm found **Good** as of inspection day 14.11.2024 and 18.11.2024 some useful suggestions given for improvements and suggestions have been well accepted by the management with very positive intent. The cGMP is a continuous process of upgradation and improvement and firm's executive management has a very good intent towards the up gradation continuous the management agreed to do the needful. The firm advised to continue the process of upgradation. The panel hence **recommends for approval of the one section i.e. (Dry Powder Penicillin)** as per letter No.F.No.01-30/2011-Lic dated 09th September 2024 for consideration of Central Licensing Board for grant of Drug Manufacturing License if deem appropriate. The panel cannot assure or responsible for any product / manufactured drug failure with regard to quality or any defect/mix-up in future being manufacturing of sensitive products i.e. penicillin. The quality of individual batches of finished drug marketed or supplied to anywhere inside or outside the country will remain the responsibility of manufacturer. Any batch failure after this inspection would be responsibility of manufacturer. ***Note:*** *The GMP inspection only ascertains the cGMP compliance; procedures adopted during visit and verify the facility of the firm. Quality of Registered Products Therapeutic Goods of individual Batches remains the responsibility of the technical staff and manufacturer. Panel could not guarantee the strength of building and safety of installed electric panels. The verification of strength of building and safety of installed electric panels is a technical job and pertains to civil and electrical engineering & building control authorities (BCA).* **Decision of the Central Licensing Board in 302nd meeting:** The Board 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 RSK Pharmaceutical Plot No.13-N, Street No. N-5, RCCI Industrial Estate, Rawat on the recommendations of the panel of experts for the following sections subject to verification of necessary testing equipments: I. Dry Powder (Penicllin) Section.			
5.	Ms. Futureceuticals, Plot No. 239, Industrial Triangle Kahuta Road, Islamabad. New License *Evaluator: - Abdullah (AD-Lic)*	12-11-2024	Good	i. Mr. Hafiz Sanaullah Babar, Deputy Director, DRAP, Islamabad. ii. Mr. Abdullah Assistant Director, DRAP, Islamabad. iii. Mr. Nafees-ur-Rehman, Deputy Director, DRAP, Islamabad.
	QC In-charge	Mr. Razaullah (Mphil Chemistry)		
	Production In-charge	Dr. Aslam Pervaiz (PhD Organic Chemistry)		
	Recommendations of the panel: -			

Keeping in view the above observations during the panel inspection of Ms. Futureceuticals, Plot No. 239, Industrial Triangle Kahuta Road, Islamabad, the panel **recommends** the grant of Drug Manufacturing License by way of Semi-Basic Manufacturing as per DRAP Islamabad letter No. F. 1-21/2022-LIC dated 29-10-2024 for following facilities:

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)

However, the panel's role does not extend to confirming the safety and structural intergrity of the building and other civil structures, as this fall under the jurisdiction of the building control authorities. The panel further recommends that the Good Manufacturing Practices (GMP) of the manufacturing facility be assessed following the issuance of the drug manufacturing license and periodically thereafter.

The panel also **recommends** the grant of following Active Pharmaceutical Ingredients (APIs):

CARDIO VASCULAR DRUG			**GLYCINATE**		
1.	Bisoprolol Fumarate	USP	2.	Cromium Glycinate (Plain/Liposomal)	USP
3.	Rosuvastatin Calcium	USP	4.	Calcium Glycinate (Plain/Liposomal)	USP
5.	Amlodipine Besylate	BP	6.	Magnesium Gluconate	USP
7.	Atorvastan Calcium	EP	8.	Potassium Gluconate	USP
QUINOLONE			9.	Manganese Gluconate	USP
10.	Ciprofloxacin (HCL Monohydrate/Lactate)	USP	11	Zinc Glycinate (Plain /Liposomal)	USP
12.	Levoflaxcin	USP	13	Calcium Lactate Gluconate	USP
			14	Ferrous/ferric Bisglycinate (Plain /Liposomal)	USP
			15	Magesium Bisglycinate (Plain /Liposomal)	USP
16.	Moxifloxacin	USP	**CITRATE**		
17.	Enrofloxacin	USP	18	Calcium Citrate Malate	
XANTHINES			19	Calcium Citrate	USP
20.	Caffein (Plain/Citrate)	USP	21	Magnesium Citrate	BP
22.	Acefylline (Piprazine)	USP	23	Zinc Citrate	USP
24.	Aminophylline	USP	25	Sodium Citrate	BP
26.	Doxofylline		27	Potassium Citrate	BP
ANTIBIOTIC			**VITAMINS & ACETATES**		
28.	Azithromycin	USP	29	Riboflavin Sodium Phosphate	BP

30.	(Calcium/Sodium/ Tromothamine)	BP	31	Pyridoxal 5 Phosphate	
32.	Colistimethate Sodium/sulphate)	BP	33	Methycobalamine	JP
ANALGESIC			34	TetrahydrofolateCalcium L-5 Methyl	
35.	Mefenamic Acid	BP	36	Niacinamide	
37.	Tramadol HCl	USP	38	Vitamin D3	BP
39.	Paracetamol	BP	40	L- Lysine Acetate (Plain/Coated)	USP
41.	Naproxen Sodium	BP	42	Retinol Acetate/palmitate	USP
43.	Ketorolac Tromethamine	USP	44	Strontium (Acetate/Ranelate)	USP
SUCCINATES			**MISCELLANEOUS PRODUCTS**		
45.	Solifenacin Succinate	USP	46	Choline (Bitartrate/Citrate)	USP
47.	Sumatriptan Succinates	USP	48	Glucosamine Sulphate (Sodium Chloride / Potasssium Chloride)	USP
ANTISEPTIC EXCIPIENTS					
49.	Povidone Iodine	USP	50	Calcium Carbonate (PPt)	USP
IRON COMPLEXES			51	Algea Calcium	USP
52.	Iron(lll) Carboxylmatose Complex	USP	53	Sodium Chloride	BP
54.	Ferrous Sulphate	USP	55	Pycnogenol	USP
56.	Iron Sucrose	BP	**SPECIAL GROUP**		
57.	Ferric (Pyrophosphate/ Pyrohosphate Citrate)	USP	58	Montelukast Sodium	USP
59.	Iron Hydroxide Polymaltose Complex	USP	60	Thalidomide	USP
61.	Ferrous Fumarate	BP	62	Ondansetron HCL	USP
63.	Ferric Ammonium Citrate	USP	64	Tretinoin	USP
GIT DRUGS			65	L- Carnitine Tartrate/Fumarate/HCL	USP
66.	Lactulose	USP	67	Domepeirone Maleate	USP
68.	Pantaprazole (Sod/ Magnesium)	BP	69	(Coated/Liposomal)	
ANTIPSYCHOTIC			70	L-Ornithine L Aspartate	USP
71.	Escitalopram Oxalate	USP	**ZOLES**		
72.	Quetiapine Fumarate	USP	73	Metronidazole (Plain/Benzoate)	USP
ANESTHETIC			74	Oxfendazole	USP
75.	Succinyl Choline	USP	76	Ricobendazole	
77.	Lidocaine HCL- USP				BP
78.	L-Bupivacaine HCL-USP				BP

79.	Sildenafil Citrate	BP
80.	Fospropofol Disodium	BP
OTHERS		
81. Calcium gluconate		USP
82. Ferrous/Ferric gluconate		USP
83. Sodium Glycerophosphate		In house
84. Calcium Glycerophosphate		USP
85. Magnese Glycerophosphate		In house
86. Potassium Glycerophosphate		In house
87. Alpha-Ketoanalogue to isoleucine calcium salt		USP
88. Alpha-Ketoanalogue to leucine calcium salt		USP
89. Alpha-Ketoanalogue to phenylalanine calcium salt		USP
90. Alpha-Ketoanalogue to valine calcium salt		USP
91. Alpha hydroxy methionine calcium salt		USP

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.	Domepeirone 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.

2. The Board, in light of recommendations of the panel, also decided that a Committee be constituted for comprehensive inspection of semi-basic manufacturing units after their operationalization to assess the quality of Active Pharmaceuticals Ingredients being produced in these

units. The Authority shall be requested to identify pool of experts for these inspection having expertise in the basic and semi-basic manufacturing.

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 Shaigan Pharmaceuticals (Pvt) Ltd., 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi. **DML No. 000984 (Semi Basic)** **API (02):** i. Esomeprazole (22.5% delayed release pellets) ii. Omeprazole (12.5% delayed release pellets) Evaluator:- Abdullah (AD-Lic)	**22-07-2024**		1. Mr. Muhammad Arif, Additional Director, DRAP, Islamabad. 2. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad. 3. Mr. Mubashar Iqbal, Deputy Director (Licensing), DRAP, Islamabad.
	Recommendations of the panel: The establishment has the process for Dispensing (Annex-A), Process Flow for Manufacturing of Spheres (Annex-B), Process Flow for Coating of Pellets (Annex-C), Process Flow for Purified Water System (Annex-D) and Process Flow for Compressed Air System (Annex-E). The Establishment has the required installed machinery / equipment and experienced technical staff for production, QC/QA, therefore, the panel recommends the semi-basic manufacturing of Esomeprazole (22.5% delayed release pellets) and Omeprazole 12.5% delayed release pellets). **Decision of the Central Licensing Board in 302nd meeting:** The Board on the recommendations of the panel of experts approved the following APIs in the name of M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi under DML No. 000984 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			

<table>
<tr><td></td><td colspan="4">Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020, if applicable and subject to signing of manufacturing process flow charts by the panel:

1. Esomeprazole (22.5% delayed release pellets)
2. Omeprazole (12.5% delayed release pellets)</td></tr>
<tr><td>2</td><td>M/s Selmore Pharmaceuticals (Pvt) Ltd., 36-Km, Multan Road, Lahore.

DML No. 000507 (Formulation)

Section (1):

i. Oral Liquid Section-II (Veterinary) (New).

Evaluator:- Abdullah (AD-Lic)</td><td>08-08-2024</td><td>Good</td><td>1. Dr. Zaka-ur-Rehman, Expert member.
2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore.
3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>
Keeping in view the manufacturing facility like building, HVAC system, sanitation, production machinery, equipment in Quality control and microbiological laboratory, testing facilities, technical person met and documentation reviewed on the day of inspection, the panel of inspectors is of the opinion to recommend the renewal of Drug Manufacturing License by way of formulation to M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-km, Multan Road, Lahore, for the following sections:
i. Bolus (Veterinary) Section.
ii. Aerosol (Veterinary) Section.
iii. Oral Liquid I (Veterinary) Section.
iv. Oral Powder (Veterinary) Section.
v. Liquid Injection (Veterinary) Section (Steroid).
vi. Oral Powder (Penicillin) (Veterinary) Section.
vii. Dry Powder for Injection (Penicillin) (Veterinary) Section.
viii. Liquid Injection (Penicillin) (Veterinary) Section.
ix. Liquid Injection (Hormone) (Veterinary) Section.
x. Liquid Injectable (Cephalosporin) (Veterinary) Section.
xi. Dry Powder Injectable (Cephalosporin) (Veterinary) Section.
xii. Liquid Injectable Vial-I (General) (Veterinary) Section.
xiii. Liquid Injectable Vial-II (General) (Veterinary) Section.
xiv. External Liquid Preparation (Veterinary) Section.
xv. External Powder Preparation (Veterinary) Section.</td></tr>
</table>

	The panel also recommends the grant of following additional section M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-km, Multan Road Lahore: i. Oral Liquid Section-II (Veterinary) (New) **<u>Decision of the Central Licensing Board in 302nd meeting:</u>** The Board on the recommendations of the panel of experts approved the following section in the name of M/s Selmore Pharmaceuticals (Pvt) Ltd., 36-Km, Multan Road, Lahore under DML No. 000507 by way of Formulation: i. Oral Liquid Section-II (Veterinary) (New)			
3	M/s Crown Pharmaceuticals, Plot No.286, Industrial Triangle Kahuta Road, Islamabad. **DML No. 000456 (Formulation)** **<u>Section (03):</u>** i. Sachet Section (General) (Additional) ii. Ointment / Cream (General) (Additional) iii. Lotion (General) (Additional). (Evaluator: - Urooj Fatima (DD-Lic)	**14-05-2024**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Ms. Saadia Mahwish, FID, DRAP, Islamabad. 3. Abdul Mughees, Assistant Director CEO Office, DRAP, Islamabad.
	<u>Recommendations of the panel:</u> Keeping in view the above facts on record, documents reviewed people met during the visit & compliance of the firm to the directions of inspection team, the panel unanimously <u>recommended renewal/revision/grant of additional sections</u> of the following sections of M/s Crown Pharmaceuticals Plot # 286, Industrial Triangle Kahuta Road, Islamabad. DML# 000456: <u>Renewal of Drug Manufacturing License by way of Formulation</u> 1. Tablet Section (General) (Revised) 2. Tablet Section (Psychotropic) (Revised) 3. Capsule Section (General) (Revised) 4. Oral Dry Powder for Suspension Section (General) (Revised) 5. Capsule Section (Cephalosporin) (Revised) 6. Oral Dry Powder for Suspension Section (Cephalosporin) (Revised) 7. Warehouse (Revised)			

	8. QC Lab (Revised) Grant of Additional Sections 1. Sachet Section (General) (Additional) 2. Ointment / Cream (General) (Additional) 3. Lotion (General) (Additional) **Decision of the Central Licensing Board in 302nd meeting:** The Board on the recommendations of the panel of experts, approved the following sections, in the name of M/s Crown Pharmaceuticals, Plot No.286, Industrial Triangle Kahuta Road, Islamabad under DML No. 000456, by way of Formulation, subject to verification of necessary equipments: 1. Sachet Section (General) (Additional) 2. Ointment / Cream (General) (Additional) The Board deferred the grant of Lotion (General) Section for verification of this section in the approved Layout Plan.			
4.	M/s Pharmasol (Pvt.) Ltd., Plot No.549, Sunder Industrial Estate, Lahore. **DML No. 000872 (Formulation)** **Sections (01):** i. Tablet Steroidal (Human) (New) Evaluator:- Abdullah (AD-Lic)	**24-09-2024 & 25-09-2024**	**Good**	1. Dr. Zaka-ur-Rehman, Expert Member. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: Keeping in view the manufacturing facility like building, HVAC system, sanitation, production machinery, equipment in Quality Control, Quality Assurance Compliance, Warehouses, Research & Development Laboratory and Microbiology Laboratory, testing facilities, technical personnel met and documentation reviewed, the panel of inspectors is of the opinion to **recommends** the renewal of Drug Manufacturing License by way of formulation to M/s Pharmasol (Pvt.) Ltd., Plot No.549, Sunder Industrial Estate, Lahore (vide letter No.F.1-17/2005-Lic (Vol-I dated 31-05-2023) for the following sections: 1. Diluents & Water for Injection Section 2. Tablet (Anti-cancer) Section 3. Capsule (Anti-cancer) Section 4. Liquid Injection (Anti-cancer) Section 5. Tablet Section (General) 6. Capsule Section (General) 7. Syrup (General) Section			

	8. Liquid Injection (General) Section 9. Dry Powder Injection (General) Section 10. Liquid Ampoule (General) Section 11. Tablet Section (General) 12. Capsule Section (General) 13. Lotion (General) Section 14. Cream/Ointment/Gel (General) Section 15. Dry Powder Suspension (General) Section 16. Dry Powder Sachet (General) Section 17. Eye Drop (General) Section 18. Capsule (Cephalosporin) Section 19. Dry Powder Suspension (Cephalosporin) Section 20. Dry Powder Injection (Cephalosporin) Section 21. Dry Powder Injection (Carbapenem) Section 22. Cream/Ointment/Gel (Steroid) Section 23. Liquid Vials & Ampoule (Steroid) Section 24. Dry Powder Vials (Steroid) section 25. Soft Gelatin Capsule Section. The panel also recommends the grant of following additional section to M/s Pharmasol (Pvt) Ltd., Plot # 549, Sunder Industrial Estate, Lahore: 1. Tablet Steroidal (Human) (New) **<u>Decision of the Central Licensing Board in 302nd meeting:</u>** The Board, on the recommendations of the panel of experts, approved the following section, in the name of M/s Pharmasol (Pvt.) Ltd., Plot No.549, Sunder Industrial Estate, Lahore under DML No. 000872, by way of Formulation: 1. Tablet Steroidal (Human) (New)			
5.	M/s Theramed Pharmaceuticals (Pvt) Ltd., 45-Km, Multan Road, Lahore. **DML No. 000696 (Formulation)** **Section:** 1. External Liquid Section (New) (Evaluator: - Abdullah (AD-Lic)	**27-08-2024**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.
	<u>Recommendations of the panel:</u> In view of 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 renewal of Drug Manufacturing License to M/s Theramed Pharmaceuticals (Pvt) Ltd., 45-Km, Multan Road, Lahore for the following sections: 1. Tablet Section (General) 2. Capsule section (General) 3. Oral Liquid Section (General) 4. Oral Dry Powder Section (General) 5. Tablet Section (Psychotropic) 6. Capsule Section (Psychotropic) The panel also recommends the grant of following additional section to M/s Theramed Pharmaceuticals (Pvt) Ltd., 45-Km, Multan Road, Lahore: 1. External Liquid Section (New) **<u>Decision of the Central Licensing Board in 302nd meeting:</u>** The Board, on the recommendations of the panel of experts, approved the following section, in the name of M/s Theramed Pharmaceuticals (Pvt) Ltd., 45-Km, Multan Road, Lahore under DML No. 000696, by way of Formulation: 1. External Liquid Section (New) (in place of Micro and QC lab) The approval is subject to verification by the panel on confirmation of relocation of Micro and QC lab as per approved Layout Plan.			
6.	M/s Martin Dow Ltd, Plot No.37, Sector 19, Korangi Industrial Area, Karachi. DML No.000267 (Formulation). **Section:** i. Oral Liquid Drops (Psychotropic)- New *Evaluator: - Akbar Ali (DD-Lic)*	02-08-2024 & 15-08-2024	Good	1. Mr. Muhammad Zahid Salik Member CLB. 2. Dr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 3. Mr. Abdullah, Assistant Director (Licensing), DRAP, Islamabad.
	<u>Recommendations of the panel: -</u> M/s Martin Dow Limited was inspected in connection with the Grant of new section of Oral Liquid Drops (Psychotropic) under Drug Manufacturing License No.000267 (Formulation) as per DRAP, Islamabad letter No.F.2-14/2000-Lic (Vol-II) dated, 13th May, 2024.Following are the observation: 1. The panel inspected in detail the targeted Section, segregated storage areas, personnel & material flow, dedicated HVAC System, utilities and discussed in detail			

	relevant & instant documents. The firm has well segregated areas for Oral Liquid Drops (Psychotropic) with the required adequate facilities. The section and allied storage services were well aligned making the section maintained at desired GMP conditions and meeting the requirements laid down under Schedule-B, B-I& B-II of Drugs Act 1976 and Rules frame thereunder. 2. The panel had also discussed in detail their approved layout plant, personnel & material flow HVAC Svstem, Organogram & reporting system with associated risks and several other relevant documents during starting meeting with all their technical persons including Mr. Muhammad Zubair Plant Director Operations, Mr. Muqeet Kazmi Director Quality Operations, Mr. Ahsan Raees Head of Regulatory Affairs and other technical persons from respective areas. 3. Based on the stated observations & facts **the panel unanimously recommends the grant of Oral Liquid Drops Section (Psychotropic)** under DML No. 000267 possessed by Ms. Martin Dow Limited Plot No. 37 Sector-19 Korangi Industrial Area Karachi. **<u>Decision of the Central Licensing Board in 302nd meeting:</u>** The Board, on the recommendations of the panel of experts, approved the following section, in the name of M/s Martin Dow Ltd, Plot No.37, Sector 19, Korangi Industrial Area, Karachi under DML No. 000267 by way of Formulation: i. **Oral Liquid Drops Section (Psychotropic) –New** This approval is 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 for Psychotropic Section.			
7.	M/s Getz Pharma (Pvt.) Ltd, Plot No.1, Sector-25, Korangi Industrial Area, Karachi DML No.000933 (Formulation). **<u>Section:</u>** i. Dry Powder Injectable (Carbapenem)-New *Evaluator: - Akbar Ali (DD-Lic)*	13-09-2024	V. Good	1. Dr. Saif-Ur-Rehman Khattak, Additional Director, DRAP Karachi. 2. Abdul Hafeez Tunio, Chief Drug Inspector Sindh. 3. Syed Hakim Masood, Area Federal Inspector of Drugs, DRAP, Karachi.
	<u>Recommendations of the panel: -</u> Based on the people met, developments as per approved layout plan, HVAC system, validated water system, qualified machinery and competent workforce, documents			

	reviewed, commitment of the management for continuous improvement, expansion and expert potential, the panel unanimously was of the view to recommend approval for grant of additional section Namely "Dry Powder Injectable (Carbapenem)" to the firm M/s Getz Pharma (Pvt) Limited situated at Plot No.01, sector 25, Korangi Industrial Area, Karachi, Pakistan under the DML No.000933 (by way of formulation). **Decision of the Central Licensing Board in 302nd meeting:** The Board, on the recommendations of the panel of experts, approved the following section, in the name of M/s Getz Pharma (Pvt.) Ltd, Plot No.1, Sector-25, Korangi Industrial Area, Karachi under DML No. 000933, by way of Formulation: i. Dry Powder Injectable (Carbapenem) - New Furthermore, the Board authorized Chairman CLB to issue the grant of the abovementioned Carbapenem Section after receiving the undertaking for establishing a segregated dedicated facility within 2 years.			
8.	M/s Hi-Med Pharmaceuticals, Plot No.208-C, Sunder Industrial Estate, Lahore. DML No. 000884 (Formulation). **Sections:** i. Liquid Injectable (SVP) (General) Section-New Evaluator: - Zunaira Faryad (DD-Lic)	23-09-2024	**Good**	1. Dr. Farzana Ch. Expert Member. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore.
	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 plan, testing facilities, technical personnel, documentation, the panel of inspectors in of the opinion to **recommend** the grant of renewal of Drug Manufacturing License and approval of new section by way of formulation to M/s Hi-Med Pharmaceuticals, 208-C Sunder Industrial Estate, Lahore for the following sections: i. Tablet Section (General) ii. Capsule Section (General) iii. Sachet Section (General) iv. Dry Powder Suspension Section (General) The panel also recommends to grant of following additional section to M/s Hi-Med Pharmaceuticals, 208-C Sunder Industrial Estate, Lahore.			

	i. Liquid Injectable (Small Volume Parenteral) (General) **Decision of the Central Licensing Board in 302nd meeting:** The Board, on the recommendations of the panel of experts, approved the following section, in the name of M/s Hi-Med Pharmaceuticals, Plot No.208-C, Sunder Industrial Estate, Lahore under DML No. 000884, by way of Formulation: i. Liquid Injectable (Small Volume Parenteral) (General) - New			
9.	M/s Weather Folds Pharmaceuticals, Plot No. 62/2 Phase-II Industrial Estate Hattar. DML No. 000644 (Formulation). **Sections:** i. Biological Non-rDNA section Evaluator: - Urooj Fatima (DD-Lic)	15-07-2024	**Good**	1. Prof. Dr. Muzamil Hasan Najmi, Biological Expert. 2. Dr. Ghazanfar Ali Khan, Additional Director (QA/LT), DRAP, Islamabad. 3. Mr. Adnan Afridi, Assistant Director, Peshawar.
	Recommendations of the panel: The panel having seen the available equipment / machinery required for production / quality control such as FTIR, UHPLC, HPLCs. UV spectrophotometer, stability chambers, etc., the approved technical persons and the commitment of the management, hence recommends the Biological Non RDNA vial / prefilled Syringes Section for approval considering the fact that the establishment has got its LOP approved from the Licensing Division as per existing lay out. Thereafter, the company applied for revision in the approved Layout plan which was discussed in the 65th meeting of LOP committee. The firm agreed to withdraw Viral Vaccine Section (Un-licensed) (LOP was approved in previous LOP) and expanded Liquid Injection vial/ Prefilled Syringe, Non rDNA section (Biological) (Unlicensed) over Biological rDNA section (rDNA Biological section was also Withdrawn). Accordingly, the revised LOP was submitted by the firm and was approved. Thereafter, the firm on 1st November, 2024 requested a corrigendum regarding the name of their section from "Biological Non-RDNA Vial/Prefilled Syringe Section" to "Biological RDNA Vial/Prefilled Syringe Section." However, the request is under consideration as the case was the revision of sections and not the typographical error. **Decision of the Central Licensing Board in 302nd meeting:** The Board deferred the case for clarification from the firm on the updated status of the construction/revision according to the approved revised LOP and subsequent re-verification by a panel.			

10.	M/s Elite Pharma (Pvt.) Ltd, 9.5-Km, Sheikhupura Road, Lahore. DML No. 000455 (Formulation). **Section (01):** i. Liquid Injectable (Ampoule) Narcotics/Psychotropic Evaluator: - Zunaira Faryad (DD-Lic)	30.07.2024	Good	1. Mr. Faisal Shahzad, Additional Director, DRAP, Islamabad. 2. Abdul Rashid Shaikh, Area FID, DRAP, Lahore. 3. Ishtaiq Shafiq, AD, DRAP, Lahore.
	Recommendations of the panel: - Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and review of the production facilities, building, equipment, quality control and quality assurance, the panel is of the opinion to recommend the grant of additional section with reference to DRAP, Islamabad letter No.F.1-5/95-Lic(Vol-III) dated 16.03.2023 to M/s Elite Pharma (Pvt.) Ltd, 9.5-Km, Sheikhupura Road, Lahore for the **Liquid Injectable (Ampoule) Narcotics/Psychotropic.** **Decision of the Central Licensing Board in 302nd meeting:** The Board, on the recommendations of the panel approved the following section, in the name of M/s Elite Pharma (Pvt.) Ltd, 9.5-Km, Sheikhupura Road, Lahore under DML No. 000455, by way of 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 date 10/11/2020: 1. **Liquid Injectable (Ampoule) Narcotics/Psychotropic (New)**			
11.	M/s Wimits Pharmaceuticals, Plot No129, Sundar Industrial Estate, Raiwind Road, Lahore. **DML No. 000789 (Formulation)** **Section (01):** 1. Tablet Section (General)-II-New	**12-08-2024**	**Good**	1. Dr. Farzana Ch., Expert Member. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Abdul Rashid Sheikh, fFID, DRAP, Lahore.

	(Evaluator: - Abdullah (AD-Lic)			

Recommendations of the panel:

In view the manufacturing facilities like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and microbiology laboratory, testing facilities, discussion with technical personnel and documentation reviewed, the panel of Inspectors is of the opinion to **recommend** the renewal of Drug Manufacturing License by way of formulation and grant of additional section to M/s Wimits Pharmaceuticals, Plot No129, Sundar Industrial Estate, Raiwind Road, Lahore for the following sections:

Human Section.

1. Liquid Injectable Section (General) Ampoule
2. Oral Liquid Section (General)
3. Tablet Section (General)
4. Capsule Section (General)
5. Capsule Section (Cephalosporin)
6. Dry Powder Suspension Section (Cephalosporin)
7. Dry Powder Injection Section (Cephalosporin)
8. Cream/Ointment/Lotion/Gel Section (General)

Veterinary Sections

9. Drench Section (General) (Veterinary)
10. Liquid Injectable Section (General) (Veterinary)
11. Bolus Section (General) (Veterinary)
12. Oral Dry Powder Section (General) (Veterinary)

The panel also recommends the grant of following additional section to M/s Wimits Pharmaceuticals, Plot No129, Sundar Industrial Estate, Raiwind road, Lahore:

1. Tablet Section (General)-II-New

However, following sections are not mentioned in the recommendation of panel:

i. Drench-II (General) Vet
ii. Dry Powder-II (General) Veterinary
iii. Bolus-II (General) Veterinary

Decision of the Central Licensing Board in 302 meeting:

The Board, on the recommendations of the panel of experts, approved the following section, in the name of M/s Wimits Pharmaceuticals, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore under DML No. 000789, by way of Formulation:

1. Tablet Section (General)-II-New

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

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Selmore Pharmaceuticals (Pvt) Ltd., 36-Km, Multan Road, Lahore. **DML No. 000507 (Formulation)** **Period:** Commencing on 16-11-2022 ending on 15-11-2027. Evaluator:- Abdullah (AD-Lic)	**08-08-2024**	**Good**	1. Dr. Zaka-ur-Rehman, Expert member. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.
	QC Incharge	Mr. Saqlain Siddiqui (Pharm-D)		
	Production Incharge	Mr. Riaz Hussain (B-Pharm)		
	Recommendations of the panel: Keeping in view the manufacturing facility like building, HVAC system, sanitation, production machinery, equipment in Quality control and microbiological laboratory, testing facilities, technical person met and documentation reviewed on the day of inspection, the panel of inspectors is of the opinion to **recommend** the renewal of Drug Manufacturing License by way of formulation to M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-km, Multan Road Lahore for the following sections: 1. Bolus (Veterinary) Section. 2. Aerosol (Veterinary) Section. 3. Oral Liquid I (Veterinary) Section. 4. Oral Powder (Veterinary) Section. 5. Liquid Injection (Veterinary) Section (Steroid). 6. Oral Powder (Penicillin) (Veterinary) Section. 7. Dry Powder for Injection (Penicillin) (Veterinary) Section. 8. Liquid Injection (Penicillin) (Veterinary) Section. 9. Liquid Injection (Hormone) (Veterinary) Section. 10. Liquid Injectable (Cephalosporin) (Veterinary) Section. 11. Dry Powder Injectable (Cephalosporin) (Veterinary) Section. 12. Liquid Injectable Vial-I (General) (Veterinary) Section. 13. Liquid Injectable Vial-II (General) (Veterinary) Section. 14. External Liquid Preparation (Veterinary) Section. 15. External Powder Preparation (Veterinary) Section.			

	The panel also recommends the grant of following additional section M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-km, Multan Road Lahore: ii. Oral Liquid Section-II (Veterinary) (New) <u>The Panel also recommended Liquid Injection (Veterinary) Section (Steroid) however, same section was replaced with Liquid Injectable Vial-II (General) (Veterinary) Section in 287th meeting of CLB, accordingly.</u> **<u>Decision of the Central Licensing Board in 302nd meeting</u>** The Board, on the recommendations of the panel of experts and as per record of licensing division (both sections i.e Liquid Injection (Veterinary) Section (Steroid) and Liquid Injectable Vial-II (General) (Veterinary) Section are available with the firm), approved the grant of renewal of DML No. 000507, by way of Formulation, in the name of M/s Selmore Pharmaceuticals (Pvt) Ltd., 36-Km, Multan Road, Lahore, for the period commencing on 16-11-2022 ending on 15-11-2027, for the following sections: 1. Bolus (Veterinary) Section. 2. Aerosol (Veterinary) Section. 3. Oral Liquid I (Veterinary) Section. 4. Oral Powder (Veterinary) Section. 5. Liquid Injection (Veterinary) Section (Steroid). 6. Oral Powder (Penicillin) (Veterinary) Section. 7. Dry Powder for Injection (Penicillin) (Veterinary) Section. 8. Liquid Injection (Penicillin) (Veterinary) Section. 9. Liquid Injection (Hormone) (Veterinary) Section. 10. Liquid Injectable (Cephalosporin) (Veterinary) Section. 11. Dry Powder Injectable (Cephalosporin) (Veterinary) Section. 12. Liquid Injectable Vial-I (General) (Veterinary) Section. 13. Liquid Injectable Vial-II (General) (Veterinary) Section. 14. External Liquid Preparation (Veterinary) Section. 15. External Powder Preparation (Veterinary) Section.			
2.	M/s Symans Pharmaceuticals (Pvt) Ltd., 10 Km, Sheikhupura Road, Lahore. **DML No. 000323 (Formulation)** **Period:** Commencing on 19-10-2020 ending on 18-10-2025. Evaluator:- Abdullah (AD-Lic)	**31-07-2024**	**Good**	1. Dr. Zaka-ur-Reman, Expert Member. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.
	QC Incharge	Mr. Muhammad Iqbal (M. Sc Chemistry)		
	Production Incharge	Mr. Muhammad Sohail (B-Pharm)		

	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 **recommends** the Renewal of Drug Manufacturing License by way of formulation for the following sections to M/s Symans Pharmaceuticals (Pvt) Ltd., 10 Km, Sheikhupura Road, Lahore: 1. Liquid Injectable Section (Vial) (Veterinary) (General) 2. Liquid Injectable (Steroidal) Vial Section (Veterinary) 3. Oral Liquid Section (Veterinary) 4. Oral Powder Section (General) (Veterinary) 5. Bolus Section (Veterinary) 6. Repacking Liquid/Powder Section (Veterinary) 7. Oral Dry Powder Penicillin Section (Veterinary) **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. 000323, by way of Formulation, in the name of M/s Symans Pharmaceuticals (Pvt) Ltd., 10 Km, Sheikhupura Road, Lahore, for the period commencing on 19-10-2020 ending on 18-10-2025, for the following sections: 1. Liquid Injectable Section (Vial) (Veterinary) (General) 2. Liquid Injectable (Steroidal) Vial Section (Veterinary) 3. Oral Liquid Section (Veterinary) 4. Oral Powder Section (General) (Veterinary) 5. Bolus Section (Veterinary) 6. Repacking Liquid/Powder Section (Veterinary) 7. Oral Dry Powder Penicillin Section (Veterinary)			
3.	M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sunder Industrial Estate, Lahore. **DML No. 000783 (Formulation)** **Period:** Commencing on 03-02-2024 ending on 02-02-2029. Evaluator:- Abdullah (AD-Lic)	**21-08-2024**	**Good**	1. Mr. Muhammad Shamoon Ch., Expert Member. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	QC Incharge	Mr. Shahzad ul Hassan (M.Sc Bio Chemistry)		
	Production Incharge	Mr. Saleem Mansoor (B-Pharm)		
	Recommendations of the panel: Keeping in view the manufacturing facility like, building, production, machinery, Equipment in Quality Control and microbiology laboratory, testing facilities, utilities and documentation			

	reviewed on the day of inspection, the panel of inspectors **recommends** the renewal of Drug Manufacturing License by way of formulation to M/s Stallion Pharmaceuticals (Pvt) Ltd., 581-Sunder Industrial Estate, Lahore for the following sections: 1. Dry Powder Injectable (Carbapenem) 2. Tablet Section (Penicillin) 3. Capsule Section (Penicillin) 4. Oral Dry for Oral Suspension Section (Penicillin) 5. Dry Powder for Injection Section (Penicillin) **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. 000783, by way of Formulation, in the name of M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sunder Industrial Estate, Lahore, for the period commencing on 03-02-2024 ending on 02-02-2029, for the following sections: 1. Tablet Section (Penicillin) 2. Capsule Section (Penicillin) 3. Oral Dry Powder Suspension Section (Penicillin) 4. Dry Powder for Injection Section (Penicillin) Furthermore, the Board authorized Chairman CLB to issue the renewal of the following Carbapenem Section after receiving the undertaking for establishing a segregated dedicated facility within 2 years: 1. Dry Powder Injectable (Carbapenem)			
4.	M/s Relizon Pharmaceuticals, Plot No.118, Sunder Industrial Estate, Raiwind Road, Lahore. **DML No. 000875 (Formulation)** **Period:** Commencing on 21-02-2023 ending on 20-02-2028. Evaluator:- Abdullah (AD-Lic)	**26-06-2024**	**Good**	1. Mr. Muhammad Tariq, Director DTL, Lahore. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.
	QC Incharge	Mr. Muhammad Abbas Sadiq (Pharm-D)		
	Production Incharge	Ms. Effat Zohra (Pharm-D)		
	Recommendations of the panel: Keeping in view the manufacturing facility like, building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation on the day of inspection, the panel of inspectors **recommends** the renewal of Drug Manufacturing License by way of formulation to M/s Relizon			

	Pharmaceuticals (Pvt.) Ltd., Plot No.118, Sunder Industrial Estate, Raiwind Road, Lahore for the following sections: 1. Tablet Section (General) 2. Capsule Section (General) 3. Dry Powder Suspension Section (General) **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. 000875, by way of Formulation, in the name of M/s Relizon Pharmaceuticals, Plot No.118, Sunder Industrial Estate, Raiwind Road, Lahore, for the period commencing on 21-02-2023 ending on 20-02-2028, for the following sections: 1. Tablet Section (General) 2. Capsule Section (General) 3. Dry Powder Suspension Section (General)			
5.	M/s Pharmasol (Pvt.) Ltd., Plot No.549, Sunder Industrial Estate, Lahore. **DML No. 000872 (Formulation)** **Period:** Commencing on 18-12-2022 ending on 17-12-2027. Evaluator:- Abdullah (AD-Lic)	**24-09-2024 & 25-09-2024**	**Good**	1. Dr. Zaka-ur-Rehman, Expert Member. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	QC Incharge	Mr. Kamal Subhani (M. Sc Chemistry)		
	Production Incharge	M. Javed Iqbal (B-Pharm)		
	Recommendations of the panel: Keeping in view the manufacturing facility like building, HVAC system, sanitation, production machinery, equipment in Quality Control, Quality Assurance Compliance, Warehouses, Research & Development Laboratory and Microbiology Laboratory, testing facilities, technical personnel met and documentation reviewed, the panel of inspectors is of the opinion to **recommends** the renewal of Drug Manufacturing License by way of formulation to M/s Pharmasol (Pvt.) Ltd., Plot No.549, Sunder Industrial Estate, Lahore (vide letter No.F.1-17/2005-Lic (Vol-I dated 31-05-2023) for the following sections: 1. Diluents & Water for Injection Section 2. Tablet (Anti-cancer) Section 3. Capsule (Anti-cancer) Section 4. Liquid Injection (Anti-cancer) Section 5. Tablet Section (General) 6. Capsule Section (General) 7. Syrup (General) Section 8. Liquid Injection (General) Section			

9. Dry Powder Injection (General) Section
10. Liquid Ampoule (General) Section
11. Tablet Section (General)
12. Capsule Section (General)
13. Lotion (General) Section
14. Cream/Ointment/Gel (General) Section
15. Dry Powder Suspension (General) Section
16. Dry Powder Sachet (General) Section
17. Eye Drop (General) Section
18. Capsule (Cephalosporin) Section
19. Dry Powder Suspension (Cephalosporin) Section
20. Dry Powder Injection (Cephalosporin) Section
21. Dry Powder Injection (Carbapenem) Section
22. Cream/Ointment/Gel (Steroid) Section
23. Liquid Vials & Ampoule (Steroid) Section
24. Dry Powder Vials (Steroid) section
25. Soft Gelatin Capsule Section.

The panel also recommends to grant of following additional section to M/s Pharmasol (Pvt) Ltd., Plot # 549, Sunder Industrial Estate, Lahore:

1. Tablet Steroidal (Human) (New)

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. 000872, by way of Formulation, in the name of M/s Pharmasol (Pvt.) Ltd., Plot No.549, Sunder Industrial Estate, Lahore, for the period commencing on 18-12-2022 ending on 17-12-2027, for the following sections:

1. Diluents & Water for Injection Section
2. Tablet (Anti-cancer) Section
3. Capsule (Anti-cancer) Section
4. Liquid Injection (Anti-cancer) Section
5. Tablet Section (General)
6. Capsule Section (General)
7. Syrup (General) Section
8. Liquid Injection (General) Section
9. Dry Powder Injection (General) Section
10. Liquid Ampoule (General) Section
11. Tablet Section (General)
12. Capsule Section (General)
13. Lotion (General) Section
14. Cream/Ointment/Gel (General) Section
15. Dry Powder Suspension (General) Section
16. Dry Powder Sachet (General) Section
17. Eye Drop (General) Section
18. Cream/Ointment/Gel (Steroid) Section
19. Liquid Vials & Ampoule (Steroid) Section
20. Dry Powder Vials (Steroid) section
21. Soft Gelatin Capsule Section

	Furthermore, the Board authorized Chairman CLB to issue the renewal of the following Cephalosporin and Carbapenem Sections after receiving the undertaking for establishing a segregated dedicated facility within 2 years: 1. Capsule (Cephalosporin) Section 2. Dry Powder Suspension (Cephalosporin) Section 3. Dry Powder Injection (Cephalosporin) Section 4. Dry Powder Injection (Carbapenem) Section			
6.	M/s Crown Pharmaceuticals, Plot No.286, Industrial Triangle Kahuta Road, Islamabad. **DML No. 000456 (Formulation)** **Period:** Commencing on 11-06-2021 ending on 10-06-2026. (Evaluator: - Urooj Fatima (DD-Lic)	**14-05-2024 & 24-06-2024**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Ms. Saadia Mahwish, FID, DRAP, Islamabad. 3. Abdul Mughees, Assistant Director CEO Office, DRAP, Islamabad
	QC Incharge	Mr. Abdul Hassan Khan (M.Sc Chemistry)		
	Production Incharge	Mr. Azmat Ullah Khan (B-Pharm)		
	Recommendations of the panel on 14-05-2024: Keeping in view the above facts on record, documents reviewed people met during the visit & compliance of the firm to the directions of inspection team, the panel unanimously **recommended renewal/**revision/grant of additional sections of the following sections of M/s Crown Pharmaceuticals Plot # 286, Industrial Triangle Kahuta Road, Islamabad. DML No. 000456: **Renewal of Drug Manufacturing License by way of Formulation** 1. Tablet Section (General) (Revised) 2. Tablet Section (Psychotropic) (Revised) 3. Capsule Section (General) (Revised) 4. Oral Dry Powder for Suspension Section (General) (Revised) 5. Capsule Section (Cephalosporin) (Revised) 6. Oral Dry Powder for Suspension Section (Cephalosporin) (Revised) 7. Warehouse (Revised) 8. QC Lab (Revised) **Grant of Additional Sections** 1. Sachet Section (General) (Additional) 2. Ointment / Cream (General) (Additional) 3. Lotion (General) (Additional) **Recommendations of the panel on 24-06-2024:**			

	Keeping in view the above facts on record, documents reviewed people met during the visits & compliance of the firm to the directions of inspection team, the panel unanimously **recommended renewal/revision** of the following sections of M/s Crown Pharmaceuticals, Plot No.286, Industrial Triangle Kahuta Road, Islamabad DML # 000456: **Renewal of Drug Manufacturing License by way of Formulation** 1. Dry Powder for injection Section (Cephalosporin) (Revised) **Decision of the Central Licensing Board in 302nd meeting** The Board, on the recommendations of the panel of experts: I. Approved the grant of renewal of DML No. 000456, by way of Formulation, in the name of M/s Crown Pharmaceuticals, Plot No.286, Industrial Triangle Kahuta Road, Islamabad for the period commencing on 11-06-2021 ending on 10-06-2026, for the following sections, subject to verification of necessary testing equipments: 1. Tablet Section (General) (Revised) 2. Capsule Section (General) (Revised) 3. Oral Dry Powder for Suspension Section (General) (Revised) 4. Warehouse (Revised) 5. QC Lab (Revised) 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 date 10/11/2020: 1. Tablet Section (Psychotropic) (Revised) III. Furthermore, the Board authorized Chairman CLB to issue the grant of renewal of the following Cephalosporin Sections after receiving the undertaking for establishing a segregated dedicated facility within 2 years: 1. Capsule Section (Cephalosporin) (Revised) 2. Oral Dry Powder for Suspension Section (Cephalosporin) (Revised) 3. Dry Powder for injection Section (Cephalosporin) (Revised)			
7.	M/s Wimits Pharmaceuticals, Plot No129, Sundar Industrial Estate, Raiwind Road, Lahore. **DML No. 000789 (Formulation)** **Period:** Commencing on 03-02-2024 ending on 02-02-2029.	**12-08-2024**	**Good**	4. Dr. Farzana Ch., Expert Member. 5. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 6. Mr. Abdul Rashid Sheikh, fFID, DRAP, Lahore.

	(Evaluator: - Abdullah (AD-Lic)			
	QC Incharge	Muhammad Rizwan (Pharm-D)		
	Production Incharge	Habib-ur-Rehman (B-Pharm)		

Recommendations of the panel:

In view the manufacturing facilities like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and microbiology laboratory, testing facilities, discussion with technical personnel and documentation reviewed, the panel of Inspectors is of the opinion to **recommend** the renewal of Drug Manufacturing License by way of formulation and grant of additional section to M/s Wimits Pharmaceuticals, Plot No129, Sundar Industrial Estate, Raiwind road, Lahore for the following sections:

Human Section.

1. Liquid Injectable Section (General) Ampoule
2. Oral Liquid Section (General)
3. Tablet Section (General)
4. Capsule Section (General)
5. Capsule Section (Cephalosporin)
6. Dry Powder Suspension Section (Cephalosporin)
7. Dry Powder Injection Section (Cephalosporin)
8. Cream/Ointment/Lotion/Gel Section (General)

Veterinary Sections

1. Drench Section (General) (Veterinary)
2. Liquid Injectable Section (General) (Veterinary)
3. Bolus Section (General) (Veterinary)
4. Oral Dry Powder Section (General) (Veterinary)

The panel also recommends the grant of following additional section to M/s Wimits Pharmaceuticals, Plot No129, Sundar Industrial Estate, Raiwind road, Lahore:

1. Tablet Section (General)-II-New

However, following sections are not mentioned in the recommendation of panel:

i. Drench-II (General) Vet
ii. Dry Powder-II (General) Veterinary
iii. Bolus-II (General) Veterinary

Decision of the Central Licensing Board in 302nd meeting

The Board, on the recommendations of the panel of experts:

I. Approved the grant of renewal of DML No. **000789,** by way of Formulation, in the name of M/s Wimits Pharmaceuticals, Plot No129, Sundar Industrial Estate, Raiwind Road, Lahore, for the period commencing on 03-02-2024 ending on 02-02-2029, for the following sections:

Human Section.

1. Liquid Injectable Section (General) Ampoule
2. Oral Liquid Section (General)
3. Tablet Section (General)

	4. Capsule Section (General) 5. Cream/Ointment/Lotion/Gel Section (General) **<u>Veterinary Sections</u>** 1. Drench Section (General) (Veterinary) 2. Liquid Injectable Section (General) (Veterinary) 3. Bolus Section (General) (Veterinary) 4. Oral Dry Powder Section (General) (Veterinary) II. Furthermore, the Board authorized Chairman CLB to issue the Renewal of following Cephalosporin Sections (Human) 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 (Cephalosporin) The Board considered the inspection report and observed that following sections are not mentioned in the recommendations of the panel, therefore, 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. **000789,** by way of Formulation, in the name of M/s Wimits Pharmaceuticals, Plot No129, Sundar Industrial Estate, Raiwind Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the the Drugs (Licensing, Registering and Advertising) Rules, 1976 for the following sections: *i. Drench-II (General) Vet* *ii. Dry Powder-II (General) Veterinary* *iii. Bolus-II (General) Veterinary*			
8.	M/s Amson Vaccines & Pharma (Pvt) Ltd., 154-Industrial Triangle, Kahuta Road, Islamabad. **DML No. 000393 (Formulation)** **Period:** Commencing on 21-06-2024 ending on 20-06-2029. (Evaluator: - Urooj Fatima (DD-Lic)	**26-09-2024 & 27-09-2024**	**Good**	1. Mr. Hafiz Sanaullah Babar, Deputy Director, DRAP, Islamabad. 2. Mr. Abdul Mughees Muddasir, Deputy Director, DRAP, Islamabad. 3. Mr. Zain Ul Abidin, Deputy Director, DRAP, Islamabad.
	QC Incharge	Muhammad Muddassir (Pharm-D)		
	Production Incharge	Sajjad Hussain (B-Pharm)		
	<u>Recommendations of the panel:</u>			

The panel is of the view 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 03 of this report in accordance with the requirements of cGMP. In conclusion, after reviewing the submitted documentation, inspecting the premises, noting the positive attitude and intent of the management, 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):-

Sr. No.	Formulation(s)	Pharmacological Category (ies)
1.	Tablet Section	General
2.	Capsule Section	General
3.	Oral Liquid Section	General
4.	Tablet Section	Psychotropic
5.	Dry Powder Injection Section	Steroid
6.	Liquid Ampoule Section	Vaccine
7.	Liquid Vial Injection Section	Vaccine / Sera
8.	Water for Injection Section	-

Decision of the Central Licensing Board in 302nd meeting

The Board, on the recommendations of the panel of experts:

I. Approved the grant of renewal of DML No. 000393, by way of Formulation, in the name of M/s Amson Vaccines & Pharma (Pvt) Ltd., 154-Industrial Triangle, Kahuta Road, Islamabad for the period commencing on 21-06-2024 ending on 20-06-2029 for the following sections subject to verification of necessary testing equipments:

Sr. No.	Formulation(s)	Pharmacological Category (ies)
1.	Tablet Section	General
2.	Capsule Section	General
3.	Oral Liquid Section	General
4.	Dry Powder Injection Section	Steroid
5.	Liquid Ampoule Section	Vaccine
6.	Liquid Vial Injection Section	Vaccine / Sera
7.	Water for Injection Section	-

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 date 10/11/2020:

<table>
<tr><td></td><td colspan="4">1. Tablet (Psychotropic) Section.</td></tr>
<tr><td>9.</td><td>M/s Theramed Pharmaceuticals (Pvt) Ltd., 45-Km, Multan Road, Lahore.

DML No. 000696 (Formulation)

Period: Commencing on 19-08-2020 ending on 18-08-2025.

(Evaluator: - Abdullah (AD-Lic)</td><td>27-08-2024</td><td>Good</td><td>4. Dr. Farzana Chaudhary, Expert Member.
5. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore.
6. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.</td></tr>
<tr><td></td><td>QC Incharge</td><td colspan="3">Ms. Meheryab (M.Sc Applied Chemistry)</td></tr>
<tr><td></td><td>Production Incharge</td><td colspan="3">Mr. Muhammad Asif Raza (B-Pharm)</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>

In view of 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 renewal of Drug Manufacturing License to M/s Theramed Pharmaceuticals (Pvt) Ltd., 45-Km, Multan Road, Lahore for the following sections:
1. Tablet Section (General)
2. Capsule section (General)
3. Oral Liquid Section (General)
4. Oral Dry Powder Section (General)
5. Tablet Section (Psychotropic)
6. Capsule Section (Psychotropic)

The panel also recommends the grant of following additional section to M/s Theramed Pharmaceuticals (Pvt) Ltd., 45-Km, Multan Road, Lahore:

1. External Liquid Section (New)

However, following sections are not mentioned in the recommendation of panel:
i. Tablet (Antibiotic) (Renewal)
ii. Capsule (Antibiotic) (Renewal)
<u>Additional/Relocation) First Floor</u>
i. Syrup (General)
ii. Powder (General)
iii. Quality Control Laboratory
iv. Microbiology Laboratory

Also the nomenclature of the new section is written as “External Liquid section (New)” instead of “External Liquid section (new) in place of Quality Control & Microbiology Laboratory which is shifted to First Floor”

<u>Decision of the Central Licensing Board in 302nd meeting</u></td></tr>
</table>

	The Board on the recommendations of the panel of experts: III. Approved the grant of renewal of DML No. 000696, by way of Formulation, in the name of M/s Theramed Pharmaceuticals (Pvt.) Ltd., 45-Km, Multan Road, Lahore, for the period commencing on 19-08-2020 ending on 18-08-2025, for the following sections subject to verification by the panel on confirmation of relocation of Micro and QC lab as per approved Layout Plan: 1. Tablet Section (General) 2. Capsule section (General) 3. Oral Liquid Section (General) 4. Oral Dry Powder Section (General) IV. Approved renewal of following sections, subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020: 1. Tablet Section (Psychotropic) 2. Capsule Section (Psychotropic) V. The Board considered the inspection report and observed that following sections are not mentioned in the recommendations of the panel, therefore, 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000696, by way of Formulation, in the name of M/s Theramed Pharmaceuticals (Pvt.) Ltd., 45-Km, Multan Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the the Drugs (Licensing, Registering and Advertising) Rules, 1976 for the following sections: 1. Tablet (Antibiotic) 2. Capsule (Antibiotic)			
10.	M/s Surge Laboratories (Pvt) Ltd., 10-Km, Faisalabad Road, Bikhi, District Sheikhupura. **DML No. 000649 (Semi-Basic Manufacture)** **Period:** Commencing on 12-12-2023 ending on 11-12-2028. (Evaluator: - Abdullah (AD-Lic)	**27-09-2024**	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drug Inspector Punjab, Lahore. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director (I&E), DRAP, Lahore
	QC Incharge	Mr. Muhammad Farhan Parvez (Pharm-D)		
	Production Incharge	Mr. Asad Imran (Pharm-D)		

Recommendations of the panel:

Keeping in view the above observations during the panel inspection of M/s Surge Laboratories (Pvt) Ltd., 10-Km, Faisalabad Road, Bikhi, District Sheikhupura, the panel **recommends** the grant of Drug Manufacturing License No.000649 by way of Semi-Basic Manufacturing as per DRAP Islamabad letter No.F.1-18/95-Lic (Vol-III) dated 12th March, 2024:

S.No.	List of Products
1.	Omeprazole (Enteric Coated Pellets)
2.	Esomeprazole (Enteric Coated Pellets)
3.	Pantoprazole (Enteric Coated Pellets)
4.	Rabeprazole (Enteric Coated Pellets)
5.	Diclofenac Sodium (Enteric Coated Pellets)
6.	Diclofenac Potassium (Enteric Coated Pellets)
7.	Mebeverine (Enteric Coated Pellets)
8.	Aspirin (Enteric Coated Pellets)
9.	Paracetamol (Taste Masked Coated Granules)
10.	Ascorbic Acid (Taste Masked Coated Granules)
11.	Clarithromycin (Taste Masked Coated Granules)
12.	Azithromycin (Taste Masked Coated Granules)
13.	Roxithromycin (Taste Masked Coated Granules)
14.	Secnidazole (Taste Masked Coated Granules)
15.	Ciprofloxacin (Taste Masked Coated Granules)
16.	Piperaquine Phosphate (Taste Masked Coated Granules)
17.	Trimethoprim (Taste Masked Coated Granules)
18.	Erythromycin (Taste Masked Coated Granules)
19.	Deferiprone (Taste Masked Coated Granules)
20.	Mefenamic Acid (Taste Masked Coated Granules)
21.	Cetirizine (Taste Masked Coated Granules)
22.	Duloxetine (Enteric Coated Pellets)
23.	Domperidone (Taste Masked Coated Granules/ Pellets)
24.	Loratidine (Coated Granules/ Pellets)
25.	Levocetrizine ((Taste Masked Coated Granules/ Pellets)
26.	Levofloxacin ((Taste Masked Coated Granules)
27.	Ibuprofen (Taste Masked Coated Granules)
28.	Sodium Bicarbonate (Coated Granules)
29.	Mebeverine Taste Masked Granules
30.	Pyridoxine (Coated Granules)
31.	Risperidone (Taste Masked Coated Granules)
32.	Citric Acid (Coated Granules)
33.	Linezolid (Taste Masked Coated Granules)
34.	Lornoxicam (Enteric Coated Granules)
35.	Ferrous Fumarate (Coated Granules)
36.	Aceclofenac SR Pellets
37.	Cyclobenzaprine HCl Pellets
38.	Riboflavin (Coated Granules)
39.	Doxycycline HCl Pellets
40.	Zinc Sulfate (Coated Granules)
41.	Itopride (Sustained Release Pellets)
42.	Itraconazole (Coated Pellets)
43.	Orlistat (Granules/ Micro Pellets)
44.	Tamsulosin HCl (Coated Pellets)

45.	Theophylline (Sustained Release Pellets)
46.	Tizanidine HCl (Sustained Release Pellets)
47.	Famotidine (Taste Masked Granules)
48.	Lansoprazole Pellets (USP41)
49.	Gabapentin Granules (Surge Specs)
50.	Mannitol Granules (Surge Specs)
51.	Mannitol Granules (Surge Specs)
52.	Vitamin B1 Pellets (Surge Specs)
53.	Pregabalin Pellets (Surge Specs)
54.	Dexlansoprazole Pellets (Surge Specs)
55.	Fenofibrate Pellets (Surge Specs)
56.	Nicotinamide Pellets (Surge Specs)
57.	Diclofenac Sodium (Sustained Release Pellets 32% w/w)
58.	Mebeverine HCl (Sustained Release Pellets 80% w/w)

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. 000649, by way of Semi-Basic Manufacture, in the name of M/s Surge Laboratories (Pvt) Ltd., 10-Km, Faisalabad Road, Bikhi, District Sheikhupura, for the period commencing on 12-12-2023 ending on 11-12-2028, for the following APIs, 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 and subject to signing of manufacturing process flow charts by the panel:

S.No.	List of Products
1.	Omeprazole (Enteric Coated Pellets)
2.	Esomeprazole (Enteric Coated Pellets)
3.	Pantoprazole (Enteric Coated Pellets)
4.	Rabeprazole (Enteric Coated Pellets)
5.	Diclofenac Sodium (Enteric Coated Pellets)
6.	Diclofenac Potassium (Enteric Coated Pellets)
7.	Mebeverine (Enteric Coated Pellets)
8.	Aspirin (Enteric Coated Pellets)
9.	Paracetamol (Taste Masked Coated Granules)
10.	Ascorbic Acid (Taste Masked Coated Granules)
11.	Clarithromycin (Taste Masked Coated Granules)
12.	Azithromycin (Taste Masked Coated Granules)
13.	Roxithromycin (Taste Masked Coated Granules)
14.	Secnidazole (Taste Masked Coated Granules)
15.	Ciprofloxacin (Taste Masked Coated Granules)
16.	Piperaquine Phosphate (Taste Masked Coated Granules)
17.	Trimethoprim (Taste Masked Coated Granules)
18.	Erythromycin (Taste Masked Coated Granules)
19.	Deferiprone (Taste Masked Coated Granules)
20.	Mefenamic Acid (Taste Masked Coated Granules)
21.	Cetirizine (Taste Masked Coated Granules)
22.	Duloxetine (Enteric Coated Pellets)
23.	Domperidone (Taste Masked Coated Granules/ Pellets)

	24.	Loratidine (Coated Granules/ Pellets)			
	25.	Levocetrizine ((Taste Masked Coated Granules/ Pellets)			
	26.	Levofloxacin ((Taste Masked Coated Granules)			
	27.	Ibuprofen (Taste Masked Coated Granules)			
	28.	Sodium Bicarbonate (Coated Granules)			
	29.	Mebeverine Taste Masked Granules			
	30.	Pyridoxine (Coated Granules)			
	31.	Risperidone (Taste Masked Coated Granules)			
	32.	Citric Acid (Coated Granules)			
	33.	Linezolid (Taste Masked Coated Granules)			
	34.	Lornoxicam (Enteric Coated Granules)			
	35.	Ferrous Fumarate (Coated Granules)			
	36.	Aceclofenac SR Pellets			
	37.	Cyclobenzaprine HCl Pellets			
	38.	Riboflavin (Coated Granules)			
	39.	Doxycycline HCl Pellets			
	40.	Zinc Sulfate (Coated Granules)			
	41.	Itopride (Sustained Release Pellets)			
	42.	Itraconazole (Coated Pellets)			
	43.	Orlistat (Granules/ Micro Pellets)			
	44.	Tamsulosin HCl (Coated Pellets)			
	45.	Theophylline (Sustained Release Pellets)			
	46.	Tizanidine HCl (Sustained Release Pellets)			
	47.	Famotidine (Taste Masked Granules)			
	48.	Lansoprazole Pellets (USP41)			
	49.	Gabapentin Granules (Surge Specs)			
	50.	Mannitol Granules (Surge Specs)			
	51.	Mannitol Granules (Surge Specs)			
	52.	Vitamin B1 Pellets (Surge Specs)			
	53.	Pregabalin Pellets (Surge Specs)			
	54.	Dexlansoprazole Pellets (Surge Specs)			
	55.	Fenofibrate Pellets (Surge Specs)			
	56.	Nicotinamide Pellets (Surge Specs)			
	57.	Diclofenac Sodium (Sustained Release Pellets 32% w/w)			
	58.	Mebeverine HCl (Sustained Release Pellets 80% w/w)			
11.	M/s Curatech Pharma (Pvt) Ltd., 35-Km, Multan Road, Lahore. **DML No. 000619 (Formulation)** **Period:** Commencing on 17-07-2022 & ending on 16-07-2027. (Evaluator: - Zunaira Faryad (DD-Lic)	**07-08-2024**	**Good**	1. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 2. Mr. Azhar Jamal Saleemi, Chief Drugs Controller Punjab, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.	

QC Incharge	Ms. Uzma Zaheer (M. Sc Chemistry)
Production Incharge	Mr. Saeed Hussain (B. Pharm)

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 in of the opinion to **recommend** the grant of renewal of Drug Manufacturing License and approval of new section by way of formulation to M/s Curatech Pharma (Pvt) Ltd., 35-Km, Multan Road, Lahore (vide letters No.F.1-4/2002-Lic (Vol-II) dated 23-06-2023) for the following section.

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

Decision of the Central Licensing Board in 302nd meeting

The Board, on the recommendations of the panel of experts:

I. Approved the grant of renewal of DML No. 000619, by way of Formulation, in the name of M/s Curatech Pharma (Pvt) Ltd., 35-Km, Multan Road, Lahore, for the period commencing on 17-07-2022 & ending on 16-07-2027, for the following sections:

    1. Syrup/Suspension Section (General)
    2. Tablet Section (General)
    3. Capsule Section (General)
    4. Sachet Section (General)

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

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

III. 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 for Injection Section (Cephalosporin)

<table>
<tr><td>12.</td><td>M/s News Pharma, Plot No. 42, Sunder Industrial Estate, Lahore.

DML No. 000775 (Formulation)

Period: Commencing 18-02-2023 & ending on 17-02-2028

(Evaluator: - Zunaira Faryad (DD-Lic)</td><td>29-05-2024</td><td>Good</td><td>1. Dr. Zaka-ur-Rehman, Expert Member.
2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore.
3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td>QC Incharge</td><td colspan="3">Mr. Waseem Arif (M.Sc. Chemistry)</td></tr>
<tr><td></td><td>Production Incharge</td><td colspan="3">Mr. Ayaz Ahmed (Pharm-D)</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>

In view the manufacturing facilities like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and microbiology laboratory, testing facilities, discussion with technical personnel and documentation reviewed, the panel of inspectors is of the opinion to recommend the renewal of Drug Manufacturing License by way of Formulation to M/s News Pharma, Plot No.42, Sunder Industrial Estate, Lahore (vide letter no.F.1-14/2006-Lic (Vol-I) dated 06-03-2024), for the following sections.
1. Liquid Injection Section (General)
2. Oral Liquid Section (General)
3. Dry Powder Injection Section (Cephalosporin)
4. Capsule Section (Cephalosporin)
5. Dry Powder Suspension Section (Cephalosporin)

<u>Decision of the Central Licensing Board in 302nd meeting</u>
The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000775, by way of Formulation in the name of News Pharma, Plot No. 42, Sunder Industrial Estate, Lahore for the period commencing on 18-02-2023 & ending on 17-02-2028, for the following sections:

1. Liquid Injection Section (General)
2. Oral Liquid 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. Dry Powder Injection Section (Cephalosporin)
2. Capsule Section (Cephalosporin)
3. Dry Powder Suspension Section (Cephalosporin)</td></tr>
<tr><td>13.</td><td>M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad.</td><td>20-05-2024, 10-07-2024 and 25-09-2024</td><td>Good</td><td>1. Dr. Qurban Ali, Ex-DG National Veterianry Laboratory, Islamabad.</td></tr>
</table>

	DML No. 000426 (Formulation) **Period:** Commencing on 25-03-2021 ending on 24-03-2026. (Evaluator: - Urooj Fatima (DD-Lic)			2. Ms. Saadia Mahwish, Area FID, DRAP, Islamabad. 3. Mr. Mubashir Iqbal, Deputy Director, DRAP, Islamabad.
	QC Incharge	Mr. Ibrar Ahmad (Pharm-D)		
	Production Incharge	Mr. Riaz Ahmed (B-Pharm)		
	Recommendations of the panel: Keeping in view the above facts on record, documents reviewed people met during the visit & compliance of the firm to the direction of inspection team, the panel unanimously **recommends renewal/regularization** of following sections of M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad DML # 000426: 1. Penicillin Section (Veterinary) (Regularization) 2. Oral Powder (Veterinary) (Regularization) 3. Oral Liquid (Veterinary) (Regularization) 4. Quality Control (Veterinary) (Regularization) 5. Micro Lab (Veterinary) (New) 6. Raw Material Store (New Building) 7. Raw Material Store (Regularization) 8. Packaging Material Store (Regularization) **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. 000426, by way of Formulation and regularized the layout plan in the name of M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad, for the period commencing on 25-03-2021 ending on 24-03-2026, for the following sections, subject to verification of necessary testing equipments: 1. Penicillin Section (Veterinary) (Renewal & Regularization) 2. Oral Powder (Veterinary) (Renewal &Regularization) 3. Oral Liquid (Veterinary) (Renewal &Regularization) 4. Quality Control (Veterinary) (Regularization) 5. Micro Lab (Veterinary) (New) 6. Raw Material Store (New Building) 7. Raw Material Store (Regularization) 8. Packaging Material Store (Regularization)			
14.	M/s Pliva Pakistan (Pvt) Limited, Plot No. B-77, Hub Industrial Trading Estate, Balochistan. DML No. 000280 (Formulation).	08.08.2024 & 09.08.2024	**Good**	1. Mr. Muhammad Salik Zahid, Chief Drug Inspector Balochistan/Member CLB. 2. Dr. Kirshan, Area FID, DRAP, Quetta.

	Period: Commencing on 22.05.2024 ending on 21.05.2029 Evaluator: - Akbar Ali (DD-Lic)			3. Mr. Abdul Waheed, Assistant Director, DRAP, Quetta.
	QC In-charge	Mrs. Rakhshanda Parveen, (B.Pharm)		
	Production In-charge	Mr. Ghulam Nabi Mahar (B.Pharm)		

Recommendations of the panel:

M/s Pliva Pakistan (Pvt) Limited, Plot B-77, H.I.T,E, Hub, Balochistan, was visited and inspected in detail on 8th & 9th August, 2024 in compliance to the directions contained in DRAP, Islamabad letter No.F.4-1/89 (Vol-V) dated 28th June, 2024, in connection with Renewal of Drug Manufacturing License (DML No. 000280).

The panel inspected the firm in detail including manufacturing sections, stores and QC Lab and found the facility constructed as per approved lay out plan and compliant. The facility has been provided with necessary utilities, machineries/equipment & sufficient Technical staff as required under the guidelines. Necessary documents related to QC, QA and production and qualification of machines/ equipments, HVAC and other utilities were seen in place & also reviewed.

Based on the technical staff met, documents reviewed, and observations made during the inspection, the panel unanimously **recommends** the renewal of Drug Manufacturing License (DML No. 000280) for the tenure of next five years w.e.f 22-05-2024 for following Sections: -

Sr.No.	Name of Section
Ground Floor	
01	Tablet (General)
02	Capsule (General)
03	Liquid Syrup (General)
04	Dry Suspension (General)
05	Cream /Ointment (General)
06	Liquid Injection (Vial/Ampoule) Svp
07	Ophthalmic Section (General)
08	Capsule Section (Penicillin)
09	Dry Suspension (Penicillin)
10	Sachet Section (General)
First Floor	
11	Capsule Section (Cephalosporin)
12	Dry Powder Injectable (Cephalosporin)
13	Tablet Section (Psychotropic)
14	Dry Powder Injectable Vial (Chloramphenicol)
15	Dry Powder Injectable (Penicillin)
16	Dry Powder Suspension (Cephalosporin)

Decision of the Central Licensing Board in 302nd meeting

The Board considered and approved the grant of renewal of DML No. 000280, by way of Formulation, in the name of M/s Pliva Pakistan (Pvt) Limited, Plot No. B-77, Hub Industrial

	Trading Estate, Baluchistan, on the recommendations of the panel of experts, for the period commencing on 22.05.2024 ending on 21.05.2029, for the following sections: **Ground Floor** 01 Tablet (General) 02 Capsule (General) 03 Liquid Syrup (General) 04 Dry Suspension (General) 05 Cream /Ointment (General) 06 Liquid Injection (Vial/Ampoule) (SVP) (General) 07 Ophthalmic Section (General) 08 Sachet Section (General) **First Floor** 01 Dry Powder Injectable Vial (Chloramphenicol) Furthermore, the Board authorized Chairman CLB to issue the renewal of the following Cephalosporin and Penicillin Sections after receiving the undertaking for establishing a segregated dedicated facility within 2 years: **Ground Floor** 01 Capsule Section (Penicillin) 02 Dry Suspension (Penicillin) **First Floor** 01 Capsule Section (Cephalosporin) 02 Dry Powder Injectable (Cephalosporin) 03 Dry Powder Injectable (Penicillin) 04 Dry Powder Suspension (Cephalosporin) 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 date 10/11/2020: **First Floor** 01 Tablet Section (Psychotropic).			
15.	M/s Helix Pharma (Pvt) Ltd, A-56, S.I.T.E., Manghopir Road, Karachi. DML No.000030 (Formulation) *Evaluator: - Akbar Ali (DD-Lic)*	01-10-2024	Good	1. Dr. Saif-ur-Rehman Khattak, Additional Director (E&M), DRAP, Karachi. 2. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Sindh. 3. Mr. Muhammad Asim, Assistant Director, CDL, Karachi.
	Recommendations of the panel: - The inspection of M/s Helix Pharma (Pvt) Ltd, Karachi was conducted on 01-10-2024 as per mandate specified vide above quoted letter of Licensing, Division, DRAP, Islamabad. The			

	panel visited the premises for the verification of constructed facility as per revised layout plan and no irregularities were found. Furthermore, the panel also verified the installation of HVAC and found as per equipment including HPLC, FTIR, UV/VIS Spectrophotometer, analytical balance, pH meter, conductivity meter, TOC analyzer, liquid particle counter etc., Calibration stickers are visible on most equipment, indicating recent calibration and trained staff for the testing of manufactured drugs as per prescribed testing methods. 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 for **regularization of revised layout** may be considered as per relevant rules/laws. Details of revised/regularized sections: i. Tablet (General) Section ii. Capsule (General) Section iii. Dry Powder Suspension (General) Section iv. Liquid Syrup (General) Section v. Warehouse (General) **<u>Decision of the Central Licensing Board in 302nd meeting</u>** The Board, on the recommendations of the panel of experts, regularized the layout plan of following sections, in the name of M/s Helix Pharma (Pvt) Ltd, A-56, S.I.T.E., Manghopir Road, Karachi DML No. 000030, by way of Formulation: i. Tablet (General) Section ii. Capsule (General) Section iii. Dry Powder Suspension (General) Section iv. Liquid Syrup (General) Section v. Warehouse (General)			
16.	M/s Avant Pharmaceuticals (Pvt.), Ltd, Plot No.M-28, Hub Industrial Estate, Hub, Balochistan. DML No. 000786 (Formulation). **Period:** Commencing on 03-02-2024 ending on 02-02-2029 Evaluator: - Akbar Ali (DD-Lic)	04.10.2024	**Good**	1. Mr. Muhammad Salik Zahid, Chief Drug Inspector Balochistan/Member CLB. 2. Dr. Kirshan, Office Incharge/Area FID, DRAP, Quetta. 3. Mst. Sanam Kausar, Assistant Director, CDL, Karachi.
	QC In-charge	Mr. Iqrar Hussain (M.Sc. Chemistry)		
	Production In-charge	Mr. Mudassir Abbas (Pharm-D)		

<table>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>
M/s Avant Pharmaceuticals (Pvt) Ltd, Plot No.M-28, H.I.T.E., Hub, Blaochistan was visited and inspected in detail on 04th October, 2024 in compliance to the directions contained in DRAP, Islamabad letter No.F.4-1/2010-Lic (Vol-I) dated 18th September, 2024, in connection with Renewal of Drug Manufacturing License (DML No. 000786) by way of formulation.

The panel inspected the firm in detail including manufacturing sections, stores and QC Lab and found the facility constructed as per approved lay out plan and compliant. The facility has been provided with necessary utilities, machineries/equipment & Technical staff as required under the guidelines. Necessary documents related to QC, QA and production and qualification of machines/ equipments, HVAC and other utilities were seen in place & also reviewed.

Based on the people met, documents reviewed, and observations made during the inspection, the panel unanimously recommends the renewal of Drug Manufacturing License (DML No. 000786) for following Sections w.e.f. 03.02.2024 : -

<table><tr><th>Sr. No.</th><th>Name of Section</th></tr><tr><td>01</td><td>Tablet (General)</td></tr><tr><td>02</td><td>Capsule (General)</td></tr></table>
<u>Decision of the Central Licensing Board in 302nd meeting:</u>
The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000786, by way of Formulation, in the name of M/s Avant Pharmaceuticals (Pvt.), Ltd, Plot No.M-28, Hub Industrial Estate, Hub, Balochistan, for the period commencing on 03-02-2024 & ending on 02-02-2029, for the following sections, subject to verification of necessary testing equipments:

<table><tr><td>Sr. No.</td><td>Name of Section</td></tr><tr><td>01</td><td>Tablet (General)</td></tr><tr><td>02</td><td>Capsule (General)</td></tr></table></td></tr>
<tr><td>17.</td><td>M/s Barret Hodgson Pakistan (Pvt.) Ltd, F/423, S.I.T.E., Karachi, Pakistan.

DML No. 000457 (Formulation).

Evaluator: - Akbar Ali (DD-Lic)</td><td>25.10.2024</td><td>Good</td><td>1. Dr. Awais Ahmed, Assistant Director, DRAP, Karachi.
2. Mrs. Mahrukh Mughal, Deputy Director, DRAP, Karachi.
3. Mrs. Mehwish Javed Khan, Assistant Director, DRAP, Karachi.</td></tr>
</table>

Recommendations of the panel:

In compliance to DRAP Islamabad Licensing division letter No.F.2-4/27-Lic (Vol-IV) dated 19th September, 2024 following panel visited the M/s Barret Hodgson Pakistan (Pvt.) Ltd on 25.10.2024. The panel visited for the verification of construction facility as per revised layout plan and it was found that the area was constructed as per revised layout plan and it was found that area was constructed as per revised layout plan and no irregularities were found. Furthermore, panel also verified the HVAC installation and qualification and found satisfactory. During audit of QC section, all relevant equipments like HPLC, GC, FTIR, UV spectrophotometer, TOC analyzer, PH meter, conductivity meter, analytical balances etc., liquid particle counter etc.

The firm was advised to work on some identified gaps in documentation. Some suggestions were also given regarding are qualification and validation of equipments.

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 regularization of revised layout may be considered as per relevant rules/laws.

Details of revised/regularized Sections:

Sr.No.	Name of Existing Sections
i.	Tablet (General)-Revised
ii.	Capsule (General)-Revised
iii.	Sachet (General)-Revised
iv.	Liquid Syrup/Suspension-Revised
v.	Cream/Ointment (General)-Revised

Decision of the Central Licensing Board in 302nd meeting

The Board, on the recommendations of the panel of experts, regularized the layout plan of following sections, under DML No. 000457, by way of Formulation, in the name of M/s Barret Hodgson Pakistan (Pvt.) Ltd, F/423, S.I.T.E., Karachi, Pakistan:

Sr.No.	Name of Existing Sections
i.	Tablet (General)-Revised
ii.	Capsule (General)-Revised
iii.	Sachet (General)-Revised
iv.	Liquid Syrup/Suspension-Revised
v.	Cream/Ointment (General)-Revised

18.	M/s Getz Pharma (Pvt.) Ltd, Plot No.29-30, Sector 27, Korangi Industrial Area, Karachi. DML No. 000284 (Formulation). Evaluator: - Akbar Ali (DD-Lic)	30.10.2024	**V. Good**	1. Mr. Affan Ali, Deputy Director, DRAP, Karachi. 2. Mrs. Mahrukh Mughal, Deputy Director, DRAP, Karachi. 3. Mr. Asfandyar Ajab Khan, Deputy Director, DRAP, Karachi.
	Recommendations of the panel:			

	M/s Getz Pharma (Pvt) Ltd, situated at Plot No.29-30, Sector-27, Korangi Industrial Area, Karachi was inspected in compliance to the instruction contained in DRAP Islamabad No.F.2-5/86-Lic (Vol-I/Pt) dated 19th September, 2024 in connection with the **regularization of Liquid Injection Vials and Cartridges (Biotech-rDNA) area.** The equipment installed are well designed and qualified. The machinery installed for filling of cartridges is newly added and qualified which can also be used for filling of pre-filled syringes by changing some parts. The facility was found well maintained and as per the cGMP requirements in compliance to schedule B-II of Drugs (Licensing, Registering and Advertising) Rules, 1976. Considering the facts stated the panel unanimously **recommends** regularization of section Liquid Injection Vials and Cartridges (Biotech-rDNA). **Decision of the Central Licensing Board in 302nd meeting** The Board, on the recommendations of the panel of experts, regularized the layout plan of following section, in the name of M/s Getz Pharma (Pvt.) Ltd, Plot No.29-30, Sector 27, Korangi Industrial Area, Karachi DML No. 000284, by way of Formulation: i. Liquid Injection Vials and Cartridges (Biotech-rDNA)			
19.	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhobattian Sikka Street, 8-Km, Raiwind Road, Lahore. DML No. 000732 (Formulation). **Period:** Commencing on 26.09.2024 & ending on 25.09.2029 Evaluator: - Zunaira Faryad (DD-Lic)	05-11-2024	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drug Controller Punjab, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	QC In-charge	Syeda Sanam Haider Bukhari Naqvi (Pham-D)		
	Production In-charge	Mr. Kashif Adnan (B-Pharm)		
	Recommendations of the panel: Keeping in view the manufacturing facility, like building, HVAC system production Machinery, Equipment's in Quality Control and Microbiology, Water Treatment Plant, Testing Facilities, Technical Personnel, documentation, the panel of inspectors is of the opinion to **recommend** the renewal of drug Manufacturing License to M/s Fizi Pharmaceutical & Chemicals Laboratories, Sikka Street 8-Km, Raiwind Road, Lahore for the following three sections only: 1. Oral Liquid Section (General) (Veterinary) 2. Oral Dry Powder Section (General) (Veterinary) 3. Liquid Injectable (SVP) Section (General) **Decision of the Central Licensing Board in 302nd meeting**			

<table>
<tr><td></td><td colspan="4">The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000732, by way of Formulation, in the name of M/s Fizi Pharmaceutical & Chemical Laboratories, Bhobattian Sikka Street, 8-Km, Raiwind Road, Lahore, for the period commencing on 26.09.2024 & ending on 25.09.2029, for the following sections:
1. Oral Liquid Section (General) (Veterinary)
2. Oral Dry Powder Section (General) (Veterinary)
3. Liquid Injectable (SVP) Section (General) (Veterinary)</td></tr>
<tr><td>20.</td><td>M/s CSH Pharmaceuticals-North (Pvt) Ltd., 38-A, Industrial Estate Hayatabad, Peshawar.

DML No.000511 (Formulation)

Period: Commencing on 20-06-2023 & ending on 19-06-2028

Evaluator: - Urooj Fatima (DD-Lic)</td><td>03-10-2024
&
08-11-2024</td><td>Good</td><td>1. Mr. Younas Khattak, Chief Drug Inspector Peshawar
2. Mr. Atiq Ul Bari, Area FID, DRAP, Peshawar.
3. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.</td></tr>
<tr><td></td><td>QC In-charge</td><td colspan="3">Mr. Muhammad Riaz (B-Pharm)</td></tr>
<tr><td></td><td>Production In-charge</td><td colspan="3">Mr. Majid Hussain (Pharm-D)</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel: -</u>
The panel unanimously recommended the Grant of Renewal of Drugs manufacturing license No.000511 by way of Formulation for following sections:

1. Tablet Section (General)
2. Capsule Section (General)
3. Oral Liquid Section (General)
4. Capsule Section (Cephalosporin)
5. Dry Powder for Suspension Section (General)
6. Tablet Section (Cephalosporin)
7. Oral Dry Powder for Suspension Section (Cephalosporin)

<u>Decision of the Central Licensing Board in 302nd meeting</u>

The Board, on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000511, by way of Formulation, in the name of M/s CSH Pharmaceuticals-North (Pvt) Ltd., 38-A, Industrial Estate Hayatabad, Peshawar, on the recommendations of the panel of experts, for the period commencing on 20-06-2023 & ending on 19-06-2028, for the following sections:

1. Tablet Section (General)
2. Capsule Section (General)
3. Oral Liquid Section (General)
4. Dry Powder for Suspension Section (General)</td></tr>
</table>

	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. Tablet Section (Cephalosporin) 3. Oral Dry Powder for Suspension Section (Cephalosporin)			
21.	M/s Hi-Med Pharmaceuticals, Plot No.208-C, Sunder Industrial Estate, Lahore. DML No. 000884 (Formulation). **Period:** Commencing on 13-06-2021 & ending on 12-06-2026. Evaluator: - Zunaira Faryad (DD-Lic)	23.09.2024	**Good**	1. Dr. Farzana Ch. Expert Member. 2. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore.
	QC In-charge	Ms. Ifra Gul (M. Sc Applied Chemistry)		
	Production In-charge	Mr. Muhammad Adnan Mushtaq (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 plan, testing facilities, technical personnel, documentation, the panel of inspectors in of the opinion to **recommended** the grant of renewal of Drug Manufacturing License and approval of new section by way of formulation to M/s Hi-Med Pharmaceuticals, 208-C Sunder Industrial Estate, Lahore for the following sections: 1. Tablet Section (General) 2. Capsule Section (General) 3. Sachet Section (General) 4. Dry Powder Suspension Section (General) The panel also recommends to grant of following additional section to M/s Hi-Med Pharmaceuticals, 208-C Sunder Industrial Estate, Lahore. 1. Liquid Injectable Section (Small Volume Parenteral General) **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. 000884, by way of Formulation, in the name of M/s Hi-Med Pharmaceuticals, Plot No.208-C, Sunder Industrial Estate, Lahore, for the period commencing on 13-06-2021 & ending on 12-06-2026, for the following sections: 1. Tablet Section (General) 2. Capsule Section (General)			

<table>
<tr><td></td><td colspan="4">3. Sachet Section (General)
4. Dry Powder Suspension Section (General)</td></tr>
<tr><td>22.</td><td>M/s Linz Pharmaceuticals (Pvt.) Ltd, Plot No.31-G & 31-H, Sector 15, Korangi Industrial Area, Karachi.

DML No. 000540 (Formulation).

Period: Commencing on 24.07.2024 ending on 23.07.2029

Evaluator: - Akbar Ali (DD-Lic)</td><td>06.11.2024</td><td>Good</td><td>1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Health Department, Sindh.
2. Mr. Asfandyar, Deputy Director, DRAP, Karachi.
3. Mrs. Sanam Kausar, Assistant Director, CDL, Karachi.</td></tr>
<tr><td></td><td>QC In-charge</td><td colspan="3">Mr. Khalil Ullah Khan (M.Sc.)</td></tr>
<tr><td></td><td>Production In-charge</td><td colspan="3">Mr. Zahid Mehmood (B.Pharm)</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>
In compliance to DRAP Islamabad letter No.F.2-10/2001-Lic (Vol-II) dated 24th September, 2024 the undersigned panel inspected M/s LINZ Pharmaceuticals (Pvt) Ltd, Plot No.31-G & 31-H, Sector 15, Korangi Industrial Area, Karachi. During Proceedings the panel inspected their QMS system documentation including Organogram, Policies, JDs & SOPS including QRM, Change management, Deviation Management, RCA, CAPA, Customer Complaints & feedback etc. The panel suggested some improvements im their documentation system, however the overall documentation system found satisfactory. Necessary record of relevant SOPs was well maintained. The panel visited their approved sections & inspected in detail all their manufacturing areas, storage areas Q.C. Lab, HVAC System, (Annex-J), Water Treatment Plan (Annex-K), Q.A. system& reviewed relevant documents, processes, SOPs and BMRs. The panel also interacted with the technical staff about their job descriptions and found them well versed in critical GMP issues and were found well trained on their JDs. The panel observed that the facility is well maintained and is at good level of compliance to cGMP requirements as per Schedule B-II of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Aforementioned in the view, the undersigned panel thorough deliberation on the proceeding of the inspection, unanimously recommends the grant of renewal of Drug Manufacturing License No. 000540 by way of formulation to M/s LINZ PHARMACEUTICALS (PVT.) LTD for the period of five years commencing from July 2024 till July 2029.

Details of sections:

<table>
<tr><td>Sr.No.</td><td>Name of Sections</td></tr>
<tr><td>i.</td><td>Tablet (General Antibiotic/Quinolone)</td></tr>
<tr><td>ii.</td><td>Capsule (General)</td></tr>
<tr><td>iii.</td><td>Liquid Injection (General)</td></tr>
<tr><td>iv.</td><td>Capsule (Cephalosporin)</td></tr>
<tr><td>v.</td><td>Dry Powder Injection (Cephalosporin)</td></tr>
</table>
</td></tr>
</table>

	vi.	Dry Powder Suspension (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. 000540, by way of Formulation, in the name of M/s Linz Pharmaceuticals (Pvt.) Ltd, Plot No.31-G & 31-H, Sector 15, Korangi Industrial Area, Karachi, for the period commencing on 24.07.2024 ending on 23.07.2029, for the following sections:

Sr.No.	Name of Sections
i.	Tablet (General Antibiotic/Quinolone)
ii.	Capsule (General)
iii.	Liquid Injection (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:

Sr.No.	Name of Sections
i.	Capsule (Cephalosporin)
ii.	Dry Powder Injection (Cephalosporin)
iii.	Dry Powder Suspension (Cephalosporin)

23.	M/s Aims Pharmaceuticals, Plot No.291, Industrial Triangle Kahuta Road, Islamabad. DML No. 000608 (Formulation). **Period:** Commencing on 21-03-2022 ending on 20-03-2027 Evaluator: - Urooj Fatima (DD-Lic)	06-05-2024, 22-05-2024, 01-08-2024 & 05-08-2024	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad. 2. Mr. Muhammad Arif Ch., Additional Director, DRAP, Islamabad. 3. Ms. Saadia Mahwish, FID-I, DRAP, Islamabad.
	QC In-charge	Mr. Junaid Umer Alvi (Pharm-D)		
	Production In-charge	Mr. Muhammad Aamir (B-Pharm)		

Recommendations of the panel:

Keeping in view the above facts on record, documents reviewed people met during the visit & the commitment of the firm for continuous improvement, the panel unanimously recommends renewal of the following sections of M/s Aims Pharmaceuticals, Plot No.291, Industrial Triangle Kahuta Road, Islamabad DML # 000608:

Renewal of Drug Manufacturing License by way of Formulation

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

	3. Capsule Section (Cephalosporin) 4. Dry Powder Suspension Section (Cephalosporin) 5. Ointment Section (General) **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. 000608, by way of Formulation, in the name of M/s Aims Pharmaceuticals, Plot No.291, Industrial Triangle Kahuta Road, Islamabad, for the period commencing on 21-03-2022 ending on 20-03-2027, for the following sections, subject to verification of necessary testing equipments: 1. Tablet Section (General) 2. Capsule Section (General) 3. Ointment 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)			
24	M/s Gelcaps (Pakistan) Ltd., Plot No.B-43, H.I.T.E., District Lasbella, Balochistan. DML No. 000282 (Semi Basic Manufacture). **Period:** Commencing on 20-06-2024 ending on 19-06-2029 Evaluator: - Akbar Ali (DD-Lic)	13-11-2024	**Good**	1. Mr. Zahid Salik, Chief Drug Inspector, Health Department, Baluchistan. 2. Mr. Asfand Yar Khan, Deputy Director, DRAP, Karachi. 3. Mr. Muhammad Yaqoob, FID, DRAP, Quetta, Baluchistan.
	Quality Control Incharge	Mr. Ahmad Saeed (M.Sc Chemistry)		
	Production Incharge	Mr. Deedar Ali (B-Pharm)		
	Recommendations of the panel: In view of above inspection proceedings and 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 e.t.c the panel of inspectors is of the opinion to **recommend the Renewal of Drug Manufacturing License** to M/s Gelcaps (Pakistan) Ltd., Plot No. B-43, H.I.T.E., District Lasbella, Baluchistan by way of Semi-Basic for the following section only: i. Empty Hard Gelatin Capsule Shells. **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. 000282, by way of Semi Basic Manufacture, in the name of M/s Gelcaps (Pakistan) Ltd., Plot No. B-43, H.I.T.E., District Lasbella, Balochistan, for the period commencing on 20-06-2024 ending on 19-06-2029, for the following sections: I. Empty Hard Gelatin Capsule Shells.			
25	M/s Healthteck (Pvt) Ltd., Plot No.14, Sector 19, Korangi Industrial Area, Karachi. DML No. 000618 (Formulation). **Period:** Commencing on 18-07-2022 ending on 17-07-2027 Evaluator: - Akbar Ali (DD-Lic)	31-08-2024	**Good**	1. Dr. Saif Ur Rehman Khattak, Additional Director, DRAP, Karachi. 2. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Govt. of Sindh, Karachi. 3. Syed Hakim Masood, FID-IV, DRAP, DRAP, Karachi.
	Quality Control Incharge	Ms. Samreen (M.Sc Chemistry)		
	Production Incharge	Mr. Asif Ali khan (B-Pharm)		

Recommendations of the panel:

M/s Healthteck (Pvt) Ltd., facilities, systems, processes & documents reviewed in detail were found in compliance to applicable regulations. The management and technical staff was highly committed for continuous improvement. Therefore, based on the people met, area visited and commitment of the management for continuous improvement, expansion and export potential, the panel unanimously was of the view to **recommend as follows:**

(i) **Renewal of Drug Manufacturing License No.000618 (By way of formulation)** to the firm M/s Healthteck (Pvt) Ltd., Karachi, with following approved sections:

Tablet (Cephalosporin)	Capsule (Cephalosporin)	Dry Powder Suspension (Cephalosporin)
Dry Powder Injection (Cephalosporin)	Liquid Ampoule (Water for Injection with diluents)	----------

(ii) Regularization and approval of the following changes in the revised existing layout plan (Annexures-C) referred in DRAP Islamabad Letter Reference No.F.2-10/2003-Lic (Vol-II) dated 13th August, 2024:

Ground Floor	**First Floor**	**Third Floor**
Packaging Material Ware house	Finished Goods Warehouse Extension	Raw & Packaging Material Warehouse
Sampling booth (Primary Packaging)	QA record room in place of QA office	**Fourth Floor**

		Rejection Area (General)	**Second Floor**	Finished Goods Warehouse	
		Change Rooms for Warehouse	Packaging Material Warehouse	----------	
		Material Receiving / Dispatch Bay	QA Office	----------	

The panel was not given the mandate for inspection of revised layout of warehouse, however, a letter No. F. 2-10/2010-Lic(Vol-I) dated 16th September, 2021 for revised layout plan for Warehouse was issued. The firm has also requested for inspection of their revised layout along with the renewal.

Decision of the Central Licensing Board in 302nd meeting

The Board on the recommendations of the panel of experts:

I. Approved the grant of renewal of DML No. 000618, by way of Formulation, in the name of M/s Healthteck (Pvt) Ltd., Plot No.14, Sector 19, Korangi Industrial Area, Karachi, for the period commencing on 18-07-2022 ending on 17-07-2027, for the following sections:

1. Liquid Ampoule (Water for Injection with diluents)

II. 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. Tablet (Cephalosporin)
2. Capsule (Cephalosporin)
3. Dry Powder Suspension (Cephalosporin)
4. Dry Powder Injection (Cephalosporin)

III. Regularized the layout plan of following Sections/facility of the firm:

Ground Floor	**First Floor**	**Third Floor**
Packaging Material Ware house	Finished Goods Warehouse Extension	Raw & Packaging Material Warehouse
Sampling booth (Primary Packaging)	QA record room in place of QA office	**Fourth Floor**
Rejection Area (General)	**Second Floor**	Finished Goods Warehouse
Change Rooms for Warehouse	Packaging Material Warehouse	----------
Material Receiving / Dispatch Bay	QA Office	----------

26.	M/s Lawari International, Valley Road, Gulkada, Saidu Sharif, Swat, Khyber Pakhtunkhwa.	05-11-2024	**Good**	1. Mr. Muhammad Ibrahim, Deputy Secretary Health, Department of Health, Khyber Pakhtunkhwa.

	DML No. 000658 (Formulation). **Period:** Commencing on 30-01-2024 ending on 29-01-2029 Evaluator: - Urooj Fatima (DD-Lic)			2. Mr. Atiq Ul Bari, FID, DRAP, Peshawar. 3. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.
	QC In-charge	Mr. Buzarg Jamhir (B-Pham)		
	Production In-charge	Mr. Saboor Ahmad (B-Pharm)		
	Recommendations of the panel: Based on documentation reviewed, technical / management people met, materials / process flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab, WFI water system and other allied facilities, the panel is of the view that the firm has good level of GMP compliance and unanimously **recommend** grant of **renewal of DML** as per DRAP Islamabad letter No.F.3-6/2008-Lic (Vol-I) dated August, 2024. 1. Tablet Section (General) 2. Capsule Section (General) 3. Oral Dry Powder for Suspension Section (Cephalosporin) 4. Capsule Section (Cephalosporin) 5. Dry Powder for Injection Vial Section (Cephalosporin) 6. Liquid Injection Ampoule Section (General) **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. 000658, by way of Formulation in the name of M/s Lawari International, Valley Road, Gulkada, Saidu Sharif, Swat, Khyber Pakhtunkhwa, for the period commencing on 30-01-2024 ending on 29-01-2029, for the following sections: 1. Tablet Section (General) 2. Capsule Section (General) 3. Liquid Injection Ampoule 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. Oral Dry Powder for Suspension Section (Cephalosporin) 2. Capsule Section (Cephalosporin) 3. Dry Powder for Injection Vial Section (Cephalosporin)			
27.	M/s Cunningham Pharmaceuticals (Pvt)	31-10-2024	**Good**	1. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore.

	Ltd, Plot No.81, Sundar Industrial Estate, Lahore DML No. 000840 (Formulation). **Period:** Commencing on 01-06-2021 ending on 31-05-2026 Evaluator: - Zunaira Faryad (DD-Lic)			2. Ms. Madiha Khalid (Director Operation), Office of the Chief Drugs Controller, Punjab, Lahore. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore
	QC In-charge	Mr. Muhammad Fazil (MSc. Chemistry)		
	Production In-charge	Mr. Muhammad Iqbal (B-Pharm)		

Recommendations of the panel:

Keeping in view the manufacturing facilities, 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 of the panel of inspector's is of the opinion to **recommend** the grant of renewal of Drug Manufacturing Licensing by way of formulation vide letter No.F.1-752011-Lic(Vol-I) dated 02-08-2021) to M/s Cunningham Pharmaceuticals Pvt Ltd., Plot No.,81, Sundar Industrial Estate, Lahore for the following sections:

1. Eye Drop Section (General)
2. Tablet Section (Psychotropic).
3. Liquid Injection SVP Section (Psychotropic).
4. Ophthalmic Section (Steroid).
5. Liquid Injectable Section SVP (General).
6. Liquid Injectable Section LVP (General).
7. Liquid Injectable (Ampoule) Section (General).
8. Tablets Section (General).
9. Capsule Section (General).
10. Sachet Section (General).
11. Capsule Section (Cephalosporin).
12. Dry Powder Injection Section (Cephalosporin).
13. Dry Powder Suspension (Cephalosporin).

Decision of the Central Licensing Board in 302nd meeting

The Board on the recommendations of the panel of experts:

I. Approved the grant of renewal of DML No. 000840, by way of Formulation, in the name of M/s Cunningham Pharmaceuticals (Pvt) Ltd, Plot No.81, Sundar Industrial Estate, Lahore, for the period commencing on 01-06-2021 ending on 31-05-2026, for the following sections:

1. Eye Drop Section (General)
2. Ophthalmic Section (Steroid).
3. Liquid Injectable Section SVP (General).
4. Liquid Injectable Section LVP (General).
5. Liquid Injectable (Ampoule) Section (General).

	6. Tablets Section (General). 7. Capsule Section (General). 8. Sachet 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 date 10/11/2020: 1. Tablet Section (Psychotropic). 2. Liquid Injection SVP Section (Psychotropic). III. 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 Injection Section (Cephalosporin). 3. Dry Powder Suspension (Cephalosporin).			
28.	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore. DML No. 000556 (Formulation). **Period:** Commencing on 03.11.2019 & ending on 02.11.2024 Evaluator: - Zunaira Faryad (DD-Lic)	05.11.2024	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab, Lahore. 2. Dr. Zaka Ur Rehman, Expert Member 3. Mr. Abdul Rashid Shaikh, FID, Lahore.
	QC In-charge	Ms. Faiza Rashid (B.Pharm)		
	Production In-charge	Ms. Faryal Sadique (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 plan, testing facilities, technical personnel, documentation on the day of inspection, the panel of inspector's in of the opinion to **recommended** the grant of renewal of Drug Manufacturing License by way of formulation (vide letter no. panel inspection of renewal of DML vide DRAP, Islamabad letter No.1-31/2001-Lic (Vol-II) dated 20.03.2023 and even numbers dated 16.09.2020, 22.01.2021 and 27.01.2023) to M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattar band Road, Thokar Niaz Baig, Lahore for following sections: 1. Cream/Ointment Section (General) 2. Eye Drops Sections (General)			

	3. Tablet Section (Psychotropic) 4. Capsule Section (Cephalosporin) 5. Capsule Section (General) 6. Sachet Section (General) 7. Tablet Section (General) 8. Syrup Section 9. Dry Powder Suspension Section (Cephalosporin) 10. External Preparation Section **Decision of the Central Licensing Board in 302nd meeting** The Board considered the inspection report and accepted the report for record since the renewal period Commencing on 03.11.2019 & ending on 02.11.2024 of DML No. 000556, by way of Formulation, in the name of M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore has already expired.

Case No. 29 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000838 (FORMULATION) OF M/S JUPITER PHARMA, RAWAT.

Case Background:

1	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. Zunaira Faryad, Assistant Director, DRAP, Islamabad.
	Recommendations of the panel: 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). Decision of the Central Licensing Board in 289th meeting 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)**	**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.

Period: Commencing on 01-06-2021 & ending on 31-05-2026. (Evaluator: - Zunaira Faryad (DD-Lic)			
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)

Case No. 30. **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000231 (FORMULATION) OF HIMONT PHARMACEUTICALS (PVT.) LTD, 17-KM, FEROZEPUR ROAD, LAHORE**

Case Background:

M/s. Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore DML No.000231 (Formulation) Period: Commencing on 27-09-2020 ending on 26-09-2025	**24-03-2022** **&** **07-04-2022**	**Good**	1. Dr. Ikram Ul Haq, Member, Central Licensing Board 2. Ms. Aisha Irfan, FID, DRAP, Lahore, 3. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

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

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

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

Decision of the Central Licensing Board in 287th meeting:

The Board considered the case and decided to defer the case till next Board meeting. The Board also decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000231 by way of Formulation of M/s. Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore may not be suspended or cancelled by the Central Licensing Board.

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

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

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

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

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

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

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

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

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

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

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

The Chairman CLB constituted a panel of experts/Inspectors for regularization of layout plan inspection and the inspection report submitted by the panel members is as under:

M/s Himont Pharmaceuticals (Pvt) Ltd., Plot 17-Km, Ferozpur Road, Lahore.	**09-08-2024**	**Good**	1. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.

(Evaluator: - Zunaira Faryad (DD-Lic)			3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
QC Incharge	Mr. Faizan A. Ansari (M.Sc. Chemistry)		
Production Incharge	Ms. Samia Asima Bukhari (Pharm-D)		

Recommendations of the panel:

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

1. Tablet (General) Section
2. Tablet (Psychotropic) Section
3. Sachet (General) Section
4. Syrup (General) Section
5. Capsule (General) Section
6. Dry Powder Suspension (General) Section

Decision of the Central Licensing Board in 302nd meeting

The Board, on the recommendations of the panel of experts dated 24-03-2022, 07-04-2022 and 09-08-2024 approved the grant of renewal of DML No. 000231, by way of Formulation and regularized the layout plan, in the name of M/s Himont Pharmaceuticals (Pvt) Ltd., Plot 17-Km, Ferozepur Road, Lahore, for the period commencing on 27-09-2020 ending on 26-09-2025, for the following sections:

1. Tablet (General) Section (Renewal & Regularization)
2. Sachet (General) Section (Renewal & Regularization)
3. Syrup (General) Section (Renewal & Regularization)
4. Capsule (General) Section (Renewal & Regularization)
5. Dry Powder Suspension (General) Section (Renewal & Regularization)
6. Liquid injectable (SVP) (General) Section (Renewal)

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 date 10/11/2020:

1. Tablet (Psychotropic) Section (Renewal & Regularization)

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

1. Capsule (Cephalosporin) Section (Renewal)
2. Dry Powder Suspension (Cephalosporin) Section (Renewal)
3. Dry Powder Injectable (Cephalosporin) Section (Renewal)

Case No. 31 **RENEWAL OF DRUG MANUFACTURING LICENSE NO.000148 (FORMULATION) OF M/S MARVI PHARMACEUTICALS, KARACHI.**

The case for renewal of Drug Manufacturing License No.000148 (Formulation) of M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi was presented in 296th meeting of CLB and decided as under;

M/s Marvi Pharmaceuticals, Plot No.70&71, Sector.24, Korangi Industrial Area, Karachi. DML No. 000148 (Formulation). **Period:** Commencing on 10-07-2020 ending on 09-07-2025. *Evaluator: - Mubashir Iqbal (DD-Lic)*	19-01-2024	Good	1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Karachi, Member CLB. 2. Mr. Abdul Rasool Shaikh, Additional Director /Federal Inspector of Drugs, DRAP, Karachi. 3. Mr. Awais Ahmad, Assistant Director, CDL, Karachi
QC In-charge	Mr. Muhammad Aamir (M.Sc Chemistry)		
Production In-charge	Mr. Adnan Saeed (B-Pharm)		

Recommendations of the panel:

M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi was visited and inspected in detail on 19-01-2024 in compliance to the directions contained in DRAP, Islamabad letter No.F.2-29/84-Lic (Vol-III) dated 08th September, 2023 regarding grant of renewal of DML. Following are the observations: -

The panel inspected the firm in detail including all the manufacturing sections, stores and QC Lab and found the facility as per approved lay out plan. The facility has been provided with necessary utilities, machineries and equipment as required under the guidelines. Necessary documents relating to QC, QA and installation qualification of machines, HVAC and other utilities were also seen in place. It is further to mention that the firm is built on Plot No.70 and 71 whereas only Plot No. 70 is mentioned on their DML. As their last submission to concerned division the firm had submitted their recent drawing clearly mentioning both plots including 71. The firm holds the ownership of both plots hence it was advised to them to go for regularization of the same and approach the concerned division for further guidance.

Based on the people met, documents reviewed and observations made during the inspection, the panel unanimously **recommends** the grant of renewal of Drug Manufacturing License No.000148 by way of formulation due on 10-07-2020 for sections as follows: -

i. Tablet (General)
ii. Capsule (General)
iii. Liquid Syrup/Suspension (General)
iv. Cream/Ointment (General)

v. *Capsule (Penicillin)*
vi. *Dry Powder Suspension (Penicillin)*

Note: The Capsule (Penicillin) and Dry Powder Suspension (Penicillin) are on the same floor along with other General Section and facility. Further, as per available record the firm has been granted DML with address/on Plot No.70, Street No.24, Korangi Industrial Area, Karachi. Whereas the firm didn't apply for Plot No.71, Street No.24, Korangi Industrial Area, Karachi in the Division of Licensing, DRAP.

Decision of the Central Licensing Board in 296th meeting

The Board considered and deferred the renewal of DML No. 000148 by way of Formulation in the name of M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi for confirmation of approval of site on plot No. 71, lay out approval and any construction over the plot.

Furthermore, the Board decided to defer the renewal of the following section and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for penicillin sections.

i. Capsule (Penicillin)
ii. Dry Powder Suspension (Penicillin)

Accordingly, a letter was issued to the firm on 04-07-2024. Now the firm has submitted reply which is re-produced as under;

"With reference to your letter No.F.2-29/84-Lic (Vol-III) dated 04th July, 2024 regarding captioned subject. It is submitted that we already came to know through Minutes of 296th meeting of Central Licensing Board held on 02nd April, 2024 available on DRAP website while consideration of our case for renewal of Drug Manufacturing Licensing No.000148 (Formulation) regarding following decision of Board:-

The Board considered and deferred the renewal of DML No. 000148 by way of Formulation in the name of M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi for confirmation of approval of site on plot No. 71, lay out approval and any construction over the plot.

Furthermore, the Board decided to defer the renewal of the following section and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for penicillin sections.

i. Capsule (Penicillin)
ii. Dry Powder Suspension (Penicillin)

Sir, as per above decision, we submitted our reply via online submission through DRAP, MIS Division vide their acknowledgement / application submission receipt on DRAP eApplication System on 11-06-2024 and tracking number of applications is 2JI-US8-7HE4 (copy enclosed) Regarding approval of site, layout approval and any construction on Plot No.71, it is stated that Marvi Pharmaceuticals was established In 1968. The manufacturing unit has been in the same location since the beginning and has not changed. We have made numerous inspections over the last 5 decades which include 5-yearly manufacturing license renewals as well as GMP inspections etc. The layout of the company had been approved by DRAP and even after renovations, the last amended layout had also been sent to DRAP in 2018 mentioning Plot 70 as well as Plot 71. The amended layout was processed and approved by the Licensing Department at DRAP and a regularization panel was created to inspect the premises as per

the layout. The team inspected the unit in April 2018 and sent the inspection report to DRAP which then approved and regularized our manufacturing unit.
We are attaching all correspondence received from DRAP regarding regularization of our units as well as the inspection report of the panel which visited as to inspect the panel.
With numerous inspection of our facility this was the first time it was pointed out to us that our DML did not include Plot 71 in our DML address. With the regularization process that took place in 2018 we had assumed that all of our documents were in check and the facility was up-to date according to the documents approved by DRAP which we now realize was an oversight.
We request the panel to consider the facts and change the address on our DML to mention both of our plots as the regularization process has already taken place in 2018 and has been approved by DRAP.
With reference to the minutes of the meeting of Licensing Board 296th meeting of central licensing board held on 2nd April, 2024, the board had directed us to halt Penicillin production in our unit as it did not comply with the new regulations issued by DRAP for Penicillin production.
We learned of the new developments and instructions issued by DRAP recently and have been working on the solution which would comply with the regulations and require time to move our Penicillin section there.
Since Penicillin is our main product, and with the current economic condition of the country survival is becoming difficult by the day, we request the panel to grant us 2 years to shift this section to our new building while we operate it in its current position.
We assure you that the current section, while being in the same building, has separate INS and out and does not, in any way, link to other manufacturing sections. With separate HVACs as well as isolating it from other sections we have eliminated the risk of cross contamination.
We can start the process of moving our section as soon as we are granted the relevant approvals and will abide by the time frame we have requested you to grant us.
In view of above submission, you are requested to renew our Drug Manufacturing License and allow us to continue the production of our penicillin products and grant us a period of 02 years to shift this section to our new building, we start the process of moving our section as soon as we are granted the relevant approvals.
Sir, we again furnished our above submission and requested to placed our case for renewal of Drug Manufacturing License in forthcoming 298th meeting of Central Licensing Board to be held on 10th July, 2024 and we also intend to avail opportunity of personal hearing on the same date and time
Your cooperation will highly be obliged."

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board considering the facts on the record and after detailed deliberation decided to serve warning to the firm. The Board Further decided that firm shall apply for amalgamation of the proposed site as per SOP.

Site Verification for Establishment of Pharmaceutical Unit (Plot Amalgamation)

Dr. Asfandyar Ajab Khan, Deputy Director, DRAP, Karachi has inspected the site and submitted that site reserved for establishment of M/s Marvi Pharmaceuticals, Plot No.71, Sector 24, Korangi Industrial Area, Karachi was inspected on dated 22nd October, 2024.Following are the observation:-

1. The firm already possesses DML No.000148 on Plot No.70, Sector 24, Korangi Industrial Area, Karachi as mentioned on DML.

2. During panel inspection regarding grant of renewal DML conducted on 19-01-2024 wherein, the panel had recommended the board for amalgamation of their both plots i.e. 70 & 71for better regulatory compliances.
3. The firm through its Director holds the ownership of the both plots.
4. The layout plan approved by DRAP categorically mentioned that their manufacturing, storage and QC facilities are built on both the plots (copy attached).
5. The plots are connected with each other inside a common boundary wall and situated in well-developed industrial areas of Korangi Industrial Area, Karachi provided with necessary utilities and other required amenities.
6. The location and surrounded of the plots complies the provisions laid down under paragraph-1 of section 1 of Schedule-B SRO.471(I)/98 dated 15.05.1998) under Rule 16(a) of Drugs (Licensing, Registering & Advertising) Rules 1976 of Drug Act, 1976.
7. Above mentioned in the view, it is recommended that necessary amalgamation of both the plots may please be documented for better regulatory compliance.

Submitted along with necessary documents for your kind information and further necessary action into the matter, please.

Decision of the Central Licensing Board in 302nd meeting

The Board considered the recommendations of site verification report and approved the amalgamation of Plot No. 71, Sector 24, Korangi Industrial Area, Karachi in the DML of M/s Marvi Pharmaceuticals, Plot No.70 Sector 24, Korangi Industrial Area, Karachi and on the recommendations of the panel, approved the grant of renewal of DML No. 000148, in the name of M/s Marvi Pharmaceuticals, Plot No.70 & 71, Sector 24, Korangi Industrial Area, Karachi, for the period commencing on 10-07-2020 ending on 09-07-2025, for the following sections subject to verification of necessary testing equipments:

i. Tablet (General)
ii. Capsule (General)
iii. Liquid Syrup/Suspension (General)
iv. Cream/Ointment (General)

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

i. Capsule (Penicillin)
ii. Dry Powder Suspension (Penicillin)

Case No. 32 RENEWAL OF DRUG MANUFACTURING LICENSE NO.000506 (FORMUALTION) OF M/S REGENT LABORATORIES, PLOT NO.C-20, S.I.T.E., SUPER HIGHWAY, KARACHI.

Case Background:

M/s Regent Laboratories, Plot No.C-20, S.I.T.E., Super Highway, Karachi.	**22-04-2024**	**Good**	1. Mr. Abdur Rasool Shaikh, Additional

DML No. 000506 (Formulation) Period: Commencing on 26-10-2022 ending on 25-10-2028. Evaluator:- Mubashir Iqbal (DD-Lic)			Director, DRAP, Karachi. 2. Mr. Sajjad Ahmed Abbasi, Deputy Director, CDL, Karachi. 3. Mrs, Sanam Kausar Jahan, Assistant Director, DRAP, Karachi
QC Incharge	Ms. Zakia Bibi D/o Abdul Samad Khan (M.Sc Chemistry) CNIC No.42201-0381513-2.		
Production Incharge	Ms. Zahida Khatoon D/o Abrar ul Haque (B-Pharm) CNIC No.42101-1506817-4.		

Recommendations of the panel:

1. As per directions of DRAP Islamabad vide Letter No.F.2-24/85-Lic (Vol-IV) dated 03rd May, 2023 the constituted panel member inspected the premises of M/s Regent Laboratories, Plot No.C-20, S.I.T.E., Super Highway, Karachi on 22/04/2024 for grant of renewal of DML No.000506 (formulation). During opening meeting their Site Master File, lay out design, HVAC design and QMS were discussed at length and found an appropriate level of compliance. Instant BMR, documents and SOPSs were also reviewed in detail. Overall an optimal level of compliance was noted.
2. Keeping in view of the above, people met, documents reviewed and attitude of the management towards continuous improvements, the panel is of the opinion to **recommend the grant of renewal of their DML No.000506 (By way of Formulation)** for the next five year for the following sections:

GROUND FLOOR	
Veterinary Powder (General)	Veterinary Liquid (General)
Veterinary Vitamins (General)	Capsule (Penicillin)
Dry Powder Suspension (Penicillin)	Tablet (Psychotropic)
Capsule (Psychotropic)	Tablet (Hormone)
Capsule (Cephalosporin)	Dry Powder Suspension (Cephalosporin)
Tablet (Antibiotic)	Dry Powder Suspension (Antibiotic)
Capsule (Antibiotic)	Tablet (General)
Capsule (General)	Liquid Syrup (General)
Sachet (General)	
FIRST FLOOR	
Cream / Ointment (General)	Cream / Ointment (Steroidal)
Cream / Ointment (General/Antibiotic)	Liquid (General) External Preparation
Quality Control Lab	Stores

Decision of the Central Licensing Board in 297th meeting

The Board observed that the firm is involved in manufacturing of diverse and specialized nature of products including Penicillin, Hormones, Cephalosporin and antibiotics requiring

segregation and dedication. The Board deferred the grant of renewal of DML No. 000506 and advised the Licensing division to review the LOP and place the case in forthcoming meeting.

Proceedings by Licensing Division in Compliance to Decision by the Central Licensing Board:

Accordingly, the layout plan committee reviewed the approved layout plan as available in record of Licensing division and found that the layout plan lacks demarcation of the name of dedicated sections required for the manufacturing of cephalosporin, Hormones and Penicillins. Moreover, the dedicated stores are also not mentioned on the layout plan which are required as a part of dedication under the section 5.2 of Schedule "B" of Drugs (Licensing, Registration & Advertisement) Rules, 1976. Therefore, firm may be advised to submit revised layout plan with proper demarcation of the sections.

Decision of the Central Licensing Board in 302nd meeting

The Board after detailed deliberations decided to direct M/s Regent Laboratories, Plot No.C-20, S.I.T.E., Super Highway, Karachi to submit layout plan with proper demarcation of the sections. After receiving the layout plan with proper demarcation, Division of Drug Licensing shall evaluate it and submit its recommendations to the CLB.

Item-V: Misc.

Case No. 1. CHANGE OF MANAGEMENT OF M/S. BARRET HODGSON PAKISTAN (PVT) LTD, KARACHI.

M/s Barret Hodgson Pakistan (Pvt) Ltd, F/423, SITE, Karachi, under DML No. 000457 (By way of formulation) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 93,000/-. The detail of management is as under: -

Previous Management as per Form-29 Year 2020	New Management as per Form-29 Year 2024
1. Mr. Hasan Tharani S/o Ismail Tharani CNIC No. 42101-6039308-9. 2. Ms. Iram Afaq W/o Shaikh Afaq Ahmed CNIC No. 42101-3890213-6 3. Mr. M.S. Habib S/o Choudhary Wali Muhammad CNIC No. 42301-0862904-5. 4. Mr. Muhammad Abbas S/o Muhammad Taufiq CNIC No. 42201-0807980-5. 5. Mr. Muhammad Feroz Alam S/o Muhammad Shafiq CNIC No. 42201-0360806-1 6. Mr. Saleem Ishrat Hashmi S/o Ishrat Ali Hashmi CNIC No. 42201-4986773-1. 7. Mr. Zubair S/o Ahmed Sulemani CNIC No. 42201-0249790-7	1. Ms. Iram Afaq W/o Shaikh Afaq Ahmed CNIC No. 42101-3890213-6 2. Mr. Hasan Tharani S/o Ismail Tharani CNIC No. 42101-6039308-9. 3. Mr. Muhammad Abbas S/o Muhammad Taufiq CNIC No. 42201-0807980-5. 4. Mr. Muhammad Feroz Alam S/o Muhammad Shafiq CNIC No. 42201-0360806-1 5. Mr. Saleem Ishrat Hashmi S/o Ishrat Ali Hashmi CNIC No. 42201-4986773-1. **6. Mr. Muhammad Hussain S/o Mr. Habib Tayub CNIC No.42301-0862904-5.**

Decision of the Central Licensing Board in 302nd meeting:

Based on **Form-29 for the Year 2024** issued by SECP, the Board considered and accepted for record, the change of management of M/s Barret Hodgson Pakistan (Pvt) Ltd, F/423, SITE, Karachi, under DML No. 000457, by way of 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 (if applicable) as under. 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 Year 2020	New Management as per Form-29 Year 2024
1. Mr. Hasan Tharani S/o Ismail Tharani CNIC No. 42101-6039308-9. 2. Ms. Iram Afaq W/o Shaikh Afaq Ahmed CNIC No. 42101-3890213-6 3. Mr. M.S. Habib S/o Choudhary Wali Muhammad CNIC No. 42301-0862904-5. 4. Mr. Muhammad Abbas S/o Muhammad Taufiq CNIC No. 42201-0807980-5. 5. Mr. Muhammad Feroz Alam S/o Muhammad Shafiq CNIC No. 42201-0360806-1 6. Mr. Saleem Ishrat Hashmi S/o Ishrat Ali Hashmi CNIC No. 42201-4986773-1. 7. Mr. Zubair S/o Ahmed Sulemani CNIC No. 42201-0249790-7	1. Ms. Iram Afaq W/o Shaikh Afaq Ahmed CNIC No. 42101-3890213-6 2. Mr. Hasan Tharani S/o Ismail Tharani CNIC No. 42101-6039308-9. 3. Mr. Muhammad Abbas S/o Muhammad Taufiq CNIC No. 42201-0807980-5. 4. Mr. Muhammad Feroz Alam S/o Muhammad Shafiq CNIC No. 42201-0360806-1 5. Mr. Saleem Ishrat Hashmi S/o Ishrat Ali Hashmi CNIC No. 42201-4986773-1. **6. Mr. Muhammad Hussain S/o Mr. Habib Tayub CNIC No.42301-1084478-3.**

Case No. 02. CHANGE IN TITLE & MANAGEMENT OF M/S. PFIZER PAKISTAN LIMITED, B-2, S.I.T.E., KARACHI UNDER DML NO. 000025 (FORMULATION).

Reference the Asset Purchase Agreement (Plant) dated May 17, 2024 between Lucky Core Industries Limited (LCI) and Pfizer Pakistan Limited (Pfizer) (the "Agreement") for the acquisition of their manufacturing facility (under DML No. 000025) situated at B-2, S.I.T.E., Karachi. Pursuant to the Agreement both the parties have agreed on the change of management and title of the manufacturing facility.

We Lucky Core Industries Limited, 5-West Wharf, Karachi therefore are applying for the change of management and title of DML No. 000025 for manufacturing site situated at B-2, S.I.T.E., Karachi as per the details below:

Change of Title:

Previous Title	New Title
M/s Pfizer Pakistan Limited	M/s Lucky Core Industries Limited

Change of Management:

Management of Pfizer approved by CLB in its 292nd meeting held on 4th October, 2023
1. Mr. S.M. Wajeehuddin S/o Muhammad Fasihuddin CNIC No.42201-4564592-3. 2. Mr. Tafazzul Khan S/o Habib Ullah Khan CNIC No.42201-878585-1. 3. Mr. Fida Hussain S/o Nazir Hussain Awan CNIC No.42201-7476012-5.
Management of Pfizer as per Form-A issued by SECP on 29.03.2024
1. Mr. Tafazzul Khan S/o Habib Ullah Khan CNIC No.42201-878585-1 2. Mr. Fida Hussain S/o Nazir Hussain Awan CNIC No.42201-7476012-5 **3. Asim Sarfraz S/o Muhammad Sarfraz Mallick CNIC No. 42101-1560854-3**
New Management of LCI as per Form-9 issued by SECP:
1. Asif Jooma S/o Omar Valli Jooma CNIC No.42301-3175078-7 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No.42301-1740521-7 3. Ariful Islam S/o Amin Ul Islam CNIC No. 42301-1035569-1 4. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No.42000-0568372-5 5. Muhammad Ali Tabba S/o Abdul Razzak Tabba CINC No.42201-6464247-3 6. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No. 42201-2111104-7 7. Amina Abdul Aziz Bawany W/o Abdul Aziz CNIC No.42000-3004991-0 8. Adnan Afridi S/o Iqbal Afridi CNIC No. 42301-3039230-3

2. The change in management of Pfizer was approved by the Central Licensing Board (CLB) in its 292nd meeting held on October 04, 2023, however the NOC from Ministry of Narcotics remained outstanding. Furthermore, another subsequent change took place in the management of Pfizer which was communicated to the CLB vide Letter dated Feb 14, 2024. The application is pending. Pursuant to the aforementioned Agreement, the rights to the manufacturing facility are transferred to LCI. Accordingly, we request you to process the change in management and title in favor of LCI. We enclose hereto the following documents in support of our application:

i. Relevant DRAP fee of Rs. 75000/- with respect to each aforestated change has been deposited
ii. Duly Certified copy of Form A and Form 9 of Lucky Core Industries Limited
iii. Duly Certified copy of Form A and Form 9 of Pfizer Pakistan Limited
iv. Duly Certified copy of Form A and Form 9 of Pfizer Pakistan Limited
v. Attested Copies of CNIC'S (Previous and Current Management)
vi. Certified Copy of Certificate of Incorporation

vii. Transfer Deeds

viii. NOC from Previous Owners on Stamp Paper.

ix. Attested Copy of Nothing Due Certificate regarding CRF

x. Firm has submitted the fee challan of 18000/= as differentials fee for change of title/management.

3. Further firm states that "instant transaction is an acquisition of certain assets by Lucky Core Industries Limited (LCI) from Pfizer Pakistan Limited. It is clarified that LCI has not acquired Pfizer Pakistan Limited, but has acquired select assets of Pfizer Pakistan Limited. Pfizer Pakistan Limited continues to subsist and operate independently. The purchased assets include a manufacturing facility located B2 SITE Karachi along with certain product registrations. Accordingly, Form A of Pfizer Pakistan Limited will contain particulars of the relinquishing management and Form A and subsequent Form 9 of LCI will contain the particulars of the incoming management."

4. Further they provide reference of 259th meeting for change of title and management case from Wyeth to ICI.

5. Firm also stated that "this transaction was not for the sale-purchase of shares, but the sale-purchase of assets. There is no share purchase agreement as no share transfer has taken place. However, since assets have been transferred, a copy of the asset purchase agreement is already provided."

6. In view of above state of firm it seems that the matter is not related of change of management and title of an existing company holding DML as per practice instead it is matter of acquisition /purchasing of assets including manufacturing plant and Drug Manufacturing License from one legal entity to another legal entity.

7. There is no such precedence of acquisition of assists along with license from one company to other and refer to example of 259th meeting is apparently simply change of title and management of company of a company registered with SECP through form-29.

8.. In view of above case is placed before CLB for consideration and personal hearing was issued to firms for better explanation of their cases.

Decision of the Central Licensing Board in 302nd meeting:

Based on **Competition Commission of Pakistan Case No. 1453/Merger-CCP/2024 dated 1st August, 2024,** Form A and Form 9 of M/s. Lucky Core Industries Limited and Pfizer Pakistan Limited, issued by SECP, the Board considered and accepted for record the change of title and management of M/s Pfizer Pakistan Limited under DML No. 000025 situated at B-2, S.I.T.E., Karachi, subject to submission of NOC (For change in the management only) 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 Title	New Title
M/s Pfizer Pakistan Limited	M/s Lucky Core Industries Limited

Change of Management:

Management of Pfizer approved by CLB in its 292nd meeting held on 4th October, 2023
1. Mr. S.M. Wajeehuddin S/o Muhammad Fasihuddin CNIC No.42201-4564592-3. 2. Mr. Tafazzul Khan S/o Habib Ullah Khan CNIC No.42201-878585-1. 3. Mr. Fida Hussain S/o Nazir Hussain Awan CNIC No.42201-7476012-5.
Management of Pfizer as per Form-A issued by SECP on 29.03.2024
1. Mr. Tafazzul Khan S/o Habib Ullah Khan CNIC No.42201-878585-1 2. Mr. Fida Hussain S/o Nazir Hussain Awan CNIC No.42201-7476012-5 3. Asim Sarfraz S/o Muhammad Sarfraz Mallick CNIC No. 42101-1560854-3
New Management of LCI as per Form-9 issued by SECP:
1. Asif Jooma S/o Omar Valli Jooma CNIC No.42301-3175078-7 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No.42301-1740521-7 3. Ariful Islam S/o Amin Ul Islam CNIC No. 42301-1035569-1 4. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No.42000-0568372-5 5. Muhammad Ali Tabba S/o Abdul Razzak Tabba CINC No.42201-6464247-3 6. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No. 42201-2111104-7 7. Amina Abdul Aziz Bawany W/o Abdul Aziz CNIC No.42000-3004991-0 8. Adnan Afridi S/o Iqbal Afridi CNIC No. 42301-3039230-3

Case No. 3 **CHANGE OF TITLE & MANAGEMENT M/S CITI PHARMA (PVT.) LTD., 3 KM HEAD BALLOKI ROAD, PHOOL NAGAR KASUR**

The firm, M/s Citi Pharma (Pvt.) Ltd., 3-Km Head Balloki Road Phool Nagar Kasur wherein the firm has submitted application for change of title & management with prescribed fee. The detail of title and management is as under;

Previous Title	**New Title as per Certification of Conversion from Private Company to Public Company**
M/s Citi Pharma (Pvt.) Ltd,	M/s Citi Pharma Ltd,

Previous Management	New Management as per Form-9
1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5.	1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5. **3. Ms. Saira Aslam W/o Rizwan Ahmad CNIC No. 35201-3753333-0.** **4. Mr. Muhammad Naeem S/o Sheikh Shar Muhammad CNIC No. 35202-2835907-9.** **5. Mr. Farzin Khan S/o Usman Hassan CNIC No. 37301-4607317-8.** **6. Mr. Zameer ul Hassan Shah S/o Gulam Hussnain Shah Naqvi CNIC No. 38302-1188338-9.** **7. Mr. Abdul Jaleel Shaikh S/o Abdul Hameed Sheikh CNIC No. 61101-3154208-9.**

Decision of the Central Licensing Board in 302nd meeting

Based on **Certification of Conversion from Private Company to Public Company and** Form-9 dated 01-03-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Citi Pharma (Pvt.) Ltd., 3-Km Head Balloki Road Phool Nagar Kasur under DML No. 000429 (Semi Basic Manufacture), 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, if applicable. 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 Title	New Title as per Certification of Conversion from Private Company to Public Company
M/s Citi Pharma (Pvt.) Ltd,	M/s Citi Pharma Ltd,

Previous Management	New Management as per Form-9
1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5.	1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5.

	3. Ms. Saira Aslam W/o Rizwan Ahmad CNIC No. 35201-3753333-0. **4. Mr. Muhammad Naeem S/o Sheikh Shar Muhammad CNIC No. 35202-2835907-9.** **5. Mr. Farzin Khan S/o Usman Hassan CNIC No. 37301-4607317-8.** **6. Mr. Zameer ul Hassan Shah S/o Gulam Hussnain Shah Naqvi CNIC No. 38302-1188338-9.** **7. Mr. Abdul Jaleel Shaikh S/o Abdul Hameed Sheikh CNIC No. 61101-3154208-9.**

Case No. 4. <u>CHANGE OF MANAGEMENT OF M/S OBS PHARMA (PVT) LTD., 108 KOTLAKHPAT INDUSTRIAL ESTATE, LAHORE</u>

M/S OBS Pharma (Pvt) Ltd., 108 Kot Lakhpat Industrial Estate, 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-29**
1. Mr. Shahzad Khan CNIC No. 35202-3335871-1. 2. Mr. Khurram Iqbal S/o Iqbal Ahmed Khan CNIC 42201-0767983-9. 3. Mr. Muhammad Umer Khan S/o Muhammad Aqil Khan CNIC No. 42101-1855430-1. 4. Mr. Muhammad Ashraf Khan S/o Allauddin Khan CNIC 42201-5263684-9. 5. Mr. Tariq Moinuddin Khan S/o K A Moinuddin Khan CNIC No. 42301-07525070-1. 6. Mrs. Adeela Tariq Khan CNIC No.42301-0683642-2 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No. 42301-9154917-3. 8. Mr. Muhammad Kamran Nasir S/o CNIC No. 37405-3917505-1.	1. Mr. Khurram Iqbal S/o Iqbal Ahmed Khan CNIC 42201-0767983-9. 2. Mr. Muhammad Umer Khan S/o Muhammad Aqil Khan CNIC No. 42101-1855430-1. 3. Mr. Muhammad Ashraf Khan S/o Allauddin Khan CNIC 42201-5263684-9. 4. Mr. Tariq Moinuddin Khan S/o K A Moinuddin Khan CNIC No. 42301-07525070-1. 5. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No. 42301-9154917-3. 6. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

<u>Decision of the Central Licensing Board in 302nd meeting</u>

Based on Form-29 dated 01-03-2024 issued by SECP, the Board considered and accepted for record the change of management of M/S OBS Pharma (Pvt) Ltd., 108 Kot Lakhpat Industrial Estate, Lahore under DML No. 000243 (**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, if

applicable. 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-29
1. Mr. Shahzad Khan CNIC No. 35202-3335871-1. 2. Mr. Khurram Iqbal S/o Iqbal Ahmed Khan CNIC 42201-0767983-9. 3. Mr. Muhammad Umer Khan S/o Muhammad Aqil Khan CNIC No. 42101-1855430-1. 4. Mr. Muhammad Ashraf Khan S/o Allauddin Khan CNIC 42201-5263684-9. 5. Mr. Tariq Moinuddin Khan S/o K A Moinuddin Khan CNIC No. 42301-07525070-1. 6. Mrs. Adeela Tariq Khan CNIC No.42301-0683642-2 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No. 42301-9154917-3. 8. Mr. Muhammad Kamran Nasir S/o CNIC No. 37405-3917505-1.	1. Mr. Khurram Iqbal S/o Iqbal Ahmed Khan CNIC 42201-0767983-9. 2. Mr. Muhammad Umer Khan S/o Muhammad Aqil Khan CNIC No. 42101-1855430-1. 3. Mr. Muhammad Ashraf Khan S/o Allauddin Khan CNIC 42201-5263684-9. 4. Mr. Tariq Moinuddin Khan S/o K A Moinuddin Khan CNIC No. 42301-07525070-1. 5. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No. 42301-9154917-3. 6. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Case No. 5. <u>CHANGE OF MANAGEMENT OF M/S SIMZ PHARMACEUTICALS (PVT) LTD., LAHORE</u>

M/s Simz Pharmaceuticals (Pvt) Ltd., Plot No. 574-575 Punjab Industrial Estate Sundar 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-29
1. Mr. Imran Hassan S/o Muhammad Hassan CNIC No.91509-0189411-3	**1. Mrs. Amber Saeed Hassan W/o Salman Hassan CNIC 91509-0245525-6.**

<u>Decision of the Central Licensing Board in 302nd meeting</u>

Based on Form-29 dated 01-03-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Simz Pharmaceuticals (Pvt) Ltd., Plot No. 574-575 Punjab Industrial Estate Sundar Lahore under DML No. 000762 (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 date 10/11/2020, if applicable. 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-29 & Digial Certified Company Profile dated 05-07-2023
1. Mr. Imran Hassan S/o Muhammad Hassan CNIC No.91509-0189411-3 2. Mr. Salman Hassan S/o Muhammad Hassan CNIC No. 91509-0173536-9	1. **Mrs. Amber Saeed Hassan W/o Salman Hassan CNIC 91509-0245525-6.** 2. Mr. Salman Hassan S/o Muhammad Hassan CNIC No. 91509-0173536-9

Case No. 6. **CHANGE OF MANAGEMENT OF M/S WEBROS PHARMACEUTICALS, PLOT NO. 01, STREET NO. S-10, NATIONAL INDUSTRIAL ZONE, RAWAT.**

M/s Webros Pharmaceuticals, Plot No. 01, Street No. S-10, National Industrial Zone, Rawat has submitted request for change in management of the firm as per partnership deed with the prescribed fee. The detail of the management of the firm is as under:

Previous Management	New management as per Partnership Deed dated 14th June, 2024
1. Mr. Anjum Ahmed S/o Rais Ahmed CNIC No. 61101-1571291-1. **2. Mrs. Rehana Anjum W/o Anjum Ahmed CNIC No. 61101-4049408-8.**	1. Mr. Anjum Ahmed S/o Rais Ahmed CNIC No. 61101-1571291-1. **2. Mr Abdul Wahab S/o Anjum Ahmed CNIC No. 61101-8789090-9.**

Decision of the Central Licensing Board in 302nd meeting

Based on Partnership deed submitted by the firm, the Board considered and accepted for record the change of management of M/s Webros Pharmaceuticals, Plot No. 01, Street No. S-10, National Industrial Zone, Rawat under DML No. 000538 (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, if applicable. 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 14th June, 2024
1. Mr. Anjum Ahmed S/o Rais Ahmed CNIC No. 61101-1571291-1. 2. **Mrs. Rehana Anjum W/o Anjum Ahmed CNIC No. 61101-4049408-8.**	1. Mr. Anjum Ahmed S/o Rais Ahmed CNIC No. 61101-1571291-1. **2. Mr Abdul Wahab S/o Anjum Ahmed CNIC No. 61101-8789090-9.**

Case No. 7. **CHANGE OF MANAGEMENT OF M/S HARRISON PHARMACEUTICALS, SARGODHA UNDER DRUG MANUFACTURING LICENSE NO. 000634 (FORMULATION).**

M/s Harrison Pharmaceuticals, 10-Km, Lahore Road, Sargodha has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm as per amended partnership deed is as under:

Previous Management as per Partnership Deed dated 3rd May, 2018	**New management as per Partnership Deed dated 16th September, 2020**
1. Mr. Sajjad Hussain S/o Muhammad Gulzar Khan CNIC No.35202-7516210-1 2. Mr. Irfan Gulzar Anjum S/o Gulzar Muhammad CNIC No.38403-2956767-5 3. Mr. Muhammad Irshad Uppal S/o M. Nawab Ud Din Uppal CNIC No.35200-7366578-3 4. Mr. Usman Ali S/o Muhammad Gulzar Khan CNIC No.35202-2193693-3 5. Mr. Muhammad Zubair Faisal S/o Muhammad Hafeez CNIC No.35202-6439427-3 6. Mr. Aamir Saeed Kazi S/o Kazi Muhammad Saeed CNIC No.35202-4171375-7 7. Mr. Adil Saeed Kazi S/o Kazi Muhammad Saeed CNIC No.35202-4066970-7 8. Mr. Muhammad Saleem S/o Muhammad Siddique CNIC No.37405-0355334-1	1. Mr. Sajjad Hussain S/o Muhammad Gulzar Khan CNIC No.35202-7516210-1 2. Mr. Irfan Gulzar Anjum S/o Gulzar Muhammad CNIC No.38403-2956767-5 3. Mr. Muhammad Irshad Uppal S/o M. Nawab Ud Din Uppal CNIC No.35200-7366578-3 4. Mr. Usman Ali S/o Muhammad Gulzar Khan CNIC No.35202-2193693-3 5. Mr. Muhammad Zubair Faisal S/o Muhammad Hafeez CNIC No.35202-6439427-3 6. Mr. Aamir Saeed Kazi S/o Kazi Muhammad Saeed CNIC No.35202-4171375-7 7. Mr. Adil Saeed Kazi S/o Kazi Muhammad Saeed CNIC No.35202-4066970-7 **8. Mrs. Nosheen Nadeem W/o Rana Dilawaiz Nadeem CNIC No.31301-7956599-6**

Decision of the Central Licensing Board in 302nd meeting:

Based on **Partnership Deed dated 16th September, 2020**, the Board considered and accepted for record the change of management of M/s Harrison Pharmaceuticals, 10-Km, Lahore Road, Sargodha under DML No. 000634 (Formulation) as under. 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 Partnership Deed dated 3rd May, 2018	**New management as per Partnership Deed dated 16th September, 2020**
1. Mr. Sajjad Hussain S/o Muhammad Gulzar Khan CNIC No.35202-7516210-1	1. Mr. Sajjad Hussain S/o Muhammad Gulzar Khan CNIC No.35202-7516210-1

2. Mr. Irfan Gulzar Anjum S/o Gulzar Muhammad CNIC No.38403-2956767-5 3. Mr. Muhammad Irshad Uppal S/o M. Nawab Ud Din Uppal CNIC No.35200-7366578-3 4. Mr. Usman Ali S/o Muhammad Gulzar Khan CNIC No.35202-2193693-3 5. Mr. Muhammad Zubair Faisal S/o Muhammad Hafeez CNIC No.35202-6439427-3 6. Mr. Aamir Saeed Kazi S/o Kazi Muhammad Saeed CNIC No.35202-4171375-7 7. Mr. Adil Saeed Kazi S/o Kazi Muhammad Saeed CNIC No.35202-4066970-7 8. Mr. Muhammad Saleem S/o Muhammad Siddique CNIC No.37405-0355334-1	2. Mr. Irfan Gulzar Anjum S/o Gulzar Muhammad CNIC No.38403-2956767-5 3. Mr. Muhammad Irshad Uppal S/o M. Nawab Ud Din Uppal CNIC No.35200-7366578-3 4. Mr. Usman Ali S/o Muhammad Gulzar Khan CNIC No.35202-2193693-3 5. Mr. Muhammad Zubair Faisal S/o Muhammad Hafeez CNIC No.35202-6439427-3 6. Mr. Aamir Saeed Kazi S/o Kazi Muhammad Saeed CNIC No.35202-4171375-7 7. Mr. Adil Saeed Kazi S/o Kazi Muhammad Saeed CNIC No.35202-4066970-7 **8. Mrs. Nosheen Nadeem W/o Rana Dilawaiz Nadeem CNIC No.31301-7956599-6**

Case No. 8 CHANGE OF MANAGEMENT OF M/S MEGA PHARMACEUTICALS LTD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000537 (FORMULATION).

M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore under DML No. 000537 (Formulation) has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm as per Form-A is as under:

Previous Management	New Management as per Form-A dated 15th April, 2024
1. Mr. Muhammad Tahir Azam S/o Turab Ali CNIC No. 35202-9287376-5. 2. Mr. Intezar Hussain S/o Muhammad Sain CNIC No. 35202-7717141-3. 3. Mr. Ahmad Khan S/o Mohammad Sharif Khan CNIC No. 35202-2691064-5. 4. Mr. Abdul Samad S/o Taj Muhammad CNIC No. 17301-1353215-9. 5. Mr. Habib Ur Rehman S/o Matee Ur Rehman CNIC No. 15602-9849631-9.	1. Mr. Muhammad Tahir Azam S/o Turab Ali CNIC No. 35202-9287376-5. 2. Mr. Abdul Samad S/o Taj Muhammad CNIC No. 17301-1353215-9. **3. Mr. Muhammad Arsal ur Rehman S/o Muhammad Tahir Azam CNIC No. 35202-8026664-7.**

Decision of the Central Licensing Board in 302nd meeting:

Based on Form-A **dated 15th April, 2024** issued by SECP, the Board considered and accepted for record the change of management of M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore under DML No. 000537 (Formulation) as under. 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 15th April, 2024
1. Mr. Muhammad Tahir Azam S/o Turab Ali CNIC No. 35202-9287376-5. 2. Mr. Intezar Hussain S/o Muhammad Sain CNIC No. 35202-7717141-3. 3. Mr. Ahmad Khan S/o Mohammad Sharif Khan CNIC No. 35202-2691064-5. 4. Mr. Abdul Samad S/o Taj Muhammad CNIC No. 17301-1353215-9. 5. Mr. Habib Ur Rehman S/o Matee Ur Rehman CNIC No. 15602-9849631-9.	1. Mr. Muhammad Tahir Azam S/o Turab Ali CNIC No. 35202-9287376-5. 2. Mr. Abdul Samad S/o Taj Muhammad CNIC No. 17301-1353215-9. **3. Mr. Muhammad Arsal ur Rehman S/o Muhammad Tahir Azam CNIC No. 35202-8026664-7.**

Case No. 9 <u>CHANGE OF MANAGEMENT OF M/S NEUTRO PHARMA (PVT) LTD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000576 (FORMULATION).</u>

M/s Neutro Pharma (Pvt.) Ltd.9.5-Km, Sheikhupura Road, Lahore under DML No. 000576 (Formulation) has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm as per Form-9 is as under:

Previous Management	New Management as per Form-9 dated 15th April, 2024 & Form-A dated 10th November, 2023
1. Mr. Zia ud Din Zia S/o Fazal Din CNIC NO. 35202-2788744-7 (CEO) 2. Mr. Muhammad Bilal Javaid S/o Muhammad Javed CNIC No. 35201-5070788-7	**1. Mr. Khurram Shahzad Alam S/o Khurshid Alam CNIC No. 35202-4321637-3 (CEO)** 2. Mr. Muhammad Bilal Javaid S/o Muhammad Javed CNIC No. 35201-5070788-7

<u>Decision of the Central Licensing Board in 302nd meeting:</u>

Based on **Form-9 dated 15th April, 2024 & Form-A dated 10th November, 2023** issued by SECP, the Board considered and accepted for record the change of management of M/s Neutro Pharma (Pvt.) Ltd.9.5-Km, Sheikhupura Road, Lahore under DML No. 000576 (Formulation as under. 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 15th April, 2024 & Form-A dated 10th November, 2023
1. Mr. Zia ud Din Zia S/o Fazal Din CNIC NO. 35202-2788744-7 (CEO) 2. Mr. Muhammad Bilal Javaid S/o Muhammad Javed CNIC No. 35201-5070788-7	1. Mr. Khurram Shahzad Alam S/o Khurshid Alam CNIC No. 35202-4321637-3 (CEO) 2. Mr. Muhammad Bilal Javaid S/o Muhammad Javed CNIC No. 35201-5070788-7

Case No. 10 CHANGE OF MANAGEMENT OF M/S BRIELL PHARMACEUTICALS (PVT) LTD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000862 (FORMULATION).

M/s Briell Pharmaceuticals (Pvt.) Ltd, Plot No. 538-C, Sundar Industrial Estate, Lahore under DML No. 000862 (Formulation) has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm as per Form-9 is as under:

Previous Management	New Management as per Form-9 dated 28th October, 2023
1. Mr. Tahir Hayat S/o Muhammad Hayat CNIC No.38403-2254860-5. 2. Mr. Malik Asghar Hayat S/o Muhammad Hayat CNIC No.38403-2254861-7..	**1. Mr. Aamir Bashir S/o Bashir Ahmed CNIC No.35202-2871425-7 (CEO).** 2. Mr. Tahir Hayat CNIC No.38403-2254860-5 (Director). 3. Mr. Malik Asghar Hayat CNIC No.38403-2254861-7 (Director).

Decision of the Central Licensing Board in 302nd meeting:

Based on **Form-9 dated 28th October, 2023** issued by SECP, the Board considered and accepted for record the change of management of M/s Briell Pharmaceuticals (Pvt.) Ltd, Plot No. 538-C, Sundar Industrial Estate, Lahore under DML No. 000862 (Formulation) as under: 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 28th October, 2023
1. Mr. Tahir Hayat S/o Muhammad Hayat CNIC No.38403-2254860-5. 2. Mr. Malik Asghar Hayat S/o Muhammad Hayat CNIC No.38403-2254861-7..	**1. Mr. Aamir Bashir S/o Bashir Ahmed CNIC No.35202-2871425-7 (CEO).** 2. Mr. Tahir Hayat CNIC No.38403-2254860-5 (Director).

	3. Mr. Malik Asghar Hayat CNIC No.38403-2254861-7 (Director).

Case No. 11 CHANGE OF TITLE & MANAGEMENT OF M/S CITI PHARMA (PVT) LTD, KASUR UNDER DRUG MANUFACTURING LICENSE NO. 000512 (FORMULATION).

M/s Citi Parma (Pvt) Ltd. 3-Km, Head Balloki Road, Phool Nagar, Distt. Kasur under DML No. 000512 (Formulation) has submitted request for change in Title & management of the firm with the prescribed fee. The detail of the title & management of the firm as per Form-9 is as under;

Previous Title	**New Title as per Certification of Conversion from Private Company to Public Company**
M/s Citi Pharma (Pvt.) Ltd,	M/s Citi Pharma Ltd,

Previous Management	**New Management as per Form-A dated 20th December, 2023**
1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5.	1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5. **3. Ms. Saira Aslam W/o Rizwan Ahmad CNIC No. 35201-3753333-0.** **4. Mr. Muhammad Naeem S/o Sheikh Shar Muhammad CNIC No. 35202-2835907-9.** **5. Mr. Farzin Khan S/o Usman Hassan CNIC No. 37301-4607317-8.** **6. Mr. Zameer ul Hassan Shah S/o Gulam Hussnain Shah Naqvi CNIC No. 38302-1188338-9.** **7. Mr. Abdul Jaleel Shaikh S/o Abdul Hameed Sheikh CNIC No. 61101-3154208-9.**

Decision of the Central Licensing Board in 302nd meeting

Based on Certification of Conversion from Private Company to Public Company and Form-A dated 20th December, 2023 issued by SECP, the Board considered and accepted for record the change of management of M/s Citi Pharma (Pvt.) Ltd., 3-Km Head Balloki Road Phool Nagar Kasur under DML No. 000512 (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 Title	**New Title as per Certification of Conversion from Private Company to Public Company**
M/s Citi Pharma (Pvt.) Ltd,	M/s Citi Pharma Ltd,

Previous Management	**New Management as per Form-A dated 20th December, 2023**
1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5.	1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5. **3. Ms. Saira Aslam W/o Rizwan Ahmad CNIC No. 35201-3753333-0.** **4. Mr. Muhammad Naeem S/o Sheikh Shar Muhammad CNIC No. 35202-2835907-9.** **5. Mr. Farzin Khan S/o Usman Hassan CNIC No. 37301-4607317-8.** **6. Mr. Zameer ul Hassan Shah S/o Gulam Hussnain Shah Naqvi CNIC No. 38302-1188338-9.** **7. Mr. Abdul Jaleel Shaikh S/o Abdul Hameed Sheikh CNIC No. 61101-3154208-9.**

Case No. 12 CHANGE OF MANAGEMENT OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000233 (FORMULATION).

M/s GlaxoSmithKline Pakistan Limited, **F-268, S.I.T.E.** Karachi under DML No. **000233** (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 Form-A dated 24th April, 2024**

1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk, Passport No. PU 125808. 3. Mr. Mark Robert Dawson, Passport No. 761323952. 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.	**1. Mr. Hasham Ali Baber S/o Aliuddin Baber CNIC No. 42301-2597573-3.** **2. Ms. Goh Lai Kuen, Passport No. A56418030.** **3. Mr. Simon John S/o Foster, Passport No. RA2559956.** 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

Decision of the Central Licensing Board in 302nd meeting:

Based on **Form-A dated 24th April, 2024** issued by SECP, the Board considered and accepted for record the change of management of M/s GlaxoSmithKline Pakistan Limited, **F-268, S.I.T.E.** Karachi under DML No. **000233** (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 date 10/11/2020 (if applicable) as under. 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 24th April, 2024
1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk, Passport No. PU 125808. 3. Mr. Mark Robert Dawson, Passport No. 761323952. 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.	**1. Mr. Hasham Ali Baber S/o Aliuddin Baber CNIC No. 42301-2597573-3.** **2. Ms. Lai Kuen Goh, Passport No. A41425052.** **~~3.~~ Mr. Simon Foster S/o Foster, Passport No. N8114602.** 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

Case No. 13 CHANGE OF MANAGEMENT OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000017 (FORMULATION).

M/s GlaxoSmithKline Pakistan Limited, **35-Dockyard Road, West Wharf** Karachi under DML No. **000017** (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 Form-A dated 24th April, 2024
1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk, Passport No. PU 125808. 3. Mr. Mark Robert Dawson, Passport No. 761323952. 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.	**1. Mr. Hasham Ali Baber S/o Aliuddin Baber CNIC No. 42301-2597573-3.** **2. Ms. Lai Kuen Goh, Passport No. A41425052.** **3. Mr. Simon Foster S/o Foster, Passport No. N8114602.** 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

Decision of the Central Licensing Board in 302nd meeting:

Based on Form-A **Form-A dated 24th April, 2024**issued by SECP, the Board considered and accepted for record the change of management of M/s GlaxoSmithKline Pakistan Limited, **35-Dockyard Road, West Wharf** Karachi under DML No. **000017** (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 date 10/11/2020 (if applicable) as under. 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 24th April, 2024
1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk, Passport No. PU 125808. 3. Mr. Mark Robert Dawson, Passport No. 761323952.	**1. Mr. Hasham Ali Baber S/o Aliuddin Baber CNIC No. 42301-2597573-3.** **2. Ms. Lai Kuen Goh, Passport No. A41425052.** **~~3.~~ Mr. Simon Foster S/o Foster, Passport No. N8114602.**

4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.	4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

Case No.14 CHANGE OF MANAGEMENT OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000248 (FORMULATION).

M/s GlaxoSmithKline Pakistan Limited, **Plot No. 05, Sector 21, Korangi Industrial Area,** Karachi under DML No. **000248** (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 Form-A dated 24th April, 2024
1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk, Passport No. PU 125808. 3. Mr. Mark Robert Dawson, Passport No. 761323952. 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.	**1. Mr. Hasham Ali Baber S/o Aliuddin Baber CNIC No. 42301-2597573-3.** **2. Ms. Goh Lai Kuen, Passport No. A56418030.** **3. Mr. Simon John S/o Foster, Passport No. RA2559956.** 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

Decision of the Central Licensing Board in 302nd meeting:

Based on Form-A dated **24th April, 2024** issued by SECP, the Board considered and accepted for record the change of management of M/s GlaxoSmithKline Pakistan Limited, **Plot No. 05, Sector 21, Korangi Industrial Area,** Karachi under DML No. **000248** (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 date 10/11/2020 (if applicable) as under. 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 24th April, 2024
1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk, Passport No. PU 125808. 3. Mr. Mark Robert Dawson, Passport No. 761323952. 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.	**1. Mr. Hasham Ali Baber S/o Aliuddin Baber CNIC No. 42301-2597573-3.** **2. Ms. Goh Lai Kuen, Passport No. A56418030.** **3. Mr. Simon John S/o Foster, Passport No. RA2559956.** 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

Case No. 15 <u>CHANGE OF MANAGEMENT OF M/S. TABROS PHARMA (PVT) LTD, KARACHI.</u>

M/s Tabros Pharma (Pvt) Ltd, Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi under DML No. 000106 (By way of formulation) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 93,000/-. The detail of management is as under: -

Existing Management	New Management
1. Mr. Muhammad Abdullah S/o Mr. Muhammad Essa CNIC No.42000-0542451-9. 2. Muhammad Yahya Essa S/o Muhammad Abdullah CNIC No. 42201-5987913-7.	1. Mr. Muhammad Abdullah S/o Mr. Muhammad Essa CNIC No.42000-0542451-9. 2. Muhammad Yahya Essa S/o Muhammad Abdullah CNIC No. 42201-5987913-7. 3. **Mr. Sulaiman Essa S/o Muhammad Abdullah CNIC No.42201-5105681-7.**

<u>Decision of the Central Licensing Board in 302nd meeting:</u>

Based on the documents submitted by the firm, the Board considered and accepted for record the change of management of M/s Tabros Pharma (Pvt) Ltd, Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi under DML No. 000106 (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

date 10/11/2020 (if applicable) as under. 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
1. Mr. Muhammad Abdullah S/o Mr. Muhammad Essa CNIC No.42000-0542451-9. 2. Muhammad Yahya Essa S/o Muhammad Abdullah CNIC No. 42201-5987913-7.	1. Mr. Muhammad Abdullah S/o Mr. Muhammad Essa CNIC No.42000-0542451-9. 2. Muhammad Yahya Essa S/o Muhammad Abdullah CNIC No. 42201-5987913-7. 3. **Mr. Sulaiman Essa S/o Muhammad Abdullah CNIC No.42201-5105681-7.**

Case No. 16 <u>CHANGE OF MANAGEMENT OF M/S BOSCH PHARMACEUTICALS (PVT) LTD, PLOT NO 221, 222 & 223, SECTOR 23, KORANGI INDUSTRIAL AREA KARACHI</u>

M/s Bosch Pharmaceuticals (Pvt) Limited, Plot No. 221, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. 000350 (Formulation)) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 93,000/- as under: -

Existing Management	New Management
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. Zakarya 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. Zakarya 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.**

<u>Decision of the Central Licensing Board in 302nd meeting:</u>

Based on documents submitted by the firm, the Board considered and accepted for record the change of management of M/s Bosch Pharmaceuticals (Pvt) Limited, Plot No. 221, 222 & 223 Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. 000350 (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 (if applicable) as under. 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
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. Zakarya 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 (CEO) 4. Mr. Zakarya Nasib S/o Ahmedf 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. 17 CHANGE OF MANAGEMENT OF M/S AVENSIS PHARMACEUTICALS, F-24/1 EASTERN INDUSTRIAL ZONE PORT QASIM KARACHI

M/s Avensis Pharmaceuticals, F-24/1 Eastern Industrial Zone Port Qasim Karachi has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm is as under:

Previous Management (Sole owner)	New management as per undertaking and NTN certificate (Sole owner)
1. Mr. Muhammad Younus S/o Abdul Malik CNIC No. 42201-2045785-1	**1. Mr. Bilal Younus S/o Muhammad Younus CNIC 42201-3136647-3.**

Decision of the Central Licensing Board in 302nd meeting:

Based on **undertaking and NTN certificate submitted by the firm**, the Board considered and accepted for record the change of management of M/s Avensis Pharmaceuticals, F-24/1 Eastern Industrial Zone Port Qasim Karachi DML No. 000894 (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 date 10/11/2020 (if applicable) as under. 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 (Sole owner)	New management as per undertaking and NTN certificate (Sole owner)
1. Mr. Muhammad Younus S/o Abdul Malik CNIC No. 42201-2045785-1	1. Mr. Bilal Younus S/o Muhammad Younus CNIC 42201-3136647-3.

Case No. 18 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S CAYLEX PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore had applied for renewal of DML No. 000451 by way of Formulation for the period of 01-08-2020 to 31-07-2025 on 30-07-2020.

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 24-08-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
iii. Detail of management, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 duly attested by SECP (original).
v. Duly attested CNIC copies of all Directors.
vi. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vii. Duly attested resignation of earlier production Incharge.
viii. Duly attested resignation of proposed production Incharge from previous firm.

The firm then filed application for approval of Production Incharge and Quality Control Incharge. Reminder letter was issued on 16-11-2021 to the firm for completion of application for renewal of DML and approval of technical staff:

i. Properly filled, signed and stamped Form-1 A (as per format).
ii. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
iii. Detail of management, if any change, apply for change of management.
iv. Latest true copy of Form-29 duly attested by SECP (original).
v. Duly attested CNIC copies of all directors.
vi. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vii. Complete set of duly attested documents (as per checklist) of proposed Production Incharge & Quality Control Incharge.

The firm replied on 08-12-2021 but application is still deficient of following documents:

i. Properly filled, signed and stamped Form-1 A (as per format).
i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management, if any change, apply for change of management.
iii. Latest true copy of Form-29 duly attested by SECP (original).
iv. Duly attested CNIC copies of all directors.
v. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vi. Complete set of duly attested documents (as per checklist) of proposed Production Incharge & Quality Control Incharge.

Decision of the Central Licensing Board in 288th meeting:

The Board while 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 No. 000451 by way of formulation of M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore on 28th November, 2022.

The firm has replied to Show cause notice on 11-01-2023 but application for renewal of DML is still deficient of following documents:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Latest true copy of Form-29 duly attested by SECP (original).
iii. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
iv. Deposit prescribed fee of Rs.15000/- for approval of Production Incharge & Quality Control Incharge.
v. Duly attested CNIC of proposed Production Incharge & Quality Control Incharge.
vi. Duly notarized undertaking as whole time employee on stamp paper (Quality Control Incharge).

A letter of personal hearing has been issued on 17-01-2023.

Proceedings and Decision by the Central Licensing Board in 289th meeting:

No one appeared on behalf of the firm before the Board. The Board while considering the facts on the record decided to offer final opportunity to the firm. The Board further decided that Area FID shall submit updated status of the firm to the Board in its upcoming meeting.

A letter of personal hearing was served on 15th December, 2023 to the said firm for 294th meeting of Central Licensing Board schedule to be held on 27th December, 2023.

Decision of the Central Licensing Board in 294th meeting

FID Lahore intimated telephonically that the owner/ Director of the firm is hospitalized due to cardiac arrest and no person appeared on behalf of the firm. The board considered and decided to give another opportunity of personal hearing to the firm.

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

A letter of personal hearing has been issued to the firm on 12-11-2024. The firm has requested for another opportunity for personal hearing as the owner of firm recently underwent cardiac surgery, but unfortunately, during the recovery process he suffered another heart attack and subsequently become paralyzed. He will undergo major surgery on 21st November, 2024 and no person appeared on behalf of the firm.

Decision of the Central Licensing Board in 302nd meeting:

The Board while considering the request of the firm decided to give another opportunity of personal hearing to the firm in the next meeting.

Case No.19 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000108 (FORMULATION) OF M/S IRZA PHARMA (PVT) LTD, 10.2 KM, SHEIKHUPURA ROAD, LAHORE.**

Case Background:

1	M/s. Irza Pharma (Pvt.) Ltd, 10.2 Km Sheikhupura Road, Lahore. DML No. 000108 (Formulation). Period: Commencing on 12-07-2019 ending on 11-07-2024.	25-11-2022	**Good**	1. Dr. Zaka Ur Rehman, Chief Operating Officer, PDTRC, Lahore. 2. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Hafiz Sanaullah Babar, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

Keeping in view the manufacturing facility like, building, production, machinery, Equipment in Quality Control and microbiology laboratory, testing facilities, utilities and documentation reviewed, the panel of inspectors **recommends** the renewal of Drug Manufacturing License and Regularization of Layout Plan to M/s. Irza Pharma (Pvt) Ltd, 10.2 Km Sheikhupura Road, Lahore for the following sections only:

i. Tablet (General) Section
ii. Capsule (General)Section.
iii. Tablet (Steroid) Section
iv. Syrup Section (General).
v. Capsule (Penicillin) Section
vi. Dry Powder Suspension (Penicillin) Section.
vii. Liquid External Preparation Section.
viii. Capsule (Cephalosporin) Section.
ix. Dry Powder Suspension (General) Section.
x. Dry Powder Suspension (Cephalosporin) Section.

And the firm also given undertaking for the following sections which are under revamping/renovation (copy of undertaking is attached) and they will not start production till the inspection of these sections:

i. Liquid Injectable (Ampoule) (General)
ii. Liquid Repacking.
iii. Drop Section.
iv. Ointment (General)

Decision of the Central Licensing Board in 289th meeting

The Board considered and approved the grant of renewal of DML No. 000108 by way of Formulation in the name of M/s. Irza Pharma (Pvt) Ltd, 10.2 Km Sheikhupura Road, Lahore

	on the recommendations of the panel of experts for the period Commencing on Commencing on 12-07-2019 ending on 11-07-2024. for the following sections: - i. Tablet (General) Section ii. Capsule (General)Section. iii. Tablet (Steroid) Section iv. Syrup Section (General). v. Capsule (Penicillin) Section vi. Dry Powder Suspension (Penicillin) Section. vii. Liquid External Preparation Section. viii. Capsule (Cephalosporin) Section. ix. Dry Powder Suspension (General) Section. x. Dry Powder Suspension (Cephalosporin) Section. The Board further decided that to serve the Show Cause to the firm and stop the production till rectifications of the observation made during inspection for following sections: i. Liquid Injectable (Ampoule) (General) ii. Liquid Repacking. iii. Drop Section. iv. Ointment (General).

Proceedings of Licensing Division in the light of decision of Central Licensing Board:

The Show Cause Notice was issued to the firm on 13th March, 2023.

The firm has replied that these sections were not inspected as they were under maintenance. Now, they have completed the renovation and requested to constitute panel for inspection of Liquid Injectable (Ampoule) Section (General) and Drops (General) Section.

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board considering the facts on the record and after detailed deliberation decided to give and opportunity of personal hearing to the firm in next meeting of the Board.

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

A letter of personal hearing has been issued to the firm on 12-11-2024.

Decision of the Central Licensing Board in 302nd meeting:

Mr. Imran Jawa, Managing Director and Mr. Iftikhar Masud, Plant Manager appeared before the Board and contended that the firm is willing to withdraw the following two sections:

i. Liquid Repacking.
ii. Ointment (General).

The Board directed the firm to formally withdraw these sections and advised the Licensing Division to direct the firm to complete the renewal application for next tenure since the renewal period commencing from 12-07-2019 ending on 11-07-2024 of DML No. 000108, by way of Formulation, in the name of M/s Irza Pharma (Pvt.) Ltd, 10.2 Km Sheikhupura Road, Lahore has already expired.

Case No.20 CHANGE OF MANAGEMENT OF M/S GREATER PHARMA, RAWAT.

Case Background:

The Central Licensing Board in its 279th Meeting held on 18th February, 2021 considered and endorsed the change of management of M/s Greater Pharma, Plot No. 35, Street No. SS-3, National Industrial Zone, RCCI, Rawat under DML No. 000896 by way of Formulation as under:

Previous Management	New Management as per Affidavit
1. Mr. Abdul Wadood Khan S/o Masood Khan CNIC No. 17301-0355625-1.	1. Mr. Muhammad Dawood S/o Haji Momeen CNIC No. 54201-2468331-5.

Accordingly**,** Decision of the Board was conveyed to the firm on 30th March, 2021.
Then, letters/complaints received from **Mr. Abdul Wadood Khan** which are reproduced as under:
"I am a sole owner of the factory "Greater Pharma" situated at Plot No.35, Street SS-3, Industrial Zone, Rawat Islamabad and a license has been issued by your worthy Office (copy Attached). Sir unluckily I was suffering from serious injuries and mental disability and was also in comma for long period due to road accident on 14-08-2020. When I came to normal life, surprisingly it reveals that my factory has been fraudantly transferred to Mr M. Dawood via fake Deed Dated 15-01-2021 by my nearest relative namely Sajid Masood S/o Manzoor and they have illegally occupied my suste factory and it's all machinery and items. Sir Mr. M. Dawood has been manufacturing the medicines/items without having any authority which is highly illegal and it may damage the public at large, thus it required attention of your worthy office. Furthermore, I did not attend any board meeting which is essential for granting permission or authority for manufacturing. It is therefore, requested, that stern action may kindly be taken against Muhammad Dawood or any other person if involved and manufacturing may discontinue in the interest of public at large."
&
"I have an accident on motorway 14th August 2020 along with wife, after accident I was admitted in RMI and North West hospital Hayatabad Peshawar. I was suffering, in comma disease and mentally abnormal. That time I was treated with Prof Tariq hashim and Khalid mufti. All hospital evidence records with me in hospital.

1. *1 have submitted complaint in DRAP Islamabad two weeks ago. But I am waiting reply from DRAP.*
2. *I have already submitted complaint in Chairman NAB Islamabad for legal action.*
3. *My factory was rented to Mr. Daud through fraud agreement.*
4. *The Meezan Bank Hayatabad Peshawar through evidence Mr. Sajid masood received all payment, ID CARD copy attaches in bank record.*
5. *The DRAP has taken decision without my presence, I have no physical visit to DRAP Islamabad, according to 1976 Rule regulation agreement is against rules, regulation and Director (Licencing) according to DRAP Rule and regulation agreement was not follow through DRAP Rules and regulation."*

Complaint of Mr. Abdul Wadood Khan was forwarded to the firm for their comments. **Reply of the firm** is as under:

"With ref of your letter dated 10/sep/2021, subjected justification and comments on complain of Mr. Abdul wadood. We here by justify the complaint as follows. I Muhammad Dawood CNIC NO 54201-2468331-5 (CEO) Greater pharmaceuticals Pvt Ltd plot 35, Street SS-3 Rawat Industrial zone Islamabd,

<u>COMMENTS OF C.E.O</u>
Abdul Wadood's complain is based on absolutely fake statement, he was in his own senses as per described with evidences as follow, his fake allegations are only based on malicious, he is just miss guiding the DRAP and doing a fraud complain and as well damaging the time and goodwill of DRAP,we have submitted all the required documents in DRAP, after the NOC of Abdul Wadood and many more documents DRAP have issued the change of management letter, on the bases of

DRAP's said letter we applied for new sections approval, after the receiving of new approved map from DRAP we started construction, we have invested a huge amount on new sections construction, machinery HVAC system, equipments, market and many more, According to his statement majorly he have dispute with his own family and he is mixing up the dispute with our deal and confusing the DRAP,

FURTHER JUSTIFICATIONS WITH EVIDENCES AND WITNESSES

Mr. Abdul Wadood's accident and discharging date. According to his statement he had accident on 17 Aug 2020 as per his hospital reports, he was hospitalized for 15 days only, from dated 17 Aug 2020 to 2 Sep 2020 and he was discharged on 2 September 2020, he was ok and his own senses.

SALE AND PURCHASE

After 6 months of his accident Mr Abdul Wodood visited the Greater pharma to us, he was absolutely in his senses, then we matured the deal (agreement attached) and Agreement was signed personally by Mr Abdul. Wadood (pictures are attached for evidence) in the presence of following witnesses. Personal appearance of all following witnesses is absolutely possible if DRAP required.

1. *Mr. Naeem shah (Ex owner of Goodman Lab rawat)*
2. *Mr. Masood khan (Father of Abdul Wodood khan)*
3. *Mr. Waheedullah (Brother of Abdul Wadood)*
4. *Mr. Sajid masood s/o Manzoor khan*
5. *Mr. Huzaifawodood (son of Abdul wadood khan)*
6. *Mr. Masood s/o (M. Dawood)*

Payments to Mr. Abdul wadood

We have paid the payment as per attached agreement to Mr. Abdul wadood by cheqs (cheq copies are attached) and Mr. Wodood personally received all the cheq (signed receipts are available) with his named title (Abdul wodood khan) and he collected all the payment from banks. (Bank record is attached).

We are requesting to DRAP kindly do not entertain such kind of nonsense complains which have no legal documents, proofs and any evidences. And this is only based on malicious."

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing both parties in next meeting of the Board.

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

Letter received from Mr. Abdul Wadood Khan which is reproduced as under:

"I HAVE GREATER PHARMA ON MY NAME. THE DRAP ISLAMABAD ISSUED LICENSE ON 05-93-2019. THEREFORE, REQUEST TO DRAP ISLAMABAD TO STOP GREATER PHARMA FACTORY PRODUCTION AND RAW MATERIAL PROCESS THE GREATER PHARMA HAS BEEN MANUFACTURE PRODUCTS SINCE JANUARY 2021. TIE DAWOOD AND HIS SON MASOOD GOT ILLEGALLY PERMISSION FROM DRAP ISLAMABAD. I HAVE DONE ACCIDENT ON MOTORWAY ADMITTED IN NORTH WEST HOSPITAL HAYATABAD. NOW I HAVE GOOD HEALTH AND MENTALLY GOOD CONDITION FROM BRAIN FIT FOR BUSINESS THROUGH DOCTORS CERTIFICATE, THE DAWOOD BELONG TO AFGHANISTAN MADE FAKE PAKISTAN JID FROM PASHEEN QUETTA. (ID CARD OF PAKISTAN :) THEREFORE KINDLY TAKE ACTION AGAINT DAWOOD AND HIS WSON MASOOD THROUGH DRAP RULES THROUGH I'IA ISLAMABAD AND STOP BANK ACCOUNT FROM FBR PAKISTAN ISLAMABAD. AFTER THIS LETTER I AM NOT RESPONSIBLE FOR DAWOOD AND MASOOD PRODUCTS IN BUSINESS MARKET."

Request for change of title also received from Mr. Abdul Wadood Khan which is reproduced as under:

Previous Title	New Title

M/s Greater Pharmaceutical, Plot No.35, Street SS-3, National Industrial Zone, Rawat, Islamabad.	M/s Al Wadood Pharmaceutical, Plot No.35, Street SS-3, National Industrial Zone, Rawat, Islamabad.

Letters of Personal hearing has been issued on 7th March, 2022 to the firm and Mr. Abdul Wadood Khan.

Proceedings and Decision by the Central Licensing Board in 285th meeting:

Mr. Masood Khan, managing Director appeared on behalf of the firm. He contended that all transactions have carried in the presence of witnesses which includes his brother and son. He further stated that his written reply may be considered as his statement. He prayed that his representation may be dropped as same are based on malafide.

The complainant Mr. Abdul Wadood Khan did not appear before the Board. The Board considering the facts observed that matter pertains to private transactions between two parties. Therefore, there is nothing to intervene. However, aggrieved party may approach court of competent jurisdiction for redressal of his grievance.

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

Decision of CLB was conveyed to the firm and Mr. Abdul Wadood Khan through letter dated 07-03-2022.

Now, Mr. Muhammad Jamal Afridi, Advocate Supreme Court, Islamabad has requested for personal hearing of Mr. Abdul Wadood before CLB as he claimed that personal hearing has not been served to his client.

Request was forwarded to Division of Legal Affairs, DRAP, Islamabad for their opinion which is reproduced as under:

"Reference to para 35/N, it is submitted that it is the rule of the Natural Justice that ***Audi Alteram Partem*** *means that no one should be condemned unheard. Hence, Central Licensing Board may grant a last & final opportunity to the complainant with warning in the personal hearing letter that if he will fail to appear before Board this time then the matter will be proceeded as ex-parte."*

Accordingly, a letter of personal hearing has been issued to Mr. Abdul Wadood Khan on 19-07-2024 but didn't appeared before the CLB.

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board considering the facts on the record and after detailed deliberation decided to give final opportunity of personal hearing to the applicants in next meeting of the Board.

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

A letter of personal hearing has been issued to Mr. Abdul Wadood Khan on 13-11-2024.

Decision of the Central Licensing Board in 302nd meeting:

Mr. Abdul Wadood Khan appeared before the Board. He informed the Board that he had filed a Civil suit in the Civil Court. The Board directed him to submit a certified copy of court case. The Board decided that as the matter is sub-judice, therefore, further proceedings be initiated after outcome of the Court case, if necessitated.

Case No.21 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000880 (FORMULATION) OF M/S FAHMIR PHARMA (PVT) LTD, DISTRICT SHEIKHUPURA.

M/s Fahmir Pharma (Pvt) Ltd., Main Mandiwala Stop, 26-Km, Lahore Jaranwala Road, Tehsil Sharaqpur Sharif, District Sheikhupura. DML No. 000880 (Formulation) Period: Commencing on 11-04-2023 ending on 10-04-2028. Evaluator:- Zunaira Faryad (AD-Lic)	21-05-2024	Good	1. Dr. Muhammad Shamoon Ch., Expert Member. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.
QC In-charge	Mr. Muhammad Shahid (M.Sc. Chemistry)		
Production In-charge	Mr. Ata Ul Mohsin (Pharm-D)		

Recommendations of the panel:

Keeping in view the manufacturing facility like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors **recommends** the renewal of DML to M/s Fahmir Pharma (Pvt) Ltd., 26-Km, Lahore Road, Sharaqpur, District Sheikhupura for the following sections:

i. Tablet Section (General) section
ii. Capsule Section (General) section
iii. Sachet Section (General) section.

It is pertinent to mention here that Mr. Laeeq Shahzad Chishti, Production In-charge of the firm has resigned from the firm w.e.f 31-05-2024 on one-month notice.

Decision of the Central Licensing Board in 298th meeting

The Board considered the facts on ground and deferred the renewal of M/s Fahmir Pharma (Pvt) Ltd., Main Mandiwala Stop, 26-Km, Lahore Jaranwala Road, Tehsil Sharaqpur Sharif, District Sheikhupura. DML No. 000880 (Formulation). A verbal complaint was also received that firm do not hire the technical persons on permanent basis. They call them as and when required. The Board further advised the Additional Director Lahore to verify the availability of technical persons in the firm.

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

Additional Director, DRAP, Lahore was requested to verify the availability of technical persons in the firm.

Letters of personal hearing have been issued to the firm and Mr. Laeeq Shahzad Chishti (ex-Production Incharge) on 13-11-2024.

Decision of the Central Licensing Board in 302nd meeting:

Mr. Hafiz Roy Umair, Director and Mr. Ata ul Mohsin, Production Incharge, appeared before the Board and denied the allegations levelled against management. Mr. Ata ul Mohsin confirmed that he is working with the firm since last one and half year.

The Board considered the submissions of the firm and on the recommendations of the panel of experts, approved the grant of renewal of DML No. 000880, by way of Formulation, in the name of M/s Fahmir Pharma (Pvt) Ltd., Main Mandiwala Stop, 26-Km, Lahore Jaranwala Road, Tehsil Sharaqpur Sharif, District Sheikhupura, for the period commencing on 11-04-2023 ending on 10-04-2028, for the following sections:

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

Case No.22 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000613 (FORMULATION) OF M/S GOODMAN LABORATORIES (PVT) LTD, RAWAT.**

Case Background:

M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat is licensed firm having DML No. 000613 by way of Formulation with validity of 20-03-2022. However, it is submitted that as per available record, application for renewal of DML No. 000613 (Formulation) for the period of 21-03-2022 to 20-03-2027 of M/s Goodman Laboratories (Pvt) Ltd, Rawat has not been received in Licensing Division. 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."

In light of above, DML No. 000613 by way of formulation, M/s Goodman Laboratories (Pvt) Ltd, Rawat is no more valid.

Proceedings and Decision by the Central Licensing Board in 287th 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 as to why Drug Manufacturing License No 000613(by way of formulation) of M/s Goodman Laboratories (Pvt) Ltd, Rawat may not be declared cancelled by the Central Licensing Board as application for renewal of Drug Manufacturing License is not filed under Rule 5 and Rule 6 of Drug (Licensing, Registering and Advertising) Rule, 1976.

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

The Show Cause Notice was issued to M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat on 4th July, 2022.

The firm has replied that they have paid DML renewal fee of Rs. 75,000/- within due date on 18-03-2022 and submitted In-Process data through PIRIMS and still waiting for approval.
A letter of Personal hearing has been issued on 6th October, 2022.

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

No person appeared on behalf of the firm. The Board considering the facts on record and after thread bare deliberation decided to cancel the Drug Manufacturing License No. 000613 (Formulation) of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat as the Drug Manufacturing License No. 000613 (Formulation) is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976.

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

DML cancellation letter was issued to the firm on 19th December, 2022. The firm then filed appeal against decision of CLB. The Appellate Board considered the case of M/s Goodman Laboratories (Pvt) Ltd, Islamabad in its 163rd meeting held on 20th December, 2022 and decided as under:

"The Drug Manufacturing License (DML) of the appellant was cancelled by the Central Licensing Board (CLB) in its 288th meeting held on 18.10.2022 due to non-submission of renewal application within prescribed time under the Drugs (Licensing, Registering and Advertising) Rules, 1976.
The appellant argued that the prescribed fee along with application (Form 1A) for renewal of DML was submitted timely on 18.03.2022 while the licensing expired on 22.03.2022. However, the DML has been erroneously cancelled by the CLB. It was further submitted that the appellant would be satisfied if the case is remanded back to the CLB for reconsideration after verification of record and the operation of the impugned decision be suspended till that time."

Admin Division of DRAP verified that M/s Goodman Labs. submitted its application of renewal of DML in R&I of DRAP on 18-March-2022.

Licensing Division evaluated the application of the firm received on 27-06-2022 and following shortcomings has been noted:

i. Properly filled, signed and stamped Form-1A along with its all annexures.
ii. Updated nothing due certificate regarding CRF.
iii. Detail of management, if any change, file application for change of management.
iv. Duly attested copies of CNIC of all Directors.
v. Approval letters of Production In-charge& Quality Control In-charge .
vi. Approval letter of sections approved by CLB, if not available, file application for regularization of layout plan.
vii. Latest certified true copy of Form-29 issued by SECP (Original).

Decision of the Central Licensing Board in 296th 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 19 , Schedule B under Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000613 (by way of formulation) of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. 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 the firm on 03-06-2024.
The firm has replied but application for renewal of DML is still deficient of following documents:

i. Updated nothing due certificate regarding CRF.
ii. Duly attested copies of CNIC of all Directors.
iii. Approval letter of sections approved by CLB, if not available, file application for regularization of layout plan.
iv. Latest certified true copy of Form-29 issued by SECP (Original).

A letter of personal hearing has been served to the firm on 19-07-2024.

Mr. Muhammad Bashir, Judge Accountability Court-I Islamabad in view of the statement of Investigation Officer and record placed on file and orders of the Director General NAB who is representative of Chairman NAB, property mentioned in para-4 of the petition which is noted below stands frozen through attachment till final disposal of the case & orders of Chairman NAB stands confirmed:

Goodman Laboratories, Plot No. 5. Road S-5, RCCI.

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board observed that the assets of the firm has been taken over by the National Accountability Bureau Rawalpindi. Mr. Zubair Saeed (Production In-charge) and Syed Shahram (Director Operations) of the firm appeared before the board. Both confirmed that the firm is paying rent to the NAB. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000613 by way of Formulation of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

Drug Manufacturing License suspension order was issued to M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat on 27-08-2024.

The firm has submitted deficient documents and completed the application for renewal of DML No 000613 (Formulation) for the period of 21-03-2022 to 20-03-2027.

Decision of the Central Licensing Board in 302nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of suspension of Drug Manufacturing Licence No 000613 (Formulation) for the further period in the name of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat.

Case No. 23 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S LAHORE PHARMA, LAHORE.

M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore had applied for renewal of DML No. 000084 by way of Formulation for the period of 26-03-2021 to 31-25-03-2026 on 22-03-2021.

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 01-07-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.
ii. Detail of premises including layout plan.
iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,
iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.
v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

The firm did not reply and Reminder letter was issued on 11-10-2021 to the firm for completion of application for renewal of DML:

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.
ii. Detail of premises including layout plan.
iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,
iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.
v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

In the meanwhile, Production Incharge of the firm has resigned and letter was issued on 02-08-2022 for appointment and approval of Production Incharge. The firm did not reply and application for renewal of DML and Production Incharge is still incomplete.

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 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No. 000084 by way of formulation of M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore on 21st November, 2022.

The firm has not replied to Show Cause Notice and application for renewal of DML is still deficient of following documents:

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.
ii. Detail of premises including layout plan.
iii. Section approval letters, if not approved by CLB, submit layout plan for regularization.
iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.
v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

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

Proceedings and Decision by the Central Licensing Board in 289th meeting:

No one appeared on behalf of the firm before the Board. The Board while considering the facts on the record decided to offer final opportunity to the firm.

A letter of personal hearing was served on 15th December, 2023 to the said firm for 294th meeting of Central Licensing Board schedule to be held on 27th December, 2023.

Proceedings and Decision by the Central Licensing Board in 294th meeting:

Mr. Tahir Saeed Managing Partner of the firm appeared before the Board. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No. 000084 (Formulation) of M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore till fulfilment of codal formalities or 3 months whichever is earlier under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering & Advertising) rules, 1976 for not complying the provisions of Rule 5 (2A) of the Drugs (Licensing, Registering & Advertising) rules, 1976.

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

Drug Manufacturing License suspension order was issued to M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore on 13-03-2024.

The firm has submitted deficient documents and completed the application for renewal of DML No 000084 (Formulation) for the period of 26-03-2021 to 31-25-03-2026.

Decision of the Central Licensing Board in 302nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of suspension of Drug Manufacturing Licence No 000084 (Formulation) for the further period in the name of M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore.

Case No.24 **GRANT OF ADDITIONAL SECTION OF M/S A&K PHARMACEUTICALS, FAISALABAD UNDER DRUG MANUFACTURING LICENSE NO. 000534 (FORMULATION).**

Case Background:

M/s A&K Pharmaceuticals (Pvt) Ltd, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad. DML No.000534 (Formulation). **Sections (02):** i. Liquid Injectable (General) (Veterinary) Section (Revised) ii. Oral Powder (Penicillin) (Veterinary) Section (New) Evaluator:- Zunaira Faryad (AD-Lic)	14-12-2023	Good	1. Mr. Muhammad Shamoon Ch., Expert Member. 2. Mr. Abdul Rashid Sh FID, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

Keeping in view the manufacturing facilities like building and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors was of the opinion to **recommend**:
The renewal and regularization of Drug Manufacturing to M/s A&K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad for the following sections:

1. Oral Powder (General) (Veterinary) Section (Renewal & Regularization)
2. Oral Liquid (General) (Veterinary) Section (Renewal & Regularization)
3. Bolus Section (Renewal)
4. Liquid Injectable (General) (Veterinary) Section (Revised)

And grant of following additional section:

1. Oral Powder (Penicillin) (Veterinary) Section (New)

Decision of the Central Licensing Board in 294th meeting:

The Board observed that the dedication of the Penicillin section is not provided hence the Board deferred the decision on additional section and advised the firm to approach Licensing division for amendments.

1. Oral Powder (Penicillin) (Veterinary) Section (New)

The CLB in its 298th meeting held on 26th July, 2024 discussed that the operations related to the manufacturing of veterinary medicinal products containing Penicillin and decided as under:

"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".

Decision of the Central Licensing Board in 302nd meeting:

The Board, on the recommendations of the panel of experts, approved the following section, in the name of M/s A&K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad under DML No. 000534, by way of Formulation:

1. Oral Powder (Penicillin) (Veterinary) Section (New)

Case No. 25 SITE VERIFICATION OF M/S CRYSTOLITE PHARMACEUTICALS, RAWAT.

M/s Crystolite Pharmaceuticals applied for verification of proposed site located at Plot No. 70 & 71, Street No. S-2, National Industrial Zone, Rawat. After application was completed by the firm, Additional Director, DRAP, Islamabad was requested to conduct site inspection of proposed site and submit report regarding suitability of plot for establishment of pharmaceutical unit.

The inspection was conducted by Dr. Ghazanfar Ali Khan, Additional Director (QALT), DRAP, Islamabad and the recommendations are as under: -

"Kindly refer to your letter No. Tracking ID: GMR-61S-QDX2 dated 26-07-2024 on the subject cited above. The undersigned visited the site located at Plot No.70 & 71, Street S-2, National Industrial Zone, Rawat and found the site suitable in terms of location and surroundings for establishment of Pharmaceutical unit as per requirement laid down under paragraph 1 of section 1 of Schedule "B" (SRO 470(I)/98 dated 15-05-1998.

2. The site is an industrial area with all amenities such as road infrastructure, sewerage, water and electricity. The following documents are enclosed:

1) Allotment Certificate for Plot No.70 measuring 1200 sq yds (72 x 150) sq ft.

2) Allotment Certificate for Plot No.71 measuring 1200 sq yds (72 x 150) sq ft.

3. It is pertinent to mention that the Plot No. 70 has a construction of room which covered area 35 x 25 sq feet (Annex-I) and Plot No. 71 has a construction of hall with covered area of 57 x 120 sq ft (Annex-II).

4. The site is **recommended** for the Pharmaceutical unit and is forwarded for consideration on case to case basis."

Decision of the Central Licensing Board in 302nd meeting:

In the light of decision recorded at S. No. 37 of Miscellaneous cases, the site is approved.

Case No. 26 SITE VERIFICATION OF M/S HIZISH BIO PHARMACEUTICALS, DISTRICT KASUR.

M/s Hizish Bio Pharmaceuticals applied for verification of proposed site located at **Khewat No. 690-691, Khatooni No.1332, 1333-1339, 01 Km, Off Lahore-Kasur Road, Mustafa Beroon, Ali Nagar Stop, District. Kasur**. After application was completed by the firm, Additional Director, DRAP, Lahore was requested to direct concerned officer to conduct site inspection of proposed site and submit report regarding suitability of plot for establishment of pharmaceutical unit.

The inspection was conducted by Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore and the recommendations are as under: -

""As at the proposed site there was a functional Brick Klin (Bhatta) was also at about 200-300 meters away from the propose site and only 12 feet wide passage approaches to this site

The above observation led to the conclusion that the site is not as per requirement, laid down under paragraph 1 of section 1 of schedule "B" (SRO 470(1)/98, dated 15-05-1998) under Rule 16(a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Hence the proposed site is **NOT suitable**, for establishment of a pharmaceuticals unit as of today."."

Decision of the Central Licensing Board in 302nd meeting:

The Board, on the recommendation of FID, DRAP, Lahore, rejected the application of M/s Hizish Bio Pharmaceuticals for verification of site located at Khewat No. 690-691, Khatooni No.1332, 1333-1339, 01 Km, Off Lahore-Kasur Road, Mustafa Beroon, Ali Nagar Stop, District. Kasur.

Case No. 27 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.

Case No. 28 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000712 OF M/S SUNRISE PHARMA (PVT) LTD, LAHORE.

M/s Sunrise Pharma (Pvt) Ltd, 594-A, Sunder Industrial Estate, Raiwind Road, Lahore had applied for renewal of DML No. 000712 by way of formulation for the period of 20-06-2021 to 19-06-2026. 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 22nd October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Detail of management at the time of previous renewal and at present renewal, if any change apply for change of management.
ii. Section approval letter by Central License Board.
iii. Certified true copy of Form-II or Form-29 by SECP.
iv. No Objection Certificate regarding CRF from STO.

For QC Incharge.

i. Experience certificate as per Drugs Licensing, Registering and Advertising Rules, it should not be less than 10 years.

All documents should be duly attested.

The firm submitted their reply on 29thSeptember, 2021. After evaluation of the submitted documents, a letter was issued on 13th December, 2021 to the firm with following shortcomings: -

For Renewal of DML.

i. Apply for change of management along with Form-29 attested by SECP along with prescribed fee.

For QC Incharge.

i. Experience certificate as per Drugs Licensing, Registering and Advertising Rules, it should not be less than 10 years.
   All documents should be duly attested.

The application of Renewal of Drug Manufacturing License and Quality Control Incharge is still deficient for following documents: -

For Renewal of DML.

i. Apply for change of management along with Form-29 attested by SECP along with prescribed fee.

For QC Incharge.

i. Experience certificate as per Drugs Licensing, Registering and Advertising Rules, it should not be less than 10 years.
   All documents should be duly attested.

The case was placed before the Central Licensing Board in its285th meeting held on 17thand 18th March, 2022 and the Board decided as under:

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 No 000712by way of formulation of M/s Sunrise Pharma (Pvt) Ltd, 594-A, Sunder Industrial Estate, Raiwind Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

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

Accordingly, showcause notice was issued to the firm on 21/05/2022.

In response to Show Couse Notice the firm submitted their response. However, the firm did not rectify following shortcoming;

i. Form -29 certified true copy by SECP (in original) is required.

Moreover, the photocopy of Form-29 submitted by firm bears the stamp of the Security and Exchange Commission of the Pakistan (SECP) as under: -

"certified true copy of the document filed by the company However, this office accepts no responsibility to the details given in the documents"

A letter of personal hearing has been issued to the applicant on 6th October, 2022.

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

Mr. Muhammad Asim Aslam GM and M. Ahmed QC Incharge of the firm appeared before the Board. They contended that they will provide/submit updated Form-29 attested as true copy (in original) without disclaimer/qualification with in 15days. The Board decided that the firm will proved such from within 15 days and the case be placed before Board in its upcoming meeting for its consideration Accordingly, letter was issued in the light of 288th meeting held on 18th October, 2022. However, as per available record in the Licensing Division, no response has been received so for. In the light of above, it is proposed that a reminder was served to the firm. However, it was returned by Pakistan Post under UMS No. 71533119, with the envelope indicating that delivery could not be completed despite multiple attempts. Furthermore, the envelope states that no one was present at the factory gate to receive the letter.

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 000712, by way of Formulation, of M/s Sunrise Pharma (Pvt) Ltd, 594-A, Sunder Industrial Estate, Raiwind Road, Lahore 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 29 STATUS OF DML OF M/S WESTMONT PHARMACEUTICALS INDUSTRY, MINI INDUSTRIAL ESTATE, G.T ROAD, GUJAR KHAN, RAWALPINDI.

The Drug Manufacturing License No.000631 by way of Formulation was issued to M/s Westmont Pharmaceuticals Industry, Mini Industrial Estate, G.T Road, Gujar Khan, Rawalpindi vide letter No. F.1-13/2006-Lic dated 20-06-2008.

The firm M/s Westmont Pharmaceuticals Industry, Mini Industrial Estate, G.T Road, Gujar Khan, Rawalpindi Drug Manufacturing License No.000631 by way of Formulation submit application for renewal of DML from for the period 19-06-2008 to 18-06-2013 and was processed accordingly. However, as per available data in the Licensing Division, DRAP, application for renewal of DML for the duration from 19-06-2018 to 18-06-2023 has not been received.

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.

Therefore, Drug Manufacturing License No. 000631 (formulation) of M/s Westmont Pharmaceuticals Industry, Mini Industrial Estate, G.T Road, Gujar Khan, Rawalpindi is invalid and stand cancelled.

In the light of above, letter of expiration of validly was issued on 30th August, 2024.

The firm applied for re-grant of DML (Afresh) for following section and application was complete. Accordingly, panel for re-grant of DML (afresh) has been constituted for following section.

I. Oral liquid (General/antibiotic)-Vet

II. oral powder (General/antibiotic)-Vet

Decision of the Central Licensing Board in 302nd meeting:

The Board endorsed the expiration of the validity of the DML of M/s Westmont Pharmaceuticals Industry, Mini Industrial Estate, G.T Road, Gujar Khan, Rawalpindi.

Case No. 30 STATUS OF DML OF M/S AVENTEK PHARMACEUTICALS (PVT) LTD, PLOT NO. 44-C, SUNDAR INDUSTRIAL ESTATE, LAHORE.

The Drug Manufacturing License No.000660 by way of Formulation was issued to M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sundar Industrial Estate, Lahore.

The firm M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sundar Industrial Estate Drug Manufacturing under License No.000660 (Formulation) submitted application of the firm for renewal of DML for the period of 27-03-2024 to 26-03-2029 has received on 16-08-2024 after 60 days of the expiry of validity of DML.

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 18th September, 2024. The firm has replied to Show Cause Notice which is reproduced as under:

"As per subject with reference we M/s Aventek Pharmaceuticals (Pvt) Ltd are writing in response to the show cause notice issued to us concerning our Drug Manufacturing License No. 000660, which is set to expire on March 26, 2024.

We sincerely apologize for the delay in submitting our renewal application. Despite our commitment to comply with all regulatory requirements, we encountered several unforeseen challenges that hindered our timely application.

1. Fee Challan Discrepancies: We initially faced significant issues while generating the fee challan due to a notification stating, "your account has license-related discrepancies." This matter was resolved on 27 may, 2024 and our submission of the renewal fee on May 27, 2024. (Evidence is attached)

2. Plant Closure and Management Transition: Our manufacturing plant was entirely closed from November 2023 to June 2024 due to a change in ownership and management. This transition complicated our operations and delayed our ability to access vital information necessary for the renewal process.

3. Health Issues of New Management: During this period, the new management faced serious health issues, including a cardiac arrest, further complicating our operations. (Record is attached)

4. Lack of Information from Previous Management: The previous management did not provide accurate information regarding the renewal of the drug license. Consequently, the new management was not privy to the necessary records or contacts of the former technical staff, resulting in significant operational delays.

5. DRAP E-Application System Issues: Our data was not authenticated on the DRAP E-application system due to the unavailability of previous records, which further hindered our ability to complete the renewal application in a timely manner.

In light of these circumstances, we paid a fee of Rs. 75,000 (Challan Form No. 709919135285) on 27-05-2024. Furthermore, we have always prioritized compliance with DRAP regulations during Management Transition we apply the change of technical staff on 26-07-2024 and get approval from licensing department on 20-09-2024.

We have consistently prioritized compliance with DRAP regulations and have made every effort to rectify this situation as promptly as possible. We kindly urge you to reconsider our DML renewal application, as we are prepared to remit payment for the 60-day period in question, during which we incurred fines of PKR 15,000 per day.

In view of the above, we respectfully request the opportunity to present our case in person to further elaborate on the situation. We also ask for your sympathetic consideration, as we have encountered several unforeseen challenges that hindered our timely application."

Therefore, Drug Manufacturing License No. 000660 (Formulation) of M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sundar Industrial Estate, Lahore is invalid and stands cancelled.

In the light of above, letter of expiration of validly as issued on 11th November, 2024.

Decision of the Central Licensing Board in 302nd meeting:

The Board endorsed the expiration of the validity of the DML of M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sundar Industrial Estate, Lahore.

Case No. **31** **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000459 (FORMULATION) OF M/S P.D.H PHARMACEUTICALS (PVT) LTD., 19 KM FEROZEPUR ROAD LAHORE.**

The Firm, M/s P.D.H., Pharmaceuticals (Pvt) Ltd., 19 Km, Ferozepur Road, Lahore under DML No. 000459 submitted application for renewal of DML and approval of regularization of LOP. The layout plan (LOP) was approved and subsequently panel was constituted for regularization of LOP and renewal of DML for following section

i. Syrup (General) Section
ii. Tablet (General) Section
iii. Capsule Section (General)
iv. Eye Drops Section
v. Tablet (Antibiotic) Section
vi. Dry Syrup (Antibiotic) Section
vii. Sachet (General) Section.
viii. Dry Suspension Section (Cephalosporin)
ix. Capsule section (Cephalosporin).

The said panel submitted following recommendations as under

"The firm M/s P.D.H., Pharmaceuticals (Pvt) Ltd., Lahore was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities.

Keeping in view the observations made on the day of inspection and after going through the documentations and overall operations, the panel was of the opinion that the firm M/s PDH Pharmaceuticals (Pvt) Ltd., Lahore may be granted renewal of Drug Manufacturing License for the following sections:

1. Syrup (General) Section
2. Tablet (General) Section
3. Capsule Section (General)
4. Ophthalmic Section
5. Tablet (Antibiotic) Section
6. Dry Syrup (Antibiotic) Section
7. Sachet (General) Section

NOTE: The section was not mentioned in DRAP's Islamabad letter for renewal of drug manufacturing license No.F.1-42/84-Lic (Vol-VI), dated 21-11-2023 however the section is present in approved lay out plan as physically and DRAP's Islamabad letter for approved lay out plan No.F.1-42/84-Lic (Vol-VI) dated 10th March, 2021.

i. Dry Suspension Section (Cephalosporin)
ii. Capsule section (Cephalosporin)."

The cases was placed before CLB in its in its 294th meeting held on 27th December, 2023 and the Board granted and approved regularization of LOP and renewal of DML of M/s P.D.H., Pharmaceuticals (Pvt) Ltd., 19 Km, Ferozepur Road, Lahore and decided as under:

> *"The Board considered and approved the grant of renewal of DML No. 000459 by way of Formulation and regularization of Lay Out Plan in the name of M/s P.D.H., Pharmaceuticals (Pvt) Ltd., 19 Km, Ferozepur Road, Lahore on the recommendations of the panel of experts for the period Commencing on 22-09-2020 and ending on 21-09-2025 for the following sections subject to verification of testing equipment's (M-290th CLB).*
>
> *1. Syrup (General) Section*

2. Tablet (General) Section

3. Capsule Section (General)

4. Eye Drops Section

5. Tablet (Antibiotic) Section

6. Dry Syrup (Antibiotic) Section

7. Sachet (General) Section

It is pertinent to mention that Dry Suspension (Cephalosporin), Capsule (Cephalosporin) sections were not reflected in the decision of the Board in its 294th meeting. Therefore, Form-2/DML Certificate along with covering letter for above mentioned sections were issued, accordingly.

Decision of the Central Licensing Board in 302nd meeting:

The Board in light of approved layout plan and availablity of sections with the firm, decided that inspection of the firm for following two sections shall be conducted for grant of renewal of DML:

1. Oral Dry Powder Suspension (Cephalosporin)
2. Capsule (Cephalosporin)

Case No. 32 STATUS OF DRUG MANUFACTURING LICENSE NO. 000904 (FORMULATION) OF M/S SHINE LABORATORIES, MASA KASWAL, 9-KM SOHAWA, MAIN GT ROAD, GUJJAR KHAN.

The firm, M/s Shine Laboratories, Masa Kaswal, 9-KM Sohawa, Main GT Road, Gujjar Khan under the Drug Manufacturing License No. 000904 (formulation) submit application for renewal of DML from 24-06-2019 to 23-06-2024 on 23-08-2024.

It is submitted that the Central Licensing Board (CLB) in its 270th meeting held on 23rd May, 2019 granted Drug Manufacturing License No. 000904 (formulation) in the name of M/s Shine Laboratories, Masa Kaswal, 9-KM Sohawa, Main GT Road, Gujjar Khan and DML of Form2 was issued w.e.f. 24-06-2019.

It is pertinent to mentioned that the Drug Manufacturing License No. 000904 (formulation) of M/s Shine Laboratories, Masa Kaswal, 9-KM Sohawa, Main GT Road, Gujjar Khan was valid from 24-06-2019 to 23-06-2024. However, M/s Shine Laboratories, Masa Kaswal, 9-KM Sohawa, Main GT Road, Gujjar Khan submit application for renewal of Drug Manufacturing License No. 000904 (formulation) on 23-08-2024. Hence the firm application is submitted after sixty days of the expiry of the period of validity of licence i.e., days are calculated as follow

DML was valid till 23-06-2024

Application for renewal of DML was submitted on on 23-08-2024

a) June- 07-days

b) July 31-days

c) Aug-23- days

Total days 61 days

It is submitted that as per Rule 6 of Drug (L, R & A) Rule, 1976 that a licence issued under the said rules, unless earlier suspended or cancelled, be in force for a period of five (5) years from the date of issue and may thereafter be renewed for periods of five (5) years at a time. Provided that if application for renewal is made before the expiry of the period of validity of a licence, the licence shall continue in "force until" orders are passed on such application. Provided further that if an application for renewal is made after the expiry of the period of validity of a licence but within sixty days of its expiry, the licence shall continue to be in force on payment of additional surcharge of rupees 9000/ for each day the application is delayed, and thereafter until order are passed on the such application. Furthermore, Rule 5(3) Drug (L, R & A) Rule, 1976 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.

In the light of above, Drug Manufacturing License No. 000904 (formulation) of M/s Shine Laboratories, Masa Kaswal, 9-KM Sohawa, Main GT Road, Gujjar Khan is invalid and stand cancelled.

In the light of above, letter of expiration of validly was issued on 25th September, 2024.

Decision of the Central Licensing Board in 302nd meeting:

The Board endorsed the expiration of the validity of the DML M/s Shine Laboratories, Masa Kaswal, 9-KM Sohawa, Main GT Road, Gujjar Khan.

CASE No. 33 SURRENDERING OF ALREADY APPROVED HUMAN SECTIONS OF M/S STANDPHARM PAKISTAN (PVT) LTD., 20 KM FEROZEPUR ROAD LAHORE.

The firm M/s Standpharm Pakistan (Pvt) Ltd., 20 Km Ferozepur Road Lahore under the DML No. 000051 (Formulation) has submitted request for surrendering of following licensed sections

1. Injectable liquid ampoule (General)
2. Injectable liquid infusion (General)

It is submitted for information that the Board it is 275th meeting held on 25th June, 2020 considered and approved the grant of renewal above mentioned section in the name of M/s Standpharm Pakistan (Pvt) Ltd, located at 20-KM, Ferozepur Road, Lahore.

Decision of the Central Licensing Board in 302nd meeting:

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)

Case No. 34 **GRANT RE-PACKING PRODUCTS M/S ZAKFAS PHARMACEUTICALS (PVT) LTD., 12-KM BOSAN ROAD LUTAFABAD MULTAN.**

The firm, M/s Zakfas Pharmaceuticals (Pvt) Ltd., 12-Km Bosan Road Lutafabad Multan under Drug Manufacturing Licence No. 000603 by way of formulation has submitted application for Grant of Re-packing drug as per Schedule-D. Firm has submitted challan Fee of 9000/ per product.

1. "Kaoline Powder
2. Sodium salicylate

Decision of the Central Licensing Board in 302nd meeting

The Board considered and approved the grant of following repacking products to M/s Zakfas Pharmaceuticals (Pvt) Ltd., 12-Km Bosan Road Lutafabad Multan under Drug Manufacturing Licence No. 000603 by way of formulation;

1. Kaoline Powder
2. Sodium salicylate

Case No. 35 **GRANT RE-PACKING PRODUCTS TO, M/S PRAY'S PHARMACEUTICALS, PLOT NO. 10 STREET SS-4 NATIONAL INDUSTRIAL ZONE (RCCI) RAWAT.**

The firm, M/s Pray's Pharmaceuticals, Plot No. 10 Street SS-4 National Industrial Zone (RCCI) Rawat under Drug Manufacturing Licence No. 000719 by way of formulation has submitted application for Grant of Re-packing drug as per Schedule-D. Firm has submitted challan Fee of 9000/ per product.

1. Castor Oil
2. Glycerin
3. Kaolin Powder
4. Liquid Paraffin Heavy
5. Salicylic Acid
6. Sodium Bicarbonate
7. Soft Yellow Paraffin
8. Zinc Oxide
9. Boric Acid

Decision of the Central Licensing Board in 302nd meeting:

The Board considered and approved the grant of approval of following repacking products to M/s Pray's Pharmaceuticals, Plot No. 10 Street SS-4 National Industrial Zone (RCCI) Rawat under Drug Manufacturing Licence No. 000719 by way of formulation;

1. Castor Oil
2. Glycerin

3. Kaolin Powder
4. Liquid Paraffin Heavy
5. Salicylic Acid
6. Sodium Bicarbonate
7. Soft Yellow Paraffin
8. Zinc Oxide
9. Boric Acid

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. 36 **REQUEST FOR EXTENSION OF VALIDITY PERIOD OF LAYOUT APPROVAL OF M/S WILSHIRE LABORATORIES (PVT) LTD., 124/1 INDUSTRIAL ESTATE KOT LAKHPAT LAHORE UNDER DML NO. 000232 (FORMULATION)**

The firm, M/s Wilshire Laboratories (Pvt) Ltd., 124/1 Industrial Estate Kot Lakhpat Lahore under DML No. 000232 (Formulation) submitted that due to unforeseen circumstances, including the COVID-19 pandemic and the resulting economic downturn in our country, they were unable to complete the development of the following sections. The firm has requested a two-year extension on the approval of the layout plans for the following section sections.

1 General Oral Liquid
2 General Nebulizing
3 General Liquid Sachet
4 General Lyophilization Section
5 General Prefilled Syringes
6 Steroid Tablet
7 Steroid Capsule
8 Steroid Nebulizing
9 Steroid ENT Drops

It is submitted that the firm's Layout Plan (LOP) was approved by the Committee on Layout Plan in the year 2022. Now, the firm has requested an extension of the validity of the Layout approval, as they have not yet started construction.

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 294th meeting held on December 27, 2023, and decided the approval of layout plans shall be valid for one year for an additional section and two years for a

new unit. If the firm does not complete the construction and installation of machinery and equipment within this period, the firm shall be required to reapply afresh.

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.

Case No. 37 **SITE APPROVAL, RENT AND GRAY STRUCTURE OF SITE/LAND FOR ESTABLISHMENT OF PHARMACEUTICAL UNIT**

The manufacturer/applicant intended to establish a pharmaceutical unit, submitted an application for site approval, and the site got approved according to para 1.1 of the Schedule B of Drugs (Licensing, Registering, and Advertising) Rules, 1976.

Para 1.1 to 1.3 of the Schedule B of Drugs (Licensing, Registering, and Advertising) Rules, 1976 states that **t**he premises shall be located preferably in an industrial area and in any case not in any residential or commercial area (**Location), p**remises shall be situated in an environment that, when considered together with measures to protect the manufacturing processes, presents minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odour or fumes or large quantities of soot, dust or smoke which may contaminate the drugs being manufactured or adversely affect their quality. Existing units shall keep the surroundings under their control to be clean (**Surroundings)** and the size of the plot shall not be less than 2000 square yards (**Size).**

It is pertinent to mention that ownership validity of site approval and grey structure (green filed) of of the land on which pharmaceutical unit is established is not clearly defined under said rule.

Furthermore, it is informed that as per practice in vogue pharmaceutical units has been allowed to established on rental premises with rental agreement between firm and the owner of the land for duration at least two renewals i.e. **15 years.**

The Central Licensing Board in its 293rd held on 20th November, 2023 in considered and decided that firms apply for site verification where a multipurpose grey structure is already constructed and it does not qualify for establishment of the pharma units. The Board also decided that in future, green field sites (without any construction) for pharmaceutical units will only be considered for approval. In certain cases, where public interest is involved, applications shall be considered on case to case basis.

Similarly matter regarding **ownership** of the land/site on which pharmaceutical unit is established was considered and decided by the Central Licensing Board in its 294th meeting of held

on 27th December, 2023 that applications to establish a pharmaceutical unit on the rented premises shall not be entertained. At least one of the owners of the plot should be part of management of the firm as a director/partner/owner.

Regarding **validity** of the site the Central Licensing Board in its 294th meeting of held on 27th December, 2023 decide that the site verification of unclassified/agricultural area/premises shall be valid only for one year and for sites in industrial zones for 2 years. The firm shall apply afresh for approval after the lapse of the period.

Decision of the Central Licensing Board in 302nd meeting:

The Board considered the request of the firm and decided that:-

I. The site verification of any site shall be valid for 2 years. The firm shall apply afresh for approval after the lapse of this period.

I. Delegated the power for extension in the validity period for one year to Chairman, CLB.

II. Site having grey structure shall be approved subject to the undertaking by the management that grey structure will be demolished, if required, during approval of the layout plan.

Case No. 38 **ISSUANCE OF NOC FOR THE RAW MATERIAL 1-CYCLOPROPYL-6-FLURO-4-OXO-7 PIPERAZINE-I-YL-QUINOLINE-3 CARBOXYLIC ACID – HYDROCHLORIC ACID (CRUDE) FOR THE MANUFACTURING OF CIPROFLOXACIN HCL.**

The firm M/s. Zenith Chemical industry Lahore udder DML No 000733 (Semi Basic Manufacture) wherein they have requested for issuance of No Objection Certificate (N.O.C) which is required by the Custom Authorities during the custom clearance of following Raw Material imported Vide Invoice No. LH-XSW24043011 Dated 14/06/2024, from M/S, Zhejiang Langhua Pharmaceutical Co., Ltd. Zhejiang Provincial Chemical and Medical Materials Base Linhai Zone, Linhai, Zhejiang, China, under G.D # KAPW-HC-6025 Dated on 11.07.2024 for the manufacturing of their enlisted API, Ciprofloxacin HCL BP/USP.

The CLB in its 227th meeting held on 1st & 2nd June, 2011 granted DML No. 000733 by way of Semi Basic Manufacture of M/s Zenith Chemical Industries (Pvt) Ltd, Moza Donday, Jia Baga, Raiwind Road, Lahore for following API,

1. Paracetamol
2. Ibuprofen
3. Cetirizine Dihydrochloride
4. Montelukast
5. Ciprofloxacin
6. Ofloxacin
7. Levofloxacin
8. Moxifloxacin HCL.

It is submitted for information that CLB in its 246th meeting held on 9th July, 2018 decided as under

"Keeping in view the above situation, the Board considered, discussed and unanimously decided for panel inspection of the above firms by following panel: -

1. *Prof. Dr. Saeed Sb. Member CLB*
2. *Dr. Ikram-ul-Haq, Member CLB*
3. *Syed Muid Ahmed, Member CLB*
4. *Syed Javed Yousuf Bukhari, Member CLB*
5. *Area FID, DRAP, Lahore*

The Board further directed the panel: -

- *to verify the complete process of manufacturing of every API as per requirement of Rule 10 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.*
- *to sign / endorse the complete report and their manufacturing process flows of APIs.*

The Board further decided that in future above procedure shall be followed for approval any new API.

In the Light of Above decision of the Board, the Panel inspected the firm and submitted its report. The Board in its 250th meeting approved flow Chart with 7-Chloro-1-Cyclopropyl-6-Fluoro-1,4-

Dihydro-4-Oxoquinoline-3-Carboxylic Acid (Cipro Q Acid) as intermediate, used in the manufacturing of Ciprofloxacin HCL (API) and decided as under

Decision.

The Central Licensing Board deliberated and decided that:

i. Report of the panel consisting of consolidated list of APIs approved for manufacture by the firm / company, consolidated list of chemicals used for manufacture of APIs, individual APIs along with chemicals used for manufacture of particular API and flow charts of manufacture of APIs shall be endorsed as such and forwarded to the Licensing Authority under the Drugs (Import and Export) Rules, 1976.

ii. The Board also decided that following panel of inspectors/ experts shall inspect the facility of pharmaceutical units manufacturing APIs as mentioned above for the purpose of determination of quantity of chemicals/reagents to be used for manufacture of each API and submit its reports with clear and candid recommendations for consideration of the Board.

1. Dr. Ikram-ul-Haq, Member CLB
2. Syed Muid Ahmed, Member CLB
3. Syed JavedYousuf Bukhari, Member CLB
4. Area FID, DRAP, Lahore
5. Dr. Akbar Ali, Assistant Director (Lic), DRAP, Islamabad.

Hence the Board approved flow Chart with 7-Chloro-1-Cyclopropyl-6-Fluoro-1,4-Dihydro-4-Oxoquinoline-3-Carboxylic Acid (Cipro Q Acid) as intermediate, used in the manufacturing of Ciprofloxacin HCL (API).

Furthermore, the Ciprofloxacin HCL flow chart with the chemical as intermediate "1-CYCLOPROPYL-6-FLURO-4-OXO-7 PIPERAZINE-I-YL-QUINOLINE-3 CARBOXYLIC ACID – HYDROCHLORIC ACID (CRUDE)" was endorsed by the Panel constituted for renewal of DML No. 000733 (Semi Basic Manufacture) of M/s Zenith Chemical Industries (Pvt) Ltd., Moza Dondey Gia Baga, Raiwind Road Lahore w.e.f. 15-06-2016.

Moreover, recommendation letter from DRAP vide letter No. F.1-25/2009-Lic(Vol-II) dated 10th May, 2022 was issued to Tariff Commission wherein it was clarified that "1-Cyclopropyl-6-Fluro-4-Oxo-7 Piperazine-I-Yl-Quinoline-3 Carboxylic Acid – Hydrochloric Acid (Crude) is used as starting material and intermediate. It was recommended that the same may be included in 5th Schedule of Pakistan Customs Act, 1969.

Now the firm has requested for regularize the attached flow chart of our approved product/API Ciprofloxacin HCl.

Decision of the Central Licensing Board in 302nd meeting:

The Board on the basis of endorsement of the Panel, constituted for renewal of DML No. 000733 (Semi Basic Manufacture) of M/s Zenith Chemical Industries (Pvt) Ltd., Moza Dondey Gia Baga, Raiwind Road Lahore, for the period commencing from 15-06-2016, endorsed the Flow Chart with "1-CYCLOPROPYL-6-FLURO-4-OXO-7 PIPERAZINE-I-YL-QUINOLINE-3 CARBOXYLIC

ACID – HYDROCHLORIC ACID (CRUDE) as starting material/intermediate for manufacturing of Ciprofloxacin HCl (API) (Annexure-B).

Case No.39 **CORRECTION IN RNEWAL OF DRUG MANUFACTURING LICENSE OF M/S JFRIN PHARMACEUTICAL LABORATORIES, PLOT NO.16, 17 & 20, H.I.T.E., BALOCHISTAN UNDER DRUG MANUFACTURING LICENSE NO. 000580 BY WAY OF (FORMULATION).**

1.	M/s. Jfrin Pharmaceutical Laboratories, Plot No. 16,17 & 20, H.I.T.E. Balochistan. DML No. 000580 (Formulation) Tenure. Commencing on 24-06-2020 and ending on 23-06-2025. **Sections:** 1) Bolus (Veterinary) 2) Powder Injection (Veterinary) 3) Powder Premixes (Veterinary) 4) Liquid Injectable (Veterinary)	**17-02-2021**	**Good**	1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi 2) FID, DRAP, Quetta. 3) Assistant Director, DRAP, Quetta.

Recommendations of the panel:

After detailed examination and inspection of operating procedures SOPs and personal met equipment checked panel in view recommend the renewal of Jfrin Pharma as it is functional and operational at satisfactory factory GMP however it's the view of **panel the management should regularized its layout from CLB as soon as possible.**

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000580) by way of Formulation in the name of M/s Jfrin Pharmaceutical Laboratories, Plot No. 16,17 & 20, H.I.T.E. Balochistan on the recommendations of the panel of experts for the period commencing on 24-06-2020 and ending on 23-06-2025.for following sections:

1) **Bolus (Veterinary)**
2) Powder Injection (Veterinary)
3) Powder Premixes (Veterinary)
4) Liquid Injectable (Veterinary)

Upon the request of the firm the DML renewal report is re-evaluated and found that evaluation performa of Oral Liquid (Veterinary) Section was submitted by inspection panel instead of Bolus (Veterinary) section. However, as per record of the Licensing Division, the firm has Bolus (Veterinary) Section.

Decision of the Central Licensing Board in 302nd meeting:

	The Board directed the firm to get layout plan regularized for Oral Liquid (Veterinary) Section and clarify the availability of Bolus (Veterinary) Section.

Case No.40 **CORRECTION IN RNEWAL OF DRUG MANUFACTURING LICENSE OF M/S W. WOODWARD PAKISTAN (PVT) LTD, KARACHIUNDER DRUG MANUFACTURING LICENSE NO. 000042 BY WAY OF (FORMULATION).**

M/s W. Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi. DML No. 000042 (Formulation). **Period:** Commencing on 13-02-2021 ending on 12-02-2026. *Evaluator: - Mubashir Iqbal (DD-Lic)*	**20-02-2024**	**Good**	1. Dr. Saif-ur-RehmanKhattak, Additional Director, CDL, DRAP, Karachi. 2. Mr. Abdul Rasool Sheikh, Additional Director (E&M), DRAP, Karachi. 3. Dr. Shoaib Ahmed, FID-III, DRAP, Karachi.
QC In-charge	Ms. Anjum Basit D/o M.A Basit Siddiqui (Pharm-D) CNIC No.42201-0319698-6.		
Production In-charge	Syed Kamranuddin Ahmed (B.Pharm)		

Recommendations of the panel:

"M/s W.Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi was inspected as per DRAP letter No.F.2-36/85-Lic (Vol-V) dated 06th September, 2021 and 06th May 2021 in connection with grant of Renewal of DML & Regularization of layout.

***Following are the observations**:*

The firm was found built as per layout plan approved by the DRAP authorities Islamabad vide letter No.F.2-36/85-Lic. (Vol-V), No.F.1-65/84-Lic (Vol-III) (M211) on dated 27th July, 18th December 2017 and 30th October 2008. All production, quality control, research and development laboratory, warehouse and storage facilities were observed well maintained and continuous monitoring system were seen in placed. Equipment were found calibrated and qualified, in general. Adequate technical personnel were available at the site and observed well conversant with the requirements of the cGMP standards. An appropriate & adequate HVAC system operating air process according to grades of rea. The facility is segregated, dedicated and fully contained for Cephalosporin products with access control for staff, who have been assigned responsibilities only for Cephalosporin facility. Key staff has required qualification, experience and skill according to the position and job description for employees.

Based on the people met and the documents reviewed and considering the findings of the inspecting Panel M/s W. Woodward Pakistan (Pvt.) Ltd., F-275, S.I.T.E., Karachi is considered to be designed, established and operating at an acceptable level of compliance of GMP requirements. Therefore, the panel unanimously ***recommends*** *the approval for the grant of Renewal of their DML no. 000042 by way of formulation and regularization of old section with reference to the DRAP letter No. F.2-36/85-Lic (Vol-V) dated 6th September 2021 & 6th May 2021.*

Following are the sections mentioned in the above referred panel letters;

i. Tablet (General-Antibiotic)
ii. Capsule (Cephalosporin)
iii. Dry Powder Suspension (Cephalosporin)
iv. Cream/ Ointment (General-Antibiotic)
v. Sachet (General)
vi. Oral Liquid Syrup (General) – Regularization
vii. Capsule (General) – Regularization
viii. Dry Powder Suspension (General) – Regularization

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of regularization and renewal of DML No. 000042 by way of Formulation in the name of M/s W. Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi on the recommendations of the panel of experts for the period commencing on 13-02-2021 ending on 12-02-2026 for the following sections subject to verification of necessary testing equipment:

i. Tablet (General)
ii. Capsule (Cephalosporin)
iii. Dry Powder Suspension (Cephalosporin)
iv. Cream/ Ointment (General)
v. Sachet (General)
vi. Oral Liquid Syrup (General) – Regularization
vii. Capsule (General) – Regularization
viii. Dry Powder Suspension (General) – Regularization

The firm has stated that one of their section "Additional Oral Liquid Syrup (General) First Floor" is missing which might be a typo error. The firm has submitted missing section evaluation form duly signed and recommended by the panel members as per direction of Central Licensing Board along with list of equipment verified by Area FID.
Firm has submitted the request that kindly incorporate missing section.

Decision of the Central Licensing Board in 298th meeting

The Board while considering the facts on the record observed that the panel of inspectors has not listed approved sections in their recommendation in inspection report. The Board decided to refer the application to Additional Director DRAP Karachi to verify the two sections i.e. Oral Liquid Syrup-I (General) and Oral Liquid Syrup-II (General) along with other approved sections. The Board authorized the Chairman CLB to issue the renewal after verification.

Recommendations of the panel:

Dr. Saif-Ur-Rehman Khattak, Additional Director, DRAP, Karachi has conducted the inspection and submitted that the firm has two sections for (General) liquid syrup manufacturing (one on the ground floor and other on the first floor) along with seven sections. Hence the following nine sections for manufacturing have been verified for your consideration please:-

Ground Floor

1. Oral Liquid syrup (General)

First Floor

1.Tablet (General Antibiotics)
2.Capsule (General)
3.Cream/ Ointment (General Antibiotics)

4.Capsule (cephalosporin)
5.Oral liquid syrup (General)
6.Dry powder suspension (General)
7.Dry powder suspension (Cephalosporin)
8.Sachet (General)

It is further submitted that information regarding the two (General) liquid syrup sections were already communicated on form-II while submitting the inspection report (dated 20th February, 2024) for renewal of DML of the firm and regularization of the layout.

Decision of the Central Licensing Board in 302nd meeting

The Board on the recommendations of Additional Director, DRAP, Karachi, approved the grant of regularization and renewal of DML No. 000042 by way of Formulation in the name of M/s W. Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi for the period commencing on 13-02-2021 ending on 12-02-2026 for the following section:

i. Oral Liquid Syrup-II (General)

Case No.41 CORRECTION IN CHANGE OF MANAGEMENT OF M/S HIMARK LABORATORIES (PVT) LTD., LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000909 BY WAY OF FORMULATION.

M/s. Himark Laboratories (Pvt) Ltd., 37-A, Sunder Industrial Estate, Lahore has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm is as under:

Previous Management	New management as per Form-A dated 20-03-2023& Form-29 dated 20-03-2023
1. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7. (**CEO**)	1. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7 (**Director**)
2. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**Director**)	2. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**CEO**)
3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3.**(Director)**	3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3.**(Director)**
4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5.**(Director)**	4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5.**(Director)**
5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**	5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**

Decision of the Central Licensing Board in 298th meeting

Based on Form-A dated 20-03-2023 & Form-29 dated 20-03-2023 issued by SECP, the Board considered and accepted for record the change of management (only CEO) of M/s. Himark Laboratories (Pvt) Ltd., 37-A, Sunder Industrial Estate, Lahore under DML No. 000909 (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 date 10/11/2020 (if applicable) as under. 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
1. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7. (**CEO**) 2. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**Director**) 3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3.**(Director)** 4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5.**(Director)** 5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**	1. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7 (**Director**) 2. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**CEO**) 3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3 **(Director)** 4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5**(Director)** 5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**

The designation of previous and new CEOs were inadvertently written incorrectly. The correct designation is as under:

Previous Management	New management as per Form-A dated 20-03-2023& Form-29 dated 20-03-2023
1. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**CEO**) 2. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7. (**Director**) 3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3.**(Director)** 4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5.**(Director)** 5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**	**1. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7 (CEO)** 2. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**Director**) 3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3 **(Director)** 4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5**(Director)** 5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**

Decision of the Central Licensing Board in 302nd meeting:

The Board based on Form-A dated 20-03-2023 & Form-29 dated 20-03-2023 issued by SECP, approved the correction and accepted for record the change of management (only CEO) of M/s. Himark Laboratories (Pvt) Ltd., 37-A, Sunder Industrial Estate, Lahore under DML No. 000909 (Formulation) as under:

Previous Management	New management as per Form-A dated 20-03-2023& Form-29 dated 20-03-2023
1. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**CEO**) 2. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7. (**Director**) 3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3.**(Director)**	**1. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7 (CEO)** 2. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**Director**) 3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3 **(Director)**

4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5.**(Director)** 5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**	4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5**(Director)** 5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**

Case No.42 **CORRECTION IN GRANT OF ADDITIONAL SECTION OF M/S CARE PHARMACEUTICALS, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000563 (FORMULATION).**

Case Background:

M/s Care Pharmaceuticals, 8-Km, Thokar Raiwind Road, Lahore. DML No. 000563 (Formulation). **Sections (06):** i. Tablet (General)(Amended/Rearranged) ii. Capsule Section (General) (New). iii. Sachet Section (New). iv. Liquid Injectable Ampoule (General) (Amended/Rearranged). v. Liquid Injectable Vial (General) (Amended/Rearranged) vi. Oral Dry Powder Suspension (General) (New).	10-04-2023	Good	1. Dr. Farzana Ch. Expert Member. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore.

Recommendations of the panel: -

In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling water treatment system, personnel and documentation etc the panel recommends the renewal of Drug Manufacturing License and grant of Additional section of the following sections to M/s Care Pharmaceutical, 8-Km, Thokar Raiwind Road, Lahore by way of formulation:

i. Tablet (General)(Amended/Rearranged)
ii. Capsule Section (General) (New).
iii. Sachet Section (New).

iv. Liquid Injectable Ampoule (General) (Amended/Rearranged).
v. Liquid Injectable Vial (General) (Amended/Rearranged)
vi. Oral Dry Powder Suspension (General) (New).

Decision of the Central Licensing Board in 290th meeting

The Board considered and approved the grant of following additional- and revised sections in the name of M/s Care Pharmaceuticals, 8-Km, Thokar Raiwind Road, Lahore DML No. 000563 (Formulation) on the recommendations of the panel of experts.

i. Tablet (General)(Revised)
ii. Capsule Section (General) (New).
iii. Sachet Section (New).
iv. Liquid Injectable Ampoule (General) (Revised).
v. Liquid Injectable (Vial) (SVP) (General) (Revised)
vi. Oral Dry Powder Suspension (General) (New).

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

Section approval letter was issued to the firm on 13th July, 2023. The firm has since clarified that all of these sections were additional/new, although some were approved as revised sections. The firm has now requested corrections to reflect the accurate status.

It is pertinent to mention here that as per available record of Licensing Division, the firm possess following three licensed sections which were renewed in 290th meeting of CLB which was held on 28th April, 2023:

i. Oral Liquid (General)
ii. Eye/Ear Drops (General)
iii. Cream/Ointment (General)

Decision of the Central Licensing Board in 302nd meeting:

The Board approved the correction for the following **additional sections** in the name of M/s Care Pharmaceuticals, 8-Km, Thokar Raiwind Road, Lahore under DML No. 000563 by way of Formulation:

1. Tablet (General)(New)
2. Capsule Section (General) (New).
3. Sachet Section (New).
4. Liquid Injectable Ampoule (General) (New).
5. Liquid Injectable (Vial) (SVP) (General) (New)
6. Oral Dry Powder Suspension (General) (New).

Case No.43 CORRECTION IN MINUTES OF 298TH MEETING OF CLB IN THE CASE OF RENEWAL OF DML M/S PRIX PHARMACEUTICAL (PVT) LTD., 05-PHARMA CITY, 30-KM, MULTAN ROAD, LAHORE

The case for grant of renewal of DML of M/s Prix Pharmaceutica (Pvt) Ltd., 05-Pharma City, 30-Km, Multan Road, Lahore was presented in 298th meeting of CLB held on 26th July, 2024. The Board considered and approved the renewal of DML No. 000587 by way of Formulation

in the name of M/s Prix Pharmaceutica (Pvt) Ltd., 05-Pharmacity, 30-Km, Multan Road, Lahore on the recommendations of the panel of experts for the period commencing on 16-10-2020 ending on 15-10-2025.

It is submitted that name of the QC incharge was inadvertently mentioned as Ghulam Mustafa (M.Sc Chemistry) instead of Mr. Majid Ali (M.Sc Chemistry) in agenda and minutes of 298th meeting of CLB held on 26th July, 2024. Furthermore, Mr Mohsin Amin S/o Malik Muhammad Amin (B-Pharm) is inadvertently mentioned as QC Incharge instead of Production Incharge.

In light of powers delegated by CLB in 278th meeting held on December 10-11, 2020, Chairman CLB has approved the correction in minutes of 298th meeting as below

QC In-charge	Mr. Majid Ali (M.Sc Chemistry)
Production In-charge	Mr Mohsin Amin (B-Pharm)

Decision of the Central Licensing Board in 302nd meeting:

The Board considered the case and ratified the correction.

Case No.44 CORRECTION IN MINUTES OF 292ND MEETING OF CLB IN THE CASE OF GRANT OF DML M/S M/S NUTRION (PVT.) LTD,, MIRPUR

The case for grant of DML of M/s Nutrion (Pvt.) Ltd, Plot No. 186, 187, 192, 193/S, New Industrial Estate, Mirpur, AJ&K was presented in 292nd meeting of CLB held on 4th October, 2023. The decision of the Board is reproduced as under:

Decision of the Central Licensing Board in 292nd meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Nutrion (Pvt) Ltd, Plot No. 186, 192, 193/S, New Industrial Estate, Mirpur, AJ&K on the recommendations of the panel of experts for the following section subject to confirmation of necessary equipment specially FTIR, TOC analyzer, HPLC Stability Chamber etc;

1. Liquid Syrup (General-Vet) Section.

It is submitted that the address of M/s Nutrion (Pvt) Ltd, has been recorded incorrectly as "Plot No. 186, 192, 193/S, New Industrial Estate, Mirpur, AJ&K" whereas the actual address is "Plot No. 186, **187,** 192, 193/S, New Industrial Estate, Mirpur, AJ&K".

In light of powers delegated by CLB in 278th meeting held on December 10-11, 2020, Chairman CLB corrected the address of the firm.

Decision of the Central Licensing Board in 302nd meeting:

The Board considered the case and ratified the correction.

Case No.45 REQUEST FOR WITHDRAWAL OF LICENSED SECTIONS OF M/S SCOTMANN PHARMACEUTICALS, ISLAMABAD.

M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad under DML No.000498 by way of Formulation has submitted request for withdrawal of following licensed sections:

1. Dry Powder Suspension Section (Cephalosporin)
2. Capsule Section (Cephalosporin)

Decision of the Central Licensing Board in 302nd meeting:

The Board approved the withdrawal of following Sections of M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad under DML No.000498 by way of Formulation and decided to notify the Drug Registration Board to take the necessary action;

1. Dry Powder Suspension Section (Cephalosporin)
2. Capsule Section (Cephalosporin)

Case No.46 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 KotLakhpat 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-chargeon 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-chargeto 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-chargeMr. AmjadIkram resigned on March 24, 2022 and the proposed production In-chargecommenced 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, Showcause 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. However, no application is received approval of production In-charge(Plant manager) so for.
4	M/s Citi Pharma (Pvt) Ltd., 3.5-Km Head Balloki Road Phool Nagar Kasur	**Production In-charge** Khurshid Alam	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

	DML No. 000429 (Semi Basic Manufacture)	Duri Aman (B. Pharm)	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-chargecommenced duty on March 2, 2024. We resubmitted an application for approval of the Proposed Production In-chargeon May 3, 2024.
5	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat 000955 Formulation	<u>QC In-charge</u> Shafiullah S/o. Muhammad Atiq (Pharm-D)	The proposed production In-chargewas 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, showcause was issued to the firm, accordingly. The firm's reply to the show cause notice indicated that the earlier QC In-chargehad resigned with only 15 days'

			notice. Due to the short time frame, hiring a new QC In-chargewas challenging. Instead, they assigned additional responsibilities to FazalUlRehman, 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 &RulzPharmceuticals (Pvt), 44-Industrial Triangle, kahuta Ltd, Islamabad. DML No. 000628 (Formulation)	QC In-charge Zia Ur Rehman Zia S/o. Khan Sherin (Msc. 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-chargewas appointment in 01-02-2024, while the previous QC In-chargehas resigned on 25-01-2024 and firm was asked to submit clarification regarding absence of QC In-chargeduring 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	Production In-charge	The proposed qualified person fulfills the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of

	Industrial State, Lahore. DML No. 000869 (Formulation)	Mr. Naveed Ahmad S/o Abdul Majeed (Pharm-D)	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. NaurinaManzar 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-chargeMs. 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-chargeof the firm resigned w.e.f 16-11-2023. The firm promoted Ms. Isma Akhtar as QC In-chargew.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. NusratZaheen 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,	Production In-charge	The firm has previously applied for change in technical staff on 20-08-2024 which was rejected due to the shortage

	Phase III, Hattar Industrial Estate Hattar DML No. 000605 (Formulation)	Saddam Hussian	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.

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 302nd meeting:
The Board deferred the case for detailed deliberation.

Case No.47 INTIMATION NOTICE CONCERNING CONTROL OF ELKO ORGANIZATION (PVT.) LIMITED, KARACHI

BACKGROUND:

FR is received from M/s Elko Organization (Pvt.) Ltd, Karachi wherein they are stated that "I am writing to intimate to you about the management situation of the subject company.
That despite the undersigned being the CEO and Director of the above mentioned company, the undersigned has been ousted from active management and control of the company since January 2022 As the other Director and the undersigned's brother Mr. Shakil Ahmed Chandna in collusion with the distributor of the company Mr. Javed Tahir.

Further, the said director Mr. Shakil Ahmed Chandna has replaced the previous professional employees of the company with his own relatives amongst his in laws despite my opposition in this regard, the undersigned has also started proceedings before the S.E.C.P. (Securities and Exchange Commission of Pakistan) for the redressal of his grievance which have yet not materialized. That the said Mr. Shakil has also tried to falsely Show before certain forums that the undersigned has been present in some management meetings of the company.
That this is false and that the said Mr. Shakil exerts sole and exclusive control over management, all production sales and other matters of the company while the undersigned has no role whatsoever since 2022.
You are thus requested to kindly note the same and for all purposes consider the undersigned to be ousted from the control and management of the company. That the said Mr. Shakil Ahmed Chandna (Director) should deemed exclusively and solely responsible for all the good and bad concerning the subject company including any liabilities howsoever arising from 2022 onwards."

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License Drug Manufacturing License No 000245 by way of formulation of M/s Elko Organization (Pvt.) Ltd, Karachi, may not be suspended or cancelled by Central Licensing Board.

Reply of the Firm:

Application is received from Mr. Shakil Ahmad Chandna, Director of M/s Elko Organization (Pvt.) Ltd, Karachi vide E-app tracking ID No.V9Z-ZQN-GGQ9 dated 22nd October, 2024. This is with reference to the captioned meeting where it was decided to serve show cause under section 41 to the company Elko Organization (Pvt.) Ltd asking as to why Drug Manufacturing License No.000245 may not be suspended or cancelled.

2. I, in the capacity of Director of the company would like to bring to your kind notice that there are some family issues over shareholding of the company that cropped up after demise of our parents against which case in Sindh High Court is pending. To be precise, the complaint has written to you under utter frustration hence, allegation levelled by him could not be relied upon.

3. Further during this dispute settlement period, I may be responsible as management for any violation committed by the company.

4. You are therefore requested not to take any such action against the company.

Decision of the Central Licensing Board in 302nd meeting:

The Board considering the facts that the matter is sub-judice in the High Court of Sindh at Karachi vide Suit No. 577/2023, decided to cease the operation of show Cause Notice under Drug Manufacturing Licence No 000245 (Formulation) of M/s Elko Organization (Pvt.) Ltd, Karachi. The Board decided to direct the firm to update the status of management, once the matter is concluded in the Court.

Case No.48 REQUEST FOR APPROVAL OF LAYOUT PLAN OF DUTASTEROID SOFT GELATIN CAPSULE SECTION

M/s Vision Pharmaceuticals (Pvt) Ltd, Islamabad hold DML (By way of Semi-Basic), vide tracking ID VHB-ZA2-YZLV requested for the approval of the Dutrasteride soft gel layout plan. Dutrasteride soft gel capsules represent a semi-finished product (i.e designed to be used in conjunction with Tamsulosin granules).This section will be considered similar to the Palletization section .

2. Dutrasteride is a 5 alpha-reductase inhibitor indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention and reduce the risk of the need for BPH-related surgery.

3. Also Dutrasteride in combination with the alpha-adrenergic antagonist, Tamsulosin, is indicated for the treatment of symptomatic BPH in men with an enlarged prostate.

4. In Pakistan Dutrasteride soft gelatin capsule is registered as finished dosage form (Cap AVODART 0.5 mg, GSK) and in combination with Tamsulosin (Duodart, GSK). Now M/s Vision

Pharmaceutical (Pvt) Ltd, Islamabad intends to establish Soft Gelatin Capsule section where in firm will manufacture Dutrasteride soft gelatin capsule by way of semi-basic manufacturing in bulk for sale purposes to other manufacturer who has registrations of Dutrasteride in combination with Tamsulosin for final filling and packing in hard gelatin capsule by way of finished formulation.

Decision of the Central Licensing Board in 302nd meeting:

The Board considering the facts on record and after threadbare deliberation decided that the layout for Dutasteride Soft Gel facility for Semi Basic Manufacturing be processed subject to fulfillment of codal formalities with the condition that the manufacturer will only supply bulk Duteride Soft Gel to those pharmaceutical manufacturers having valid Registration of Dutasteride in combination with Tamsulosin**.**

Case No. 49 DELEGATION OF POWERS UNDER RULE 8 (10) OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.

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

Decision by the Central Licensing Board in 273rd meeting

The Central Licensing Board approved and delegated its functions/powers related to Division of Drug Licensing to its Chairman and Secretary under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board as under:

S#.	Powers	Powder to be Delegated to
1.	Issuance of Inspection Book	Secretary CLB
2.	Approval of layout plan and constitution of committee for evaluation of layout plan. (The committee shall be constituted for the purpose of evaluation / assessment and analysis of the layout plan and shall furnish its recommendations accordingly to the Chairman CLB for approval).	Chairman CLB
3.	Approval of change of name/management of a firm for unlicensed units (after the site approval).	Chairman CLB
4.	Constitution / amendments in constitution of panel for inspection for grant/renewal of Drug Manufacturing License, Grant of Additional Sections and Verification / Checking of conditions of License etc of firms.	Chairman CLB
5.	Correction of typographical error in recording of agenda and minutes of the CLB.	Chairman CLB
6.	Approval of Technical Staff	Secretary CLB

7.	Site approval for establishment of pharmaceutical units.	Chairman CLB

The delegation of power accorded in any of the previous meetings shall stand superceeded with immediate effect.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board discussed and deliberated that powers delegated to Director(Licensing) in its 273rd meeting of Central Licensing Board shall be exercised by Additional Director (Licensing) in case of occurrence of vacancy on the post of Director (Licensing) or leave for the period more than ten (10) days.

Proposal:

The powers authorized to Secretary CLB i.e. Issuance of Inspection Book and Approval of Technical Staff may also be authorized to be exercised by the Chairman CLB for smooth execution of the routine work.

Decision of the Central Licensing Board in 302nd meeting:

The Board clarified that power delegated to Secretary CLB can also be exercised by Chairman CLB.

CASE No.1: ***<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 Mension 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 G lobal M/s Caplet Pvt Ltd M-15, D-2. D-3, Ind Area Sonepat - 131001(Hr) India

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 Medicco & 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 Medicco & 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 and found 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.

7. 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

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.

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.

CASE No.2: RAID AT M/S BIOTECH PAKISTAN, HOUSE NO. 233, PHASE-6, KHAYABANE ITEHAD, DHA, KARACHI

Area FID Karachi, submitted that on source information of FIA, Corporate Crime Circle he along with Mr. Abdul Rasool Sheikh, Additional Director, Mrs. Muneeza Khan, Deputy Director, Dr. Asfandyar Ajab Khan, Assistant Director and Abdul Waheed, Assistant Director, DRAP, Karachi and Team of FIA, Corporate Crime Circle, Karachi raided the unlicensed premises situated at House No.233, street No. 32, phase 6, Khayaban-e-Ittethad, DHA, Karachi on 02nd January 2024.

2. During the search of the said premises team recovered huge quantity of unregistered stock of Drugs. The suspected stocks were ordered Not to Dispose off and the unregistered premises was locked and Sealed under section 18(1)(h) of Drugs Act 1976.

3. During the raid on 02.01.2024 at the Illegal/unauthorized godown/premises of M/s Biotech Pakistan at House No 233 Street No 32 Khayaban-e-Ittehad DHA Phase-VI Karachi, FID-III DRAP Karachi duly seized unregistered pharmaceutical products on prescribed Form-2 bearing Serial No. 008, u/section 18(F) of the Drugs Act 1976 and sample of unregistered drugs were taken on form-3 for the purpose of test analysis.

4. Detail of Drug seized on prescribed Form-2 and sample taken for test/analysis purpose is as under:

S. No.	Name of Drug	Quantity	Batch No.	Mfg. Date	Exp. Date	Purported to be Mfg. By
1	Aerrane (Isoflurane 100% USP)	1×250ml×6×360cartons	N004A313	01/2023	12/2027	M/s Baxter Healthcare Corporation, Route 3, Km 144.2, guayama, Puetro Rico, USA.
2	Seroflurane USP	1×250ml×6×6cartons	A004A315	11/2022	10/2025	-do-
3	Suprane (Desflurane USP)	1×240ml×6×7cartons	H096H126	08/2021	09/2024	-do-

5. FID concluded that following accused persons violating section 23(1)(a)(vi), 23(1)(a) (vii), 23(1)(a)(x), 23(1)(e) and 23(1)(I) of the Drugs Act 1976, punishable under section 27 of the Drug Act 1976. Complete case detail was forwarded to Director QA & LT, DRAP, Islamabad vide this office of even number dated 02nd January 2024.

6. That Director Quality Assurance & Lab Testing, DRAP, Islamabad vide his e-office permission No.F.02-01/2024-FID-III dated 03rd January 2024 communicated the approval of FIR with the request to lodge FIR against following accused persons.

i. M/s Biotech Pakistan, as a legal person through its sole-proprietor Kashif Latif S/o Muhammad Latif Ur Rehman, House No.233, street No. 32, phase 6, Khayaban-e-Ittethad, DHA, Karachi. (Un-Authorize Importer).
ii. Mr. Kashif Latif s/o Muhammad Latif ur Rehman, CNIC No. 42101-1727422-7 owner of M/s. Blotech Pakistan, House No.233, street No. 32, phase 6, Khayaban-e- Ittethod, DHA, Karachi. (Main accused)
iii. Qazi Farhan Jamal s/o Qazi Jamal Ahmed, CNIC No. 42501-0431676-9 Manager of M/s. Biotech Pakistan House No.233, street No. 32, phase 6, Khayaban-e-Ittethad, DHA, Karachi. (Co-accused)

7. I/O FIA Assistant Director CCC Karachi submitted complete challan/final investigation report in case FIR No. 01/2024 vide letter No. FIA/CCC/C-01-2024/FCS/2024/8678-79 dated 5th August, 2024, to area FID, regarding illegal import & sale of un-registered drugs and medical devices by M/s Biotech Pakistan, Karachi. As per challan, the record of sale of un-registered pharmaceutical products namely Isoflurane & Sevoflurane by Biotech Pakistan, as well as recovery of Delivery Challans in respect of these drugs, constitute an offence u/section 23,27 R/w 30 Drugs Act 1976 and nominated the following accused

i. Mr. Kashif Latif s/o Muhammad Latif ur Rehman, CNIC No. 42101-1727422-7 owner of M/s. Biotech Pakistan, House No.233, street No. 32, phase 6, Khayaban-e- Ittethod, DHA, Karachi. (Main accused)
ii. Qazi Farhan Jamal s/o Qazi Jamal Ahmed, Manager of M/s. Biotech Pakistan House No.233, street No. 32, phase 6, Khayaban-e-Ittethad, DHA, Karachi. (Co-accused)
iii. M/s Biotech Pakistan, House No.233, street No. 32, phase 6, Khayaban-e-Ittethad, DHA, Karachi. (Un-Authorize Importer).

8. Division of QA&LT issued Show cause notice vide letter no. 04-43/2024-ADQC-V dated 12th September 2024 to the accused.

9. M/s Biotech Pakistan submitted reply of show cause notice vide their letter No. Nil dated 25th September, 2024 wherein, *firm denied all allegations as all the seized medical drugs and medical devices were imported after fulfilling all the codal formalities.*
They further submitted that Islamabad Medical and Surgical Hospital was issued NOC dated 08-06-2023 by DRAP. M/s Biotech was allowed to import the same for said hospital pursuant to SRO 134(1)/2021 dated 02nd February 2021, due to non-availability of the same in the market. They quoted reference of clearance certificate bearing number F.5-5/2022 dated 26th June 2023 but has not attached any such certificate.
They mentioned that pursuant to SRO 224(1)/2023 different classes of medical devices were exempted from enlistment and registration requirements for a certain period of time. Therefore, medical devices imported by firm falls within exemptions pursuant to section 36 of Drugs act 1976.
Firm explained that they have Drug Licenses and License to import medical devices (Form-4) and because of controlled temperature storage conditions they kept the same at House No.233, St No.

32, Phase VI, DHA, Karachi as devices & drugs were not stored at approved address (as on DSL & Form-4).

10. At the time of raid on 02-01-2024, the complainant Dr Shoaib Ahmed, FID-III, DRAP Karachi further ordered not to dispose of the stock u/section 18(1) (i) of the Drugs Act 1976 on prescribed Form-I bearing serial No. 127 and serial No. 128, requiring not to dispose of the stock of drugs from the premises House No 233 Street No 32 Khayaban-e- Ittehad DHA Phase-VI Karachi. The stock includes medical devices and matter was taken up by MDB. A show cause notice from Division of MDMC, DRAP, Islamabad for importing expired & un-registered Class-C & D medical devices was also issued to the firm.

11. Status of registration of said drugs as per confirmation from PER Division, is as follow:

Drug	**Registration Status**
Aerrane (Isoflurane 100% USP)	Not Registered from M/s Baxter, USA.
Sevoflurane USP	Not Registered from M/s Baxter, USA at time of raid
Suprane (Desflurane USP)	Not Registered

12. Division of QA&LT issued a notice of personal hearing vide letter No F.03-44/2024-QALT (302-CLB) dated 13th November, 2024 under Section 41 of the Drug Act 1976, to nominated accused for violating section 23(1)(a)(vi), 23(1)(a) (vii), 23(1)(a)(x), 23(1)(e) and 23(1)(I) of the Drugs Act 1976, punishable under section 27 of the Drug Act 1976.

i. M/s Biotech Pakistan, as a legal person through its sole-proprietor Kashif Latif S/o Muhammad Latif Ur Rehman, House No.233, street No. 32, phase 6, Khayaban-e-Ittethad, DHA, Karachi. (Un-Authorize Importer).
ii. Mr. Kashif Latif s/o Muhammad Latif ur Rehman, CNIC No. 42101-1727422-7 owner of M/s. Blotech Pakistan, House No.233, street No. 32, phase 6, Khayaban-e- Ittethod, DHA, Karachi. (Main accused)
iii. Qazi Farhan Jamal s/o Qazi Jamal Ahmed, CNIC No. 42501-0431676-9 Manager of M/s. Biotech Pakistan House No.233, street No. 32, phase 6, Khayaban-e-Ittethad, DHA, Karachi. (Co-accused)

Proceeding and Decision of 302nd Meeting of CLB

Qazi Farhan Jamal S/o Qazi Jamal Ahmed, Accountant, M/s Biotech Pakistan, Karachi appeared before Central Licensing Board in its 302nd meeting held on 20th November 2024 and explained that their case is already under process in Drug Court Sindh, Karachi. On query, he added that the subject case is related to bail of the accused persons. He is an employee of firm and working as "Accountant" and not aware about the technical matters. The Board inquired about Mr. Kashif Latif s/o Muhammad Latif ur Rehman, CNIC No. 42101-1727422-7, owner of M/s. Biotech Pakistan,. Qazi Farhan inform that he is not available due to his personal reasons.

The Board, after deliberation and keeping in view statement of accused person Qazi Farhan Jamal S/o Qazi Jamal Ahmed, Accountant decided to grant permission for prosecution to FID for following accused.

i. M/s Biotech Pakistan, as a legal person through its sole-proprietor Kashif Latif S/o Muhammad Latif Ur Rehman, House No.233, street No. 32, phase 6, Khayaban-e-Ittethad, DHA, Karachi. (Un-Authorize Importer).

ii. Mr. Kashif Latif s/o Muhammad Latif ur Rehman, CNIC No. 42101-1727422-7 owner of M/s. Blotech Pakistan, House No.233, street No. 32, phase 6, Khayaban-e- Ittethod, DHA, Karachi. (Main accused)

iii. Qazi Farhan Jamal s/o Qazi Jamal Ahmed, CNIC No. 42501-0431676-9 Manager of M/s. Biotech Pakistan House No.233, street No. 32, phase 6, Khayaban-e-Ittethad, DHA, Karachi. (Co-accused)

CASE NO 3. INSPECTION OF M/S BATALA PHARMACEUTICALS, GUJRANWALA.

The inspection of M/s Batala Pharmaceuticals, 23/B, Small Industrial Estate, Near Wapda Town, Khiali Bypass Gujranwala conducted on 1st & 2nd July 2024 by a panel in compliance to this office letter dated 28.06.2024.

The panel has reported 03 Critical deficiencies pertaining to the HVAC, Control of Contamination & Cross Contamination and Validation & Qualification respectively. Furthermore, the panel has rated 11 deficiencies as Major pertaining to various aspects of Pharmaceutical Quality System, Premises, Utilities, Practices in Production and Quality Control of Materials.
The panel has concluded that:

> *" The inspection was conducted for the evaluation of overall cGMP. Based on the findings of the inspection, review of documents and records, systems, utilities, physical inspection of areas in the manufacturing facility mentioned above, and interview of personnel, it is concluded that the firm is not operating at an acceptable level of cGMP compliance. Several critical and major deficiencies were observed related to the risk of contamination and cross contamination, product quality, data integrity, qualification of processes, personnel, equipment, and overall facility"*

The panel has made the following recommendations:

"Based on the observations and findings detailed above, the inspection team recommends the following:

1. *To stop all manufacturing activities in the general tablet and capsule sections facility till the up-gradation and validation of facility, processes, systems, utilities and controls.*
2. *Suspension of drug manufacturing license of Cream/Ointment Section*
3. *Sampling and testing of already manufactured and marketed products.*

"

The matter was placed before the competent Authority i.e. Director QA&LT DRAP Islamabad, who considered the facts and ordered the Suspension of production activities in Tablet (General), Capsule (General) and Cream/Ointment Sections with immediate effect vide letterNo.F.4-16/2001-QA dated 24-07-2024.

Ms. Batala Pharmaceuticals submitted compliance report vide Ref No.BP-03528/2024 dated 06-08-2024. The response was evaluated and was found deficient as all observations of report were neither addressed, nor root cause analysis have been performed along with CAPA. Firm has directed to submit detailed CAPA vide office letter of even numbers dated 23-08-2024.

M/s Batala Pharmaceuticals, Gujranwala has submitted detailed CAPA covering all the aspects. In view of CAPA, Director QA&LT has constituted a 3 members panel for the verification of CAPA (as authorized by CLB in its 273rd meeting) dated 12-09-2024.

Panel submitted the report of inspection which was focused on verification of the improvements made by the firm with reference to the CAPA report dated 03-9-2024 submitted by the firm to the QA&LT Division, DRAP, Islamabad. Panel concluded that:-

"The inspection was conducted on 16,18-09-2024 for verification of the improvements made by the firm with reference to the CAPA report dated 03-9-2024 submitted by the firm to the QA&LT Division, DRAP, Islamabad.

Based on the findings of the inspection, review of documents and records, systems, utilities, physical inspection of areas in the manufacturing facility and quality control laboratory mentioned above, and interview of personnel, it is concluded that

> *"The firm has made improvements and rectified many of the shortcomings in the facility. However, remaining deficiencies still need active rectifications like the microbiology laboratory, HVAC system re-qualification and fluidized bed dryers for which the firm was advised to submit compliance report to the Competent Authority."*

Based on the observations and findings detailed above, the inspection team recommends the following actions:

1. Production may be resumed in the Capsule (General) Section.
2. Production may remain suspended in the Tablet (General) Section till submission of compliance to the following:
3. Re-qualification of HVAC system;
4. Re-qualification of both Fluidized Bed Dryers after replacement of the drying trolleys and provision of purified air coming in contact with the product.
5. The production activities in the Cream/Ointment Section may remain suspended till the commissioning and qualification of the facility as no commercial batch has been manufactured in this section since the grant of drug manufacturing license.

Subsequently, firm submitted their response and explained regarding Fluid bed dryer:

1. 03 filters are installed already before heating system for purification of air supply i.e. pre filter, bag filter and HEPA filter.
2. New heating burner system installed.
3. After heating system installed mesh filter along with Pre filter for clean air to product.
4. Further we have installed FBD trolley mesh filter
5. Termite has been removed as treatment by termite specialist company, certificate is attached.

Firm has also submitted performance qualification documents of HVAC. During evaluation of documents, it has been noted that firm has submitted pictorial evidence of Fluid bed dryer filters, heating burner system, certificate of termite treatment and records of qualification of HVAC in different sections. However, detail of AHUs like total no. of AHUs available in the premises and their supply to the specific areas were not provided. In light of the DRAP's panel report and CAPA documents submitted by the firm. It is decided that:

i. Resumption of Production in the Capsule (General) and Tablet (General) Sections.
ii. Cream/Ointment Section will remain suspended till the qualification of the manufacturing facility as no commercial batch has been manufactured in this section since the grant of drug manufacturing license.
iii. DRAP's panel will conduct inspection within two months of active production to access the cGMP status along with verification of compliance report submitted by the firm including

qualification of HVAC system, fluidized bed dryer and water system, provision of HEPA filter in AHUs to prevent cross-contamination etc.

The resumption of production letter (capsule section {general}, tablet section {general}) was issued on 28-10-2024.

Case is placed before Board in the light of decision of 273rd meeting of CLB i.e.

"[…] 4. Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members. Where the panel is constituted by the Director (QA&LT). However, the cases shall be placed before the CLB for information."

Proceeding and Decision of 302nd Meeting of CLB

The Board noted the information regarding resumption of production of Batala Pharmaceuticals, 23/B, Small Industrial Estate, Near Wapda Town, Khiali Bypass Gujranwala in the following sections:

i. Capsule Section (general)
ii. Tablet Section (general)

Case No 4. DELEGATION OF FUNCTIONS / POWERS RELATED TO THE DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING.

The Central Licensing Board in its 273rd meeting delegated its powers retrospectively with certain modifications to Director Quality Assurance and Laboratory Testing under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board.

S. No.	Functions / Powers	Function / Power Delegated to
1.	Issuance of Show Cause Notice regarding contravention of any of the provision of DRAP Act, 2012 and rules framed there under (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
2.	Advisory letters, explanation letters or any other action as deems fit for the purpose of improvement (in case of GMP matters)	Director Quality Assurance and Laboratory Testing
3.	Suspension of Production (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
4	Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members. Where the panel is constituted by the Director (QA&LT). However the cases shall be placed before the CLB for information.	Director Quality Assurance and Laboratory Testing
5.	Permission to Lodge FIR	Director Quality Assurance and Laboratory Testing
6.	Panel Constitution (GMP Inspection and related issues etc)	Director Quality Assurance and Laboratory Testing

7.	Constitution / amendments in constitution of panel for inspection for GMP compliance and quality control matters.	Director Quality Assurance and Laboratory Testing
8.	To continue the period of "not to dispose-of stocks orders passed by FID" for three months or till the finalization of the case (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
9.	To continue custody of the seized stocks by the FID till decision of the case (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
10.	To grant approval for sending Board's portion of drug samples to the Appellate Laboratory (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
11.	Grant of extension in the time of testing to Federal Government Analyst (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
12.	Issuance of Show Cause Notices/Personal hearing letters/Circulars/Communication of Minutes/Decisions/Directions of the Board to the Concerned quarters regarding GMP and Quality Control matters on behalf of Secretary Board. The letter shall be issued with Name & Designation of the officer.	Assistant Director (QA&LT) / Deputy Director (QA&LT)

At S. No. 04; Resumption of Production is subject to re-inspection and recommendation of a panel comprising at least 3 members. Where the panel is constituted by the Director (QA&LT).

Director, QA&LT has observed that inspections were delayed due to insufficient HR. It is, therefore proposed that panel for resumption of production may be comprises of two members.
Submitted for the consideration of the Central Licensing Board.

Proceeding and Decision of 302nd Meeting of CLB

The Board after deliberation and keeping in view insufficient human resource at present, decided to accede proposal of QA&LT Division for reinspection of the firm with two panel members, to verify CAPA / rectification status of the observation noted during last inspection, for resumption of production activities.