DRAFT MINUTES OF 290th MEETING OF CENTRAL LICENSING BOARD HELD ON 28th April, 2023

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290th meeting of the Central Licensing Board (CLB) was held on 28th April, 2023 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Dr. Obaidullah, Director (Licensing), Drug Regulatory Authority of Pakistan, Islamabad Chaired the meeting. Following members attended the meeting: -

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

Mr. Nadeem Alamgir (Pharma Bureau), Mr. Adnan Hirani & Mr. Amanullah Shaikh (PPMA) and Mr. Kamran Anwar (PCDA) attended the meeting as observers

The meeting started with the recitation of Holy verses.

Mrs. Ume Laila Additional. Director / Secretary Licensing Board presented the agenda before the Board. Mr. Mubashir Iqbal Deputy Director (Lic), Ms. Zunaira Faryad, AD (Lic), Mr. Hasan Afzal, Deputy Director (QA) DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 289TH MEETING**

289th meeting of Central Licensing Board was held on 23rd January, 2023. Accordingly, draft minutes of 289th meeting of Central Licensing Board were circulated among members on 17-02-2023 through WhatsApp and email for perusal and comments (if any). All members consented the draft minutes through WhatsApp/email and after approval of Chairman CLB, fair minutes were circulated among relevant Divisions / Sections for implementation / compliance of decisions.

The Central Licensing Board (CLB) formally confirmed the minutes of 289th meeting of the Central Licensing Board (CLB).

The CLB discussed that grant, renewal of drug Manufacturing Licenses and additional sections of already licensed manufacturing units are based on availability of requisite manufacturing, quality control and quality assurance facilities. These facilities are verified during panel inspections conducted specifically for aforementioned purposes. The Board observed that some inspection reports do not have details for availability of necessary equipment required for testing of drug substances and relevant products like HPLC, FTIR (required for pharmacopeial identification testing of most of drug substances), product stability chambers (for real time and accelerated stability testing), Liquid Particle Counter and Total Organic Carbon Analyzer (for parenteral products) etc. The Board after thorough deliberation decided as follows:

a. To process cases where inspection reports confirm availability of above mentioned equipment.
b. To process cases where above mentioned equipment have not been endorsed in panel inspection reports, upon submission of purchase documents along with Installation Qualification and Operational qualification reports, of these equipment by the manufacturer / applicant. Such facilities will be subsequently verified / confirmed by any inspection (GMP/Panel) and will be reported and informed to Licensing Division accordingly.
c. To issue instructions that in future all panel inspections (grant of DML/renewal of DML/additional section) need to specifically mention availability of above mentioned and other necessary equipment required for testing of drug substances and relevant products / dosage form (product monograph / general chapter in pharmacopeia) intended to be manufactured in the facility for consideration of CLB.

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 M.A. Kamil Farma (Pvt) Ltd., Plot No.H-17, S.I.T.E., Super Highway, Phase-II, Karachi.	**15-03-2023**	**Good**	1. Additional Director (E&M), DRAP, Karachi. 2. Area Federal Inspector of Drugs, DRAP, Karachi. 3. Assistant Director, DRAP, Karachi.

Recommendations of the panel:

"M/s M.A. Kamil Farma (Pvt) Ltd., situated at Plot No.H-17, S.I.T.E., Super Highway, Phase-II, Karachi was visited and inspected in detail on 15th March, 2023 in compliance to the directions contained in DRAP, Islamabad letters No.F.2-3/2018-Lic dated 13th March 2023, for the grant of DML (formulation) applied by them. The panel inspected all the manufacturing sections, stores and QC Lab and found the facility built as per approved lay out plan. The facility has been provided with necessary documents relating to QC, QA and installation qualification of machines, HVAC and other utilities were also verified under the scope and noted an appropriate level of compliance.

Based on the people met, documents reviewed, facilities built & utilities provided, the panel unanimously recommends the grant of Drug Manufacturing License by way of Formulation to the firm for the following sections:

S.No.	Name of Section
01.	Oral Liquid (General) – Veterinary - I
02.	Oral Liquid (General) – Veterinary - II
03.	Oral Powder (Jar Packing) (General) - Veterinary
04.	Oral Powder (Sachet) (General) – Veterinary
05.	Oral Powder (Penicillin) - Veterinary

Decision of the Central Licensing Board in 290th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s M.A. Kamil Farma (Pvt) Ltd., Plot No.H-17, S.I.T.E., Super Highway, Phase-II, Karachi on the recommendations of the panel of experts for the following sections.

1. Oral Liquid (General) – Veterinary - I
2. Oral Liquid (General) – Veterinary - II
3. Oral Powder (Jar Packing) (General) - Veterinary
4. Oral Powder (Sachet) (General) – Veterinary
5. Oral Powder (Penicillin) - Veterinary

2.	M/s Albarkat Pharmaceuticals Industries, Plot No.B-66A, S.I.T.E., Noori Abad, Jamshoro	**12-04-2023**	**Good**	1. Additional Director (E&M), DRAP, Karachi. 2. Area Federal Inspector of Drugs, DRAP, Karachi. 3. Assistant Director, DRAP, Karachi.

Recommendations of the panel:

"The panel inspected the premises of M/s Albarkat Pharmaceuticals Industries, Plot No. B-66A, S.I.T.E., Noori Abad, Jamshoro, Sindh, in compliance of DRAP Islamabad Letter No.F.2-7/2017-Lic dated 06th March, 2023 and recommends as follows:
Based on the people met, areas visited and commitment of management for continuous improvement and up-gradation. The panel of the view to recommend the grant of Drug Manufacturing License (By way of Formulation to the firm M/s Albarkat Pharmaceuticals Industries for following Sections namely:

Eye Ointment (General)	Eye/Ear Drops (General)
Liquid Injectable Vial SVP (General)	Liquid Ampoule (General)

Decision of the Central Licensing Board in 290th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Albarkat Pharmaceuticals Industries, Plot No. B-66A, S.I.T.E., Noori Abad, Jamshoro on the recommendations of the panel of experts for the following sections.

1. Eye Ointment (General)
2. Eye/Ear Drops (General)
3. Liquid Injectable Vial SVP (General)
4. Liquid Ampoule (General)

3.	M/s Amazon Pharmaceutical (Pvt) Ltd, Plot No. 10/A, and 29/B, Small Industrial Estate, Bhimber, AJK.	**26-01-2023**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Mr. Abdullah, Deputy Director, Controlled Drugs DRAP, Islamabad. 3. Mr. Fahad Nadeem, Deputy Director, QA/LT DRAP, Islamabad.

"The firm has maintained SOPs for internal audit and to handle the market complaints. They are concerned with the training of the employees; procedures for waste management are defined. It is advised to strengthen the QA to meet the requirements of existing sections and devise a mechanism for approval of SOPs through MR. Keeping in view the facts observed during inspection, the panel (constituted vide letter No.F.5-1/2019-Lic dated 18-01-2023) unanimously recommends grant of DML by way of (Formulation) (Vet) to **M/s Amazon Pharmaceutical (Pvt) Ltd, Plot No. 10/A, and 29/B, Small Industial Estate, Bhimber, AJK,** with following sections: -

Approved section as per layout plan.	Sections as per inspection report.
1. Bulk Powder Section-I Vet. (General). 2. Bulk Powder Section-II Vet. (General).	1. Oral Dry Powder-I (General) (Vet). 2. Oral Dry Powder-II (General) Vet. 3. Oral Liquid-I (General) Vet.

	3. Spray Section Vet. (General). 4. Liquid Section-I Vet. (General). 5. Liquid Section-II Vet. (General). 6. Liquid Injection Section Vet. (General). 7. Liquid Injectable Section Vet (Steroid). 8. Liquid Injectable Penicillin (Vet). 9. Dry Powder Injectable Penicillin (Vet). 10. Bulk Powder Penicillin Section (Vet). 11. Quality Control Lab. & Microbiology. 12. Stores (General) (Vet). 13. Store (Penicillin) (Vet).			4. Oral Liquid-II (General) Vet. 5. Liquid Injectable (General) Vet. 6. Spray (General) Vet. 7. Liquid Injectable (Steroid) Vet. 8. Dry Powder Injectable (Penicillin) Vet. 9. Oral Powder (Penicillin) Vet. 10. Liquid Injectable (Penicillin) Vet. 11. Stores (General) Vet. 12. Quality Control Laboratory (Vet). 13. Microbiology Laboratory General (Vet).
	<u>Decision of the Central Licensing Board in 290th meeting:</u> The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Amazon Pharmaceutical (Pvt) Ltd, Plot No. 10/A, and 29/B, Small Industrial Estate, Bhimber, AJK on the recommendations of the panel of experts for the following sections subject to submission of application along with prescribed fee for approval of change in nomenclature of Bulk Powder Section-I, Bulk Powder Section-II, Spray sections. 1. Bulk Powder Section-I Vet. (General). 2. Bulk Powder Section-II Vet. (General). 3. Spray Section Vet. (General). 4. Liquid Section-I Vet. (General). 5. Liquid Section-II Vet. (General). 6. Liquid Injection Section Vet. (General). 7. Liquid Injectable Section Vet (Steroid). 8. Liquid Injectable Penicillin (Vet). 9. Dry Powder Injectable Penicillin (Vet). 10. Bulk Powder Penicillin Section (Vet). 11. Quality Control Lab. & Microbiology. 12. Stores (General) (Vet). 13. Store (Penicillin) (Vet).			
4	M/s Poulvet Pharmaceuticals (Pvt) Ltd, 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan **<u>Sections (03):</u>** i. Oral Powder (General) I. (Veterinary) ii. Oral Powder (General) II. (Veterinary)	17-03-2023	Good	1. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, , FID, DRAP, Lahore. 3. Ishtiaq Shafiq, AD, DRAP, Lahore.

	iii. Oral Liquid / Drench (General) (Veterinary)			
	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 recommend the grant of Drug Manufacturing License (by way of formulation) (Veterinary) to M/s Poulvet Pharmaceutical (Pvt) Ltd, 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan for the following three sections." i. Oral Powder (General) I. (Veterinary) ii. Oral Powder (General) II. (Veterinary) iii. Oral Liquid / Drench (General) (Veterinary) **Decision of the Central Licensing Board in 290th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Poulvet Pharmaceuticals (Pvt) Ltd, 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan on the recommendations of the panel of experts for the following sections. i. Oral Powder (General) I. (Veterinary) ii. Oral Powder (General) II. (Veterinary) iii. Oral Liquid / Drench (General) (Veterinary).			
5	M/s. Skywin Pharmaceutical, Plot No. 01, Al-Badar Industrial Estate, Phase II, 18-Km, Sheikhupura Road, Lahore **Sections (11):** i. Dry Powder Suspension (Penicillin) ii. Dry Powder Injection (Penicillin) iii. Tablet Section (Penicillin) iv. Capsule Section (Penicillin) v. Tablet Section (Hormone) vi. Liquid Injection Ampoule (Hormone) vii. Dry Powder Suspension Section (General)	22-03-2023	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, AD, DRAP, Lahore.

viii. Sachet Section (General) ix. Tablet Section (General) x. Capsule Section (General) xi. Liquid Vial Section (General)				

Recommendations of the panel:

"Based on the areas inspected, the personnel interacted with, discussion held during inspection, the documents reviewed and considering the findings of the inspection, the panel recommend the grant of Drug Manufacturing License to M/s. Skywin Pharmaceutical, Plot No. 01, Al-Badar Industrial Estate, Phase II, 18-Km, Sheikhupura Road, Lahore, for the following 11 sections namely:

i. Dry Powder Suspension (Penicillin)
ii. Dry Powder Injection (Penicillin)
iii. Tablet Section (Penicillin)
iv. Capsule Section (Penicillin)
v. Tablet Section (Hormone)
vi. Liquid Injection Ampoule (Hormone)
vii. Dry Powder Suspension Section (General)
viii. Sachet Section (General)
ix. Tablet Section (General)
x. Capsule Section (General)
xi. Liquid Vial Section (General)

Decision of the Central Licensing Board in 290th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s. Skywin Pharmaceutical, Plot No. 01, Al-Badar Industrial Estate, Phase II, 18-Km, Sheikhupura Road on the recommendations of the panel of experts for the following sections.

1. Dry Powder Suspension (Penicillin)
2. Dry Powder Injection (Penicillin)
3. Tablet Section (Penicillin)
4. Capsule Section (Penicillin)
5. Dry Powder Suspension Section (General)
6. Sachet Section (General)
7. Tablet Section (General)
8. Capsule Section (General).

Furthermore, the Central Licensing Board deferred 3 sections due to following reasons:

a. Tablet Section (Hormone) and Liquid Injection Ampoule (Hormone) for confirmation whether steroidal or non-steroidal.
b. Liquid Vial Section (General) for confirmation whether SVP or LVP with supporting documents..

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 Mafins Pharma, Plot No. A-5, S.I.T.E., Super Highway Industrial Area, Karachi **Sections (07):** 1. Sterile Dry Powder Injection (General) 2. Sterile Ampoule & Vial Injection (Steroid) 3. Sterile Liquid Vial Injection (General) 4. Sterile Liquid Ampoule Injection (General) 5. Dry Powder Syrup (Cephalosporin) Section 6. Sterile Dry Powder Injectable (Cephalosporin) 7. Capsule (Cephalosporin) 8. Sterile Eye & Ear Drops	08-02-2023	Good	1. Mr. Muhammad Salik Zahid, Chief Drug Inspector, Balochistan. 2. Area FID, DRAP, Karachi. 3. Assistant Director, DRAP, Karachi
	Recommendations of the panel: "*M/s Mafins Pharma, Plot No. A-5, S.I.T.E., Super Highway Industrial Area, Karachi was inspected as per directions contained in DRAP Islamabad letter No.F.2-10/2009-Lic (Vol-I) dated 30th December, 2022 on 08-02-2023.Durin the inspection, panel thoroughly inspected their newly developed production areas given at first floor, QC Lab, Stores, Utilities and reviewed several control documents. The Panel met their technical personnel in respective areas as well to know their expertise, trainings and job responsibilities. The panel reviewed QA documents during the inspection. In all the sections the panel noticed substantial GMP compliance level and based on their current level of compliance the panel unanimously* ***recommends*** *the grant of following additional sections & regularization of their Sterility room of Microbiology Lab under their DML No.00820 By way of Formulation: -*			

	i. *Sterile Dry Powder Injection (General)* ii. *Sterile Ampoule & Vial Injection (Steroid)* iii. *Sterile Liquid Vial Injection (General)* iv. *Sterile Liquid Ampoule Injection (General)* v. *Dry Powder Syrup (Cephalosporin) Section* vi. *Sterile Dry Powder Injectable (Cephalosporin)* vii. *Capsule (Cephalosporin)* viii. *Sterile Eye & Ear Drops* Note: As per available record of the Division of licensing the word "*sterile"* was not mentioned in the layout approval letter and the panel inspection letter for the first four sections of the firm and the new nomenclature was used by the panel in its report. **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of following additional sections in the name of M/s Mafins Pharma, Plot No. A-5, S.I.T.E., Super Highway Industrial Area, Karachi under DML No. 000820 (Formulation) on the recommendations of the panel of experts: i. Dry Powder Injection (General) Section **New** in place of Ampoule and Vial Injection (Steroid) **unlicensed Section.** ii. Ampoule & Vial Injection (Steroid) **New** in place of Ampoule and Vial Injection (Psychotropic) **unlicensed section.** iii. Liquid Vial Injection (General) iv. Liquid Ampoule Injection (General) v. Dry Syrup (Cephalosporin) Section vi. Dry Powder Injectable (Cephalosporin) vii. Capsule (Cephalosporin) viii. Eye & Ear Drops Section.			
2	M/s Scilife Pharma (Pvt) Ltd., FD-57/58-A-2, Korangi Creek Industrial Park (KCIP), Karachi **Sections (05):** 1. Tablet (General) - Revised 2. Capsule (General) - Revised. 3. Raw Material Store (General) – Revised 4. Sachet (General) – Revised 5. Dry Powder Suspension (General) – Revised.	14-04-2023	Good	1. Additional Director, DRAP, Karachi. 2. Mr. Ghulam Ali Lakho, CDI, Karachi. 3. Area FID, DRAP, Karachi.

	Recommendations of the panel: *"M/s Scilife Pharma (Pvt) Ltd., FD-57/58-A-2, Korangi Creek Industrial Park was visited and inspected on 14th April 2023, in compliance to the direction contained in DRAP Islamabad Letter No.F.2-4/2011-Lic (Vol-I) dated 30th March 2023 in connection with the Grant of Amendments in certain Sections as per revised approved design. The amendments mentioned above have been made as per revised layout plan approved by DRAP authorities Islamabad vide DRAP letter No.F.2-4/11-Lic (Vol-I) Dated 30th March 2023 (Copy enclosed).* *During an opening meeting their previous layout plan and revised approved design were discussed at length in connection to the amendments, made in their manufacturing sections for better compliance. Change Control was noted taken as per approved SOPs in place and planned deviations opted during these amendments were also carried out as per SOPs in place. Documents relating to de-commissioning & re-commissioning of certain equipment like Sachet filling machine, DP filling machines were also reviewed in detail during the opening meeting. After these changes the firm will have now better, spacious and compliant production and dispensing areas. Necessary utilities like HVAC, Compressed air & Purified water have also satisfactorily been relocated at the amended ends. Necessary documents relating to QC, QA, ad installation qualification of machines, HVAC and other utilities were also verified under the scope and found satisfactory.* *Based on the above stated facts the panel unanimously **recommends** the grant of Amendments in Section as described above in their revised approved layout plan under DMLNo.000837 may be regularized for better regulatory compliance."* **Note:** It is pertinent to mention that in the panel letter five sections were mentioned for inspection however in inspection report the panel has recommended one extra section i.e. Cream/Ointment section (General) in its report. **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of following Revised sections and in the name of M/s Scilife Pharma (Pvt) Ltd., FD-57/58-A-2, Korangi Creek Industrial Park (KCIP), Karachi under DML No. 000837 (Formulation) on the recommendations of the panel of experts for following sections. 1. Tablet (General) - Revised 2. Capsule (General) - Revised. 3. Raw Material Store (General) – Revised 4. Sachet (General) – Revised 5. Dry Powder Suspension (General) – Revised. Furthermore, the Board observed that the panel in its inspection report has mentioned an extra section i.e. Cream / Ointment Section (General) which has not been approved by CLB, thus the Board directed the firm to submit application as per SOP for grant of any other section if required.			
3	M/s. Gray's Pharmaceuticals, Plot No.	27-02-2023	Good	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.

	2, Street No. N-3, National Industrial, Zone, Rawat. DML No.000518 (Formulation). **Section (01):** i. Dry Powder for Suspension (General) Section in place of Tablet (Psychotropic) Section.			2. Mr. Adil Saeed, Deputy Director (PE&R), DRAP, Islamabad. 3. Mr. Muhammad Yaqoob, Assistant Director Lic, DRAP, Islamabad.
	Recommendations of the panel: - Keeping in view the facts observed during inspection, the panel unanimously recommends grant of following additional section in place of Tablet (Psychotropic) Section to M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone, Rawat (DML No.000518): i. Dry Powder for Suspension (General) Section. **Decision of the Central Licensing Board in 290th meeting** The Board considered and approved the grant of following additional section in the name of M/s. Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial, Zone, Rawat under DML No. 000518 (Formulation) on the recommendations of the panel of experts for following section. i. Dry Powder for Suspension (General) Section in place of Tablet (Psychotropic) Section.			
4.	M/s Searle IV Solutions (Pvt) Ltd, 1.5-Km, Manga Raiwind Road, Manga Mandi, District Lahore. DML No. 000586 (Formulation) **Section (01):** i. Liquid Injectable Vial SVP-II (General).	24-01-2023	Good -	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Dr. Zaka ur Rehman, COO, PDTRC, Lahore 3. Ms. Mehwish Jamil, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "In light of inspection conducted by the panel and based on the findings, the panel of inspectors **recommends** the grant of following Additional Section under Drug Manufacturing License bearing No. 000586 issued in favor of M/S Searle Iv Solutions (Pvt) Ltd, 1.5-Km, Manga Raiwind Road, Manga Mandi, District Lahore: - i. Liquid Injectable Vial SVP-II (General). **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of following additional section in the name of M/S Searle Iv Solutions (Pvt) Ltd, 1.5-Km, Manga Raiwind Road, Manga Mandi, District			

	Lahore under DML No. 000586 (Formulation) on the recommendations of the panel of experts for following section. i. Liquid Injectable Glass Vial SVP-II (General).			
5.	M/s Moreno Iglisias Research Laboratory (Pvt) Ltd, 21-Km, Ferozepur Road, Lahore. DML No. 000478 (Formulation)	20-01-2023	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Dr. Syed Zia Husnain, FID, DRAP, Lahore 3. Ms. Anam Saeed, Assistant Director, DRAP, Lahore
	Recommendations of the panel: "Firm has been inspected by the panel comprehensively and evaluated various documents revealed by the firm management regarding Quality Assurance, Quality Control and Production operations. Diverse technical aspects were also deliberated with firm management at length. Based on the physical inspection of the unit, evaluation of the documents revealed by the firm management and discussion with technical staff, panel was of the opinion to **recommend** grant of following additional section to M/s Moreno Iglisias Research Laboratory (Pvt) Ltd, 21-Km, Ferozepur Road, Lahore." i. Liquid Injectable Section (General) (Veterinary) **Decision of the Central Licensing Board in 290th meeting** The Board considered and approved the grant of following additional section in the name of M/s Moreno Iglisias Research Laboratory (Pvt) Ltd, 21-Km, Ferozepur Road, Lahore. under DML No. 000478 (Formulation) on the recommendations of the panel of experts. **Section (01):** i. Liquid Injectable Section SVP Vial (General) (Veterinary)			
6.	M/s Surge Laboratories (Pvt) Ltd, 10th Km, Faisalabad Road, Bhikhi, District Sheikhupura. DML No. 000649 (by way of Semi-Basic)	02-12-2022	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore 3. Ms. Anam Saeed, Assistant Director, DRAP, Lahore
	Recommendations of the panel: *"Keeping in view the above observations the infrastructure, machinery, capacity and technical staff, the panel **recommends** the grant of registration of following 02 APIs under DML No. 000649 (By way of Semi-Basic Manufacturing)* 1. Diclofenac Sodium (Sustained Release Pellets 32% w/w) 2. Mebevrine HCI (Sustained Release Pellets 80% w/w)			

	& approval of Manufacturing Process Flow Charts of the following 06 Products: 1. Itraconazole Coated Pellets 22.2% w/w 2. Clarithromycin Taste Masked Coated Granules 27.5% w/w 3. Clarithromycin Taste Masked Coated Granules 42.0% w/w 4. Azithromycin Taste Masked Coated Granules 22.2% w/w 5. Diclofenac Sodium Sustained Release Pellets 32% w/w 6. Mebevrine HCI Sustained Release Pellets 80% w/w *The Process flow charts (signed by the panel of inspectors), manufacturing methods and testing methods of above mentioned products as provided by the management and duly signed and stamped by firm's representative are annexed with the report"* **Decision of the Central Licensing Board in 290th meeting** The Board considered and approved the grant of following additional API and Manufacturing Flow Chart in the name of M/s Surge Laboratories (Pvt) Ltd, 10th Km, Faisalabad Road, Bhikhi, District Sheikhupura under DML No. 000649 (Semi-Basic Manufacture) on the recommendations of the panel of experts subject to confirmation from the firm regarding pharmacopeia. **API (02)** 1. Diclofenac Sodium (Sustained Release Pellets 32% w/w) 2. Mebevrine HCI (Sustained Release Pellets 80% w/w) **Manufacturing Process Flow Charts of the following 06 Products:** 1. Itraconazole Coated Pellets 22.2% w/w 2. Clarithromycin Taste Masked Coated Granules 27.5% w/w 3. Clarithromycin Taste Masked Coated Granules 42.0% w/w 4. Azithromycin Taste Masked Coated Granules 22.2% w/w 5. Diclofenac Sodium Sustained Release Pellets 32% w/w 6. Mebevrine HCI Sustained Release Pellets 80% w/w			
7.	M/s Crystolite Pharmaceuticals, Plot No.1&2, S-2, National Industrial Zone, Rawat. DML No. 000778 (Formulation). **Sections (04):** i. Dry Vial Injection Section (Cephalosporin).	18-01-2023 & 11-04-2023	Good	1. Mr. Ajmal Sohail Asif, Director (QA&LT), DRAP, Islamabad. 2. Mr. Adnan Shahid Ullah, Deputy Director (QA&LT), DRAP, Islamabad. 3. Mr. Hassan Afzaal, Deputy Director (QA&LT), DRAP, Islamabad.

	ii. Dry Vial Injection Section (Carbapenem). iii. Oral Dry Suspension Section (Cephalosporin). iv. Capsule Section (Cephalosporin).			
	Recommendations of the panel: - Keeping in view the above facts, detailed visit of facility and supporting documents provide by the company, the panel unanimously **recommended** M/s Crystolite Pharmaceuticals, Plot No.1&2, S-2, RCCI, Rawat, Rawalpindi for the grant of additional sections namely; 1. Dry Vial Injection Section (Cephalosporin). 2. Dry Vial Injection Section (Carbapenem). 3. Oral Dry Suspension Section (Cephalosporin). 4. Capsule Section (Cephalosporin). **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of following additional sections in the name of M/s Crystolite Pharmaceuticals, Plot No.1&2, S-2, National Industrial Zone, Rawat under DML No. 000778 (Formulation) on the recommendations of the panel of experts. 1. Dry Vial Injection Section (Cephalosporin). 2. Dry Vial Injection Section (Carbapenem). 3. Oral Dry Suspension Section (Cephalosporin). 4. Capsule Section (Cephalosporin).			
8.	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)	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.

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

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).

09	M/s Winbrains Research Laboratories, Hattar. DML No. 000725 (Formulation). **Section (01):** **i.** Liquid Injectable Section with Lyophilized Facility.	**26-04-2023**	**Good**	i. Mr. Faisal Shahzad, Additional Director / Area Federal Inspector of Drugs, DRAP, Peshawar. ii. Mr. Muneeb Ahmed Cheema, Deputy Director, (Registration), DRAP, Islamabad.

				iii. Mr. Adnan Ali Shah, Assistant Director, DRAP, Peshawar.

Recommendations:

Based on documentation reviewed, technical / management people met, materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel unanimously recommends revised **Liquid Injectable Section with Lyophilized Facility** as per DRAP Islamabad letter No.F.3-7/2007-Lic (Vol-I) dated 12-01-2023. The panel also recommends that firm shall install automatic filling and stoppering machine for better process controls and shall submit process validation data for products to be manufactured with registration applications at the time of consideration of registration by the Registration Board.

Decision of the Central Licensing Board in 290th meeting

The Board considered and deferred the grant of additional section for recommendation of the committee regarding use of semi-automatic filling machine (details in M/s Welwink Pharmaceutical case).

Item-IV: **GRANT OF RENEWAL OF DML.**

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses. 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 Pakistan Institute of Nuclear Science and Technology (PINSTICH), Nilore, Islamabad. DML No.000730 (Formulation). Period: Commencing on 25-06-2021 ending on 24-06-2026.	**25-01-2023**	**Good**	1. Muhammad Akhtar Abbas Khan, Director (Licensing Division), DRAP, Islamabad. 2. Mrs. Tehreem Sara, FID-IV, DRAP, Islamabad. 3. Muhammad Yaqoob Kakkar, Assistant Director (Licensing Division), DRAP, Islamabad.

Recommendation of the Panel:

The observations were discussed in detail with the management of the firm on 07th March, 2023**.** The firm has submitted their request stating that

"This is with reference to subject cited above and subsequent meeting at your office on 07th March 2023. We would like to thank you for giving us the opportunity of discussion on observation during the visit. We understand the importance of ensuring the safety and efficacy of our product, and we are committed to taking the necessary steps to address the points discussed in the meeting.

In response to your findings, we commit to relocating our sterile products operations (Freeze dried kits & Inj. Adenosine) to a new sterile are (at phase-2), in coming years. We will work diligently to ensure that this new facility meets all regulatory requirements and guidelines to ensure the quality and safety of our products.

Additionally, we acknowledge the importance of providing validation and calibration data, as well as water system testing data, to DRAP. We obligate to submitting this data within the next year to ensure that our operations meet all necessary regulatory requirements. Due to some official constraints, we may not be able to provide import data of APIs for inj. Adenosine & Normal Saline. However, GMP grade APIs for aforesaid products will be ensured in future.

We appreciate DRAP guidance and oversight in this matter, and we will continue to work closely with you to ensure that we meet all necessary regulatory requirements and maintain the highest standards of quality and safety in our operations." (Annex).

"Keeping in view the above evaluation, discussion and being the sole manufacturer in Pakistan to produce these specialized products. The panel is of the opinion to recommend the grant of Renewal of Drug Manufacturing License (DML No. 000730) by way of Formulation.

Decision of the Central Licensing Board in 290th meeting:

	The Board considered and approved the grant of renewal of DML No. 000730 by way of Formulation in the name of M/s Pakistan Institute of Nuclear Science and Technology (PINSTICH), Nilore, Islamabad on the recommendations of the panel of experts for the period Commencing on 25-06-2021.			
2	M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Estate, 20-km, Ferozepur Road, Lahore. DML No.000736 (Formulation). Period: Commencing on 01-08-2022 & ending on 31-07-2027.	03-02-2023	**Good**	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Ufaq Tanveer, 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 of inspectors **recommends** to renewal of Drug Manufacturing License to M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo town, 20-km, Ferozepur Road, Lahore for the following sections only:

1. Oral Powder Section (Veterinary) General
2. Oral Liquid Section (Veterinary)
3. Liquid Injectable Vial Section (Veterinary) General
4. Powder Injectable (Penicillin) Section (Veterinary)
5. Oral Powder (Penicillin) Section (Veterinary).

It is pertinent to mention here that as per available record of Licensing Division, the firm got section approval from CLB with the title of Dry Powder Suspension (General) (Veterinary) however, the panel has recommended Oral Powder (Veterinary) (General) section.

Decision of the Central Licensing Board in 290th meeting:

The Board considered and approved the grant of renewal of DML No. 000736 by way of Formulation in the name of M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Estate, 20-km, Ferozepur Road, Lahore on the recommendations of the panel of experts for the period Commencing on 01-08-2022 & ending on 31-07-2027 for the following sections.

i. Dry Powder Suspension Section (Veterinary) (General)
ii. Oral Liquid Section (Veterinary)
iii. Liquid Injectable Vial Section (Veterinary) General.
iv. Powder Injectable (Penicillin) Section (Veterinary).
v. Oral Powder (Penicillin) Section (Veterinary).

3	M/s Amaan pharma, 30- Km, Sheikhupura Road, Lahore. DML No. 000808 (Formulation) Period: Commencing on 25-02-2020 & ending on 24-02-2025	25-01-2023	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: - Panel has inspected the unit comprehensively and assessed documentation revealed by the firm management in connection with Quality assurance, Quality Control and Production operations. Different technical aspects were also discussed with firm management at length. Based on the physical inspection of the unit, evaluation of the documents revealed by the firm management and discussion with the technical staff, panel decided to recommend the renewal of Drug Manufacturing License to M/s Amaan pharma, 30-Km, Lahore-Sheikhupura road, Sheikhupura for following three sections only. i. Liquid Ampoule (General) Section. ii. Liquid Ampoule (Hormone) Section. iii. Liquid Ampoule (Steroid) Section. **It is pertinent to mention here that as per available record of Licensing Division, the firm got section approval from CLB with the following title:** **i. Liquid Injection (Ampoule) (General) Section.** **ii. Liquid Injection (Ampoule) (Hormone) Section.** iii. **Liquid Injection (Ampoule) (Steroid) Section.** **<u>Decision of the Central Licensing Board in 290th meeting:</u>** The Board considered and approved the grant of renewal of DML No. 000808 by way of Formulation in the name of M/s Amaan pharma, 30-Km, Lahore-Sheikhupura Road, Sheikhupura on the recommendation of the panel of experts for the period Commencing on 25-02-2020 & ending on 24-02-2025 for the following sections. i. Liquid Injection (Ampoule) (General) Section. ii. Liquid Injection (Ampoule) (Hormone) Section. iii. Liquid Injection (Ampoule) (Steroid) Section.			
4	M/s Basel Pharmaceuticals, 277-Phase-II, Multan Industrial Estate, Multan. DML No. 000726 (Formulation).	**16-03-2023**	**Good**	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore.

	Period: Commencing on 21-06-2021 & ending on 20-06-2026.			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, Technical personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation to M/s Basel Pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan for following two sections only: i. Tablet (General) Section. ii. Capsule (General) Section. **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of renewal of DML No. 000726 by way of Formulation in the name of M/s Basel Pharmaceuticals, 277-Phase-II, Multan Industrial Estate, Multan on the recommendation of the panel of experts for the period commencing on 21-06-2021 & ending on 20-06-2026 for the following sections. i. Tablet (General) Section. ii. Capsule (General) Section.			
5	M/s Baariq Pharmaceuticals, Plot No. 600, Sunder Industrial Estate, Sunder Raiwind Road, Lahore. DML No. 000715 (Formulation). Period: Commencing on 15-06-2021 & ending on 14-06-2026.	21-03-2023	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Nafees ur Rehman, Assistant Director, 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 renewal of Drug Manufacturing License No.000715, by way of formulation to M/s Baariq Pharmaceuticals situated at Plot No.600, Sunder Industrial Estate, Sunder Raiwind Road, Lahore, for the following sections:			

	i. Vet. Oral Powder (General Antibiotics) ii. Vet. Oral Liquid (General) iii. Vet. Oral Powder-II. iv. Liquid Injection (General) Veterinary v. Oral Powder (Penicillin) Veterinary. vi. Liquid Injection (Penicillin) Veterinary. **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of renewal of DML No. 000715 by way of Formulation in the name of M/s Baariq Pharmaceuticals, Plot No. 600, Sunder Industrial Estate, Sunder Raiwind Road, Lahore recommendation of the panel of experts for the period commencing on 15-06-2021 & ending on 14-06-2026 for the following sections. i. Vet. Oral Powder (General Antibiotics) ii. Vet. Oral Liquid (General) iii. Vet. Oral Powder-II. iv. Liquid Injection (General) Veterinary v. Oral Powder (Penicillin) Veterinary. vi. Liquid Injection (Penicillin) Veterinary.			
6.	M/s Prays Pharmaceuticals, Plot No. 10, Street No. SS-4, National Industrial Zone, Rawat DML No.000719 (Formulation). Period: Commencing on 20-06-2021ending on19-06-2026.	30-1-2023	Good	1. Dr. Mahmood Ahmad, Expert member, Ex-Dean Faculty of Pharmacy& Alternative Medicine, IUB. 2. Ch. Zeeshan Nazir Bajar, Secretary, Registration Board, DRAP, Islamabad 3. Mr. Shahrukh Ali, AD (QC), 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 thereunder. The Panel Unanimously **recommends** for Renewal of Drug Manufacturing License No. 000719 of M/s Prays Pharmaceuticals, Plot No. 10, Street No. SS-4, National Industrial Zone, Rawat for following sections only":- i. Tablet Section(General). ii. Capsule Section(General). iii. Ointment / Cream (General). iv. Dry Powder for Suspension (Cephalosporin). v. Capsule Section (Cephalosporin). vi. Powder Repacking. vii. Liquid Repacking. **Decision of the Central Licensing Board in 290th meeting:**			

	The Board considered and approved the grant of renewal of DML No. 000719 by way of Formulation in the name of M/s Prays Pharmaceuticals, Plot No. 10, Street No. SS-4, National Industrial Zone, Rawat on recommendation of the panel of experts for the period commencing on 20-06-2021ending on19-06-2026 for the following sections. 1. Tablet Section(General). 2. Capsule Section(General). 3. Ointment / Cream (General). 4. Dry Powder for Suspension (Cephalosporin). 5. Capsule Section (Cephalosporin). 6. Powder Repacking. 7. Liquid Repacking.			
7.	M/s Majestic Pharma, Plot No. 21, Phase 1-A, M-3, Industrial City, Sahianwala, Faisalabad. DML No. **000873** (Formulation) Period: Commencing on **18-12-2022** ending on **17-12-2027**.	**07-03-2023**	**Good**	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Farooq Aslam, AD, DRAP, Lahore.
	Recommendations of the panel: "The firm 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 documentation and overall operations, the panel **recommends** Renewal of Drug Manufacturing License No. 000873 (by way of formulation) to M/s Majestic Pharma, Plot No. 21, Phase 1-A, M-3, Industrial City, Sahianwala, Faisalabad for following sections: - 1. Oral Liquid Section (General) 2. Oral Powder section (General) **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of renewal of DML No. 000873 by way of Formulation in the name of M/s Majestic Pharma, Plot No. 21, Phase 1-A, M-3, Industrial City, Sahianwala, Faisalabad on recommendation of the panel of experts for the period commencing on **18-12-2022** ending on **17-12-2027** for the following sections. i. Oral Liquid Section (General) Veterinary ii. Oral Powder section (General) Veterinary			
8.	M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate, Lahore Road, Sargodha. DML No. **000609** (Formulation)	**03-03-2023**	**Good**	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Muhammad Shamoon Charudhry.

	Period: Commencing on 21-03-2022 ending on 20-03-2027.			3. Mr. Nafees ur Rehman, 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 renewal of Drug Manufacturing License No. 000609, by way of formulation to M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate, Lahore Road, Sargodha for the following sections":- i. Tablet Section-I (General) ii. Tablet Section-II (General) iii. Capsule Section (General) iv. Sachet Section (General) **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of renewal of DML No. 000609 by way of Formulation in the name of M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate, Lahore Road, Sargodha on recommendation of the panel of experts for the period commencing on 21-03-2022 ending on 20-03-2027 for the following sections. i. Tablet Section-I (General) ii. Tablet Section-II (General) iii. Capsule Section (General) iv. Sachet Section (General)			
9.	M/s. Medella Pharmaceuticals (Pvt) Ltd, 569/570, Sunder Industrial Estate, Lahore. DML No. **000749** (Formulation) Period: Commencing on **30-08-2022** ending on **28-08-2027**	**13-04-2023**	**Good**	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Farooq Aslam, AD, DRAP, Lahore.
	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 **recommends** the renewal of Drug Manufacturing License (by way of formulation) to M/s. Medella Pharmaceuticals (Pvt) Ltd, 569/570, Sunder Industrial Estate, Lahore by way of formulation for the following sections: i. Tablet Section (General) ii. Capsule Section (General) iii. Dry Powder Suspension Section (General) iv. Sachet Section (General)			

v. Oral Liquid Section

Decision of the Central Licensing Board in 290th meeting:

The Board considered and approved the grant of renewal of DML No. 000749 by way of Formulation in the name of M/s. Medella Pharmaceuticals (Pvt) Ltd, 569/570, Sunder Industrial Estate, Lahore on recommendation of the panel of experts for the period commencing on **30-08-2022** ending on **28-08-2027** for the following sections.

i. Tablet Section (General).
ii. Capsule Section (General).
iii. Dry Powder Suspension Section (General).
iv. Sachet Section (General).
v. Oral Liquid Section

10.	M/s. Pharmawise Labs (Pvt) Ltd, 25-Km, Kot Lakhpat Industrial Estate, Lahore. DML No. **000182** (Formulation) Period: Commencing on **20-12-2019** ending on **19-12-2024**	**21-03-2023**	**Good**	1. Mr. Azher Jamal Saleemi, Chief Drug Controller, Government of Punjab, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Nafees-ur-Rehman, AD, DRAP, Lahore.

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 **recommends** the grant of renewal of Drug Manufacturing License &Regularization of Layout Plan to M/s. Pharmawise Labs (Pvt) Ltd situated at 25-Km, Kot Lakhpat Industrial Estate, Lahore, for the following sections:

i. Oral Liquid Section (Syrup / Suspension)
ii. External Application / Antiseptic Liquid Section
iii. Cream / Ointment Section
iv. Tablet Section (General)
v. Oral Dry Powder Sachet Section
vi. Repacking Section
vii. Capsule Section
viii. Oral Dry Powder for Suspension (General Antibiotic)
ix. Tablet (General Antibiotic Section)
x. Tablet (Steroid) Section

As per available record of Licensing Division, the detail of sections is as under:-

Ground Floor		First Floor	
S.No	**Name of Section**	**S.No**	**Name of Section**
1.	Syrup (General).	1.	Capsule (Penicillin)

2.	**External Application (Antiseptic Liquid)**	2.	**Tablet (General/Antibiotic)**
3.	**Cream/Ointment/Gel (General)**	3.	Dry Powder (General/Antibiotic)
4.	Packing	4.	**Tablet (Steroid)**
5.	Sachet ORS (General)	5.	Quality Control Laboratory
6.	Microbiology Laboratory	6.	Packing material Store
7.	Finished Goods Store		
8.	**Repacking Section**		
9.	Raw Material Store.		

Decision of the Central Licensing Board in 290th meeting:

The Board considered and approved the grant of renewal of DML No. 000182 by way of Formulation and Regularization of Layout Plan in the name of M/s. Pharmawise Labs (Pvt) Ltd, 25-Km, Kot Lakhpat Industrial Estate, Lahore on recommendation of the panel of experts for the period commencing on **20-12-2019** ending on **19-12-2024** for the following sections.

Ground Floor		**First Floor**	
S. No	**Name of Section**	**S. No**	**Name of Section**
1.	Syrup (General).	1.	Capsule (Penicillin)
2.	**External Application (Antiseptic Liquid)**	2.	**Tablet (General/Antibiotic)**
3.	**Cream/Ointment/Gel (General)**	3.	Dry Powder (General/Antibiotic)
4.	Packing	4.	**Tablet (Steroid)**
5.	Sachet ORS (General)	5.	Quality Control Laboratory
6.	Microbiology Laboratory	6.	Packing material Store
7.	Finished Goods Store		
8.	**Liquid Repacking Section**		
9.	Raw Material Store.		

11.	M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd., B-10, Block-B, S.I.T.E., North Karachi. DML No.000626 (Formulation) **Period:** Commencing on 05-10-2022 & ending on 04-10-2027.	07-03-2023	Good	1. Chief Drug Inspector, Karachi. 2. Additional Director, DRAP, Karachi. 3. Mr. Affan Ali, Assistant Director, CDL, Karachi.

	Recommendations of the panel: As per instructions contained in DRAP, Islamabad Letter No.F.2-16/2007-Lic Dated: 28th November 2022, a detailed inspection of Ms. ZAFA Pharma Lab (Pvt) Ltd situated at B-10, Block-B, S.I.T.E., North Karachi was carried out on 07th March 2023. During opening meeting their Organogram, JDs, SMF, approved design, HVAC provision and design, an APQR of frequently manufactured product, Self- audit report, medical reports of employees, training records and several working SOPs were discussed at length and found an adequate retrieval and an appropriate maintenance of key documents. The firm is find built as per approved design and necessary changes as per current design are satisfactorily carried out. Total 7 AHUs are provided in production areas for better compliance & to control the hazards of contamination. The compact line for sterile dry powder injection was noted adequately validated likewise other key production machines, Lab equipment were seen calibrated and with proper log books. Quality manuals, IP testing records and line clearance documents were also in place. Keeping in view the above stated facts and based on the attitude of the management towards continuous improvements, the panel unanimously recommends the grant of renewal of their DML No.000626 (By way of formulation) for next five years and also recommends the regularization of current lay out plan. **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of renewal of DML No. 000626 by way of Formulation in the name of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd., B-10, Block-B, S.I.T.E., North Karachi on recommendation of the panel of experts for the period commencing on 05-10-2022 & ending on 04-10-2027 for the following sections. 1. Tablet (Cephalosporin) 2. Capsule (Cephalosporin) 3. Dry Powder Suspension (Cephalosporin) 4. Dry Powder Injectable (Cephalosporin) 5. Ware House (Cephalosporin) 6. Quality Control Laboratory			
12.	M/s Care Pharmaceuticals, 8-Km, Thokar Raiwind Road, Lahore. DML No.000563 (Formulation). Period: Commencing on 31-12-2019 & ending on 30-12-2024.	10-04-2023	Good	1. Dr. Farzana Ch. Expert Member. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ishtiaq 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. Oral Liquid (General) (Renewal). ii. Eye/Ear Drops (General) (Renewal). iii. Cream/Ointment (Semi Solid) (Steroidal/Non-Steroidal) (General) (Renewal) **Decision of the Central Licensing Board in 290th meeting:** The Board considered and approved the grant of renewal of DML No. 000563 by way of Formulation in the name of M/s Care Pharmaceuticals, 8-Km, Thokar Raiwind Road, Lahore on recommendation of the panel of experts for the period Commencing on 31-12-2019 & ending on 30-12-2024 for the following sections. i. Oral Liquid (General) (Renewal). ii. Eye/Ear Drops (General) (Renewal). iii. Cream/Ointment (General) (Renewal).			
13	M/s Pakcure Pharma, Plot No. 17, S-6, RCCI, Rawat. DML No.000763 (Basic Manufacturing). Period: Commencing on 16-10-2017 ending on 15-10-2022.	**25-01-2023**	**Good**	1. Dr. Noor Us Saba, Director (Biological Evaluation & Registration), DRAP, Islamabad. 2. Mr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 3. Mr. Hassan Afzaal, Assistant Director (QA), DRAP, Islamabad.
	Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously Recommended M/s Pakcure Pharma, Plot No. 17, S-6, RCCI, Rawat, Rawalpindi for the grant of renewal of Drug Manufacturing License (000763) for Basic Manufacturing. **Decision of the Central Licensing Board in 290th meeting:** As the period 16-10-2017 to 15-10-2022 for which panel inspection was conducted on 25-01-2023 has expired the Board accepted the report of grant of renewal of DML No. 000763 by way of Formulation in the name of M/s M/s Pakcure Pharma, Plot No. 17, S-6, RCCI, Rawat. Moreover. the Board authorized the same panel for inspection of the firm for the purpose of grant of Renewal of DML for next tenure commencing on 16-10-2022.			

Case No. 1 **CHANGE OF TITLE OF M/S GLAXOSMITHKLINE CONSUMER HEALTH CARE PAKISTAN LTD, PETARO ROAD, JAMSHORO, PAKISTAN.**

The firm, M/s GlaxoSmithKline Consumer Health Care Pakistan Limited, Petaro Road, Jamshoro, Pakistan has submitted application for change of name of firm with relevant fee of Rs. 75,000/. The firm has submitted the notarized copy of certificate of incorporation on change of name issued by the Additional Registrar, SECP, Karachi along with other relevant documents as per approved checklist. The detail of the firm title is as under;

Previous Title of the firm	**New Title of the firm**
M/s GlaxoSmithKline Consumer Health Care Pakistan Limited.	M/s Haleon Pakistan Limited.

Decision of the Central Licensing Board in 290th meeting

The Board considered and accepted for record the change of title of, M/s GlaxoSmithKline Consumer Health Care Pakistan Limited, Petaro Road, Jamshoro, Pakistan DML No.000000 (By way of Formulation) as under

Previous Title of the firm	**New Title of the firm**
M/s GlaxoSmithKline Consumer Health Care Pakistan Limited.	M/s Haleon Pakistan Limited.

Case No. 2. CHANGE OF TITLE OF M/S MOON PHARMACEUTICALS, PLOT NO. 5, STREET NO. SS-4, NATIONAL INDUSTRIAL ZONE RCCI, RAWAT UNDER DML NO. 000833 (FORMULATION).

M/s Zam Zam Pharma, Plot No. 5, Street No. SS-4, National Industrial Zone, Rawat [*Formerly* Moon Pharmaceuticals] wherein the firm has submitted an application for change of title of the company under Drug Manufacturing License No.000833 by way of (Formulation). The firm has deposited fee of Rs.75000/-.

Change of Title	
Previous Title	**New Title**
M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, Rawat.	**M/s Zam Zam Pharma,** Plot No. 5, Street No. SS-4, National Industrial Zone, Rawat.

Decision of the Central Licensing Board in 290th meeting

The Board considered and accepted for record the change of title of, M/s Zam Zam Pharma, Plot No. 5, Street No. SS-4, National Industrial Zone, Rawat [*Formerly* Moon Pharmaceuticals] DML No.000833 (By way of Formulation) as under

Change of Title	
Previous Title	**New Title**
M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, Rawat.	**M/s Zam Zam Pharma,** Plot No. 5, Street No. SS-4, National Industrial Zone, Rawat.

Case No. 3 **CHANGE OF MANAGEMENT M/S. RECKITT BENCKISER PAKISTAN LTD., F-18, S.I.T.E., KARACHI.**

M/s. Reckitt Benckiser Pakistan Ltd., F-18, S.I.T.E., Karachi submitted application for change of management under Drug Manufacturing License No. 000022 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

Previous management	**Retiring management**	**New management**
1. Mr. Syed Kashan Hassan S/o Syed Anwar Saghir, CNIC No.42301-0816739-3. 2. Mr. Akbar Ali Shah S/o Mazhar Hussain Shah, CNIC No.42000-5264192-9. 3. Mr. Atif Hashmi S/o Hameed Akhtar Hashmi, CNIC No.42101-1403487-3. 4. Mr Adil Saeed Khan S/o Saeed Ahmed Khan, CNIC No.42201-0426657-7. 5. Mr. Shahzeb Mahmood S/o Maten Mahmood Mohajir, CNIC No.42301-0844790-7. 6. Mr. Aslam Khaliq S/o Abdul Khaliq, CNIC No.61101-2180699-9.	1. Mr. Syed Kashan Hassan S/o Syed Anwar Saghir, CNIC No.42301-0816739-3. 2. Mr. Akbar Ali Shah S/o Mazhar Hussain Shah, CNIC No.42000-5264192-9. 3. Mr. Atif Hashmi S/o Hameed Akhtar Hashmi, CNIC No.42101-1403487-3. 4. Mr Adil Saeed Khan S/o Saeed Ahmed Khan, CNIC No.42201-0426657-7. 5. Mr. Shahzeb Mahmood S/o Maten Mahmood Mohajir, CNIC No.42301-0844790-7.	1. Mr. Faisal Waheed S/o Abdul Waheed, CNIC No.42201-4067042-5. 2. Syed Ahmed Mujtaba Rizvi S/o Syed Ayyaz Haider Rizvi, CNIC No.31202-9312697-1. 3. Mr. Faraz Janoo S/o Jabir Janoo, CNIC No.42201-3909712-3. 4. Samrah Anis W/o Kamil Hafeez, CNIC No.42201-8756573-0. 5. Syed Naveed Husain S/o Syed Ijaz Haider Zaidi, CNIC No.35200-1457453-7. 6. Mr. Aslam Khaliq S/o Abdul Khaliq, CNIC No.61101-2180699-9.

Decision of the Central Licensing Board in 290th meeting:

The Board considered and accepted for record the change of management of M/s. Reckitt Benckiser Pakistan Ltd., F-18, S.I.T.E., Karachi DML No.000022 (By way of Formulation) as under**;**

Previous management	New management
1. Mr. Syed Kashan Hassan S/o Syed Anwar Saghir, CNIC No.42301-0816739-3. 2. Mr. Akbar Ali Shah S/o Mazhar Hussain Shah, CNIC No.42000-5264192-9. 3. Mr. Atif Hashmi S/o Hameed Akhtar Hashmi, CNIC No.42101-1403487-3. 4. Mr Adil Saeed Khan S/o Saeed Ahmed Khan, CNIC No.42201-0426657-7. 5. Mr. Shahzeb Mahmood S/o Maten Mahmood Mohajir, CNIC No.42301-0844790-7. 6. Mr. Aslam Khaliq S/o Abdul Khaliq, CNIC No.61101-2180699-9.	1. Mr. Faisal Waheed S/o Abdul Waheed, CNIC No.42201-4067042-5. 2. Syed Ahmed Mujtaba Rizvi S/o Syed Ayyaz Haider Rizvi, CNIC No.31202-9312697-1. 3. Mr. Faraz Janoo S/o Jabir Janoo, CNIC No.42201-3909712-3. 4. Samrah Anis W/o Kamil Hafeez, CNIC No.42201-8756573-0. 5. Syed Naveed Husain S/o Syed Ijaz Haider Zaidi, CNIC No.35200-1457453-7. 6. Mr. Aslam Khaliq S/o Abdul Khaliq, CNIC No.61101-2180699-9.

Case No.4 **CHANGE OF MANAGEMENT M/S NEWTON HEALTH CARE (PVT) LTD., PLOT NO. N-8&9, HITE, HUB, BALOCHISTAN**

M/s Newton Health Care (Pvt) Ltd., Plot No. N-8&9, HITE, Hub, Baluchistan has submitted application for change of management under Drug Manufacturing License No. 000870 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

Previous management	New management As per Form-29
1. Shazia Zeb W/o Farooq Ahmed Qazi CNIC No.43203-5513610-4 2. Jawaid Ahmed Qureshi S/o Abdul Majeed Qureshi CNIC No.43203-8926177-1. 3. Muhammad Khalid Qazi S/o Abdul Ghafoor CNIC No.43203-1568676-5. 4. Qadeer Ahmed S/o Ghulam Rasool Somroo CNIC No.42301-3103594-1. 5. Muhammad Tariq Qazi S/o Abdul Ghafoor Qazi CNIC No.43203-5129028-1.	1. Shafaq Sultana D/o Farooq Ahmed Qazi CNIC No.43203-7952187-0. 2. Farooq Ahmed Qazi S/o Abdul Ghafoor CNIC No.43203-9496796-7 3. Jawaid Ahmed Qureshi S/o Abdul Majeed Qureshi CNIC No.43203-8926177-1. 4. Muhammad Khalid Qazi S/o Abdul Ghafoor CNIC No.43203-1568676-5. 5. Qadeer Ahmed S/o Ghulam Rasool Somroo CNIC No.42301-3103594-1. 6. Muhammad Tariq Qazi S/o Abdul Ghafoor Qazi CNIC No.43203-5129028-1.

Decision of the Central Licensing Board in 288th meeting:

The Board observed that the details of the directors (ceasing of officer/retirement/resignation) is not mentioned in Form-29. The case is deferred for clarification by the firm.

Accordingly, a letter was issued to the firm on 16-11-2022 to submit certified true copy of form-29 with the details of the directors (ceasing of officer/retirement/resignation).

In reply to the above refer letter the firm has submitted Form-29 for the year 2020 wherein the New appointment of Shafaq Sultana holding CNIC No 43203-7952187-0 is mentioned and the Ceasing officer name is mentioned as Shazia Zaib holding CNIC No. 4320355136104.

Decision of the Central Licensing Board in 290th meeting:

The Board considered and accepted for record the change of management of, M/s Newton Health Care (Pvt) Ltd., Plot No. N-8&9, HITE, Hub, Balochistan DML No.000870 (By way of Formulation) as under**;**

Previous management	New management As per Form-29
1. Shazia Zeb W/o Farooq Ahmed Qazi CNIC No.43203-5513610-4 2. Jawaid Ahmed Qureshi S/o Abdul Majeed Qureshi CNIC No.43203-8926177-1. 3. Muhammad Khalid Qazi S/o Abdul Ghafoor CNIC No.43203-1568676-5. 4. Qadeer Ahmed S/o Ghulam Rasool Somroo CNIC No.42301-3103594-1. 5. Muhammad Tariq Qazi S/o Abdul Ghafoor Qazi CNIC No.43203-5129028-1.	1. Shafaq Sultana D/o Farooq Ahmed Qazi CNIC No.43203-7952187-0. 2. Farooq Ahmed Qazi S/o Abdul Ghafoor CNIC No.43203-9496796-7 3. Jawaid Ahmed Qureshi S/o Abdul Majeed Qureshi CNIC No.43203-8926177-1. 4. Muhammad Khalid Qazi S/o Abdul Ghafoor CNIC No.43203-1568676-5. 5. Qadeer Ahmed S/o Ghulam Rasool Somroo CNIC No.42301-3103594-1. 6. Muhammad Tariq Qazi S/o Abdul Ghafoor Qazi CNIC No.43203-5129028-1.

Case No. 5 **CHANGE OF MANAGEMENT M/S. SEARLE PAKISTAN LTD., PLOT NO.C-14, MANGHOPIR ROAD, S.I.T.E., KARACHI.**

M/s. Searle Pakistan Ltd., Plot No.C-14, Manghopir Road, S.I.T.E., Karachi submitted application for change of management under Drug Manufacturing License No. 000012 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

Previous management	Retiring management	New management as per Form-29
1. Munis Abdullah S/o Rashid Abdullah, CNIC No.42201-9982517-1. 2. Mr. Mr. Zubair Razzak Palwala S/o Abdul	1. Munis Abdullah S/o Rashid Abdullah, CNIC No.42201-9982517-1.	1. Mr. Mufti Zia Ul Islam S/o Mr. Taus Khan, CNIC No.42000-0467228-3. 2. Mr. Mr. Zubair Razzak Palwala S/o Abdul

Razzak Palwala, CNIC No.42201-5080780-3. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No.42301-0859989-9. 4. Mr. Mobin Alam S/o Muhammad Aziz Alam, CNIC No.42301-4675803-3. 5. Ms. Fareen Naz Qureshi D/o Muhammad Hassan Azwar CNIC No.42301-0763444-4. 6. Mr. Tahir Ahmed S/o Maqbool Ahmed, CNIC No.42201-0169711-5. 7. Mr. Muhammad Zubair Haider Shaikh S/o Haider Buksh Shaikh, CNIC No.42301-9578130-3.		Razzak Palwala, CNIC No.42201-5080780-3. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No.42301-0859989-9. 4. Mr. Mobin Alam S/o Muhammad Aziz Alam, CNIC No.42301-4675803-3. 5. Ms. Fareen Naz Qureshi D/o Muhammad Hassan Azwar CNIC No.42301-0763444-4. 6. Mr. Tahir Ahmed S/o Maqbool Ahmed, CNIC No.42201-0169711-5. 7. Mr. Muhammad Zubair Haider Shaikh S/o Haider Buksh Shaikh, CNIC No.42301-9578130-3.

Decision of the Central Licensing Board in 290th meeting

The Board considered and accepted for record the change of management of M/s. Searle Pakistan Ltd., Plot No.C-14, Manghopir Road, S.I.T.E., Karachi DML No.000012 (By way of Formulation) as under

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

7. Mr. Muhammad Zubair Haider Shaikh S/o Haider Buksh Shaikh, CNIC No.42301-9578130-3.	

Case No.6 **CHANGE OF MANAGEMENT M/S. MEDICAIDS PAKISTAN (PVT) LTD., KARACHI**

M/s. Medicaids Pakistan (Pvt) Ltd., Plot No.10, Sector 27, Korangi Industrial Area, Karachi has submitted application for change of management under Drug Manufacturing License No. 000139 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

Previous management	Retiring management	New management
1. Mr. Amjad Ali Khan S/o Shafqat Ali Khan, CNIC. No. 42000-0392632-7. 2. Mr. Waqas Ali Khan S/o Amjad Ali Khan, CNIC. No. 42000-6778912-9.	1. Mr. Amjad Ali Khan S/o Shafqat Ali Khan, CNIC. No. 42000-0392632-7. 2. Mr. Waqas Ali Khan S/o Amjad Ali Khan, CNIC. No. 42000-6778912-9.	1. Mr. Fazal Farooq S/o Fazal Rehman, CNIC. No. 42201-6322881-1. 2. Mr. Ahmad Farooq S/o Fazal Farooq, CNIC. No. 42201-5252387-9. 3. Mr. Muhammad Bin Farooq S/o Fazal Farooq, CNIC. No. 42201-4649512-1.

Decision of the Central Licensing Board in 290th meeting

The Board considered and accepted for record the change of title of management of M/s. Medicaids Pakistan (Pvt) Ltd., Plot No.10, Sector 27, Korangi Industrial Area, Karachi DML No.000139(By way of Formulation) as under:

Previous management	Retiring management	New management
3. Mr. Amjad Ali Khan S/o Shafqat Ali Khan, CNIC. No. 42000-0392632-7. 4. Mr. Waqas Ali Khan S/o Amjad Ali Khan, CNIC. No. 42000-6778912-9.	3. Mr. Amjad Ali Khan S/o Shafqat Ali Khan, CNIC. No. 42000-0392632-7. 4. Mr. Waqas Ali Khan S/o Amjad Ali Khan, CNIC. No. 42000-6778912-9.	4. Mr. Fazal Farooq S/o Fazal Rehman, CNIC. No. 42201-6322881-1. 5. Mr. Ahmad Farooq S/o Fazal Farooq, CNIC. No. 42201-5252387-9. 6. Mr. Muhammad Bin Farooq S/o Fazal Farooq, CNIC. No. 42201-4649512-1.

Case No. 7. **CHANGE OF MANAGEMENT OF M/S UNISA PHARMACEUTICAL INDUSTRIES LTD, MAIN GT ROAD, ADAMZAI, AKORA KHATTAK, DISTRICT NOWSHERA UNDER DRUG MANUFACTURING LICENSE NO. 000740 BY WAY OF (FORMULATION).**

M/s Unisa Pharmaceutical Industries Ltd, Main GT Road, Adamzai, Akora Khattak, District Nowshera, Drug Manufacturing License No.000740 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of the management of the firm is as under: -

Outgoing management as per Form-29	Outgoing Management	New management as per Form-29.
1. Mr. Muhammad Ismail S/o Abdul Razzaq. 2. Mr. Aqib Ismail S/o Muhammad Ismail CNIC No 16102-4074941-1 3. Mr. Najmul Saqib S/o Muhammad Ismail, CNIC No. 16102-7018888-9. 4. Mr. Shah Fahad S/o Muhammad Ismail CNIC No. 16102-5249657-1.	Mr. Muhammad Ismail S/o Abdul Razzaq.	1. Mr. Aqib Ismail S/o Muhammad Ismail CNIC No 16102-4074941-1. 2. Mr. Najmul Saqib S/o Muhammad Ismail, CNIC No. 16102-7018888-9. 3. Mr. Shah Fahad S/o Muhammad Ismail CNIC No. 16102-5249657-1.

Decision of the Central Licensing Board in 290th meeting

The Board considered and accepted for record the change of title of management of M/s Unisa Pharmaceutical Industries Ltd, Main GT Road, Adamzai, Akora Khattak, District Nowshera, DML No.000740 (By way of Formulation) as under

Outgoing management as per Form-29	Outgoing Management	New management as per Form-29.
1. Mr. Muhammad Ismail S/o Abdul Razzaq. 2. Mr. Aqib Ismail S/o Muhammad Ismail CNIC No 16102-4074941-1 3. Mr. Najmul Saqib S/o Muhammad Ismail, CNIC No. 16102-7018888-9. 4. Mr. Shah Fahad S/o Muhammad Ismail CNIC No. 16102-5249657-1.	Mr. Muhammad Ismail S/o Abdul Razzaq.	1. Mr. Aqib Ismail S/o Muhammad Ismail CNIC No 16102-4074941-1. 2. Mr. Najmul Saqib S/o Muhammad Ismail, CNIC No. 16102-7018888-9. 3. Mr. Shah Fahad S/o Muhammad Ismail CNIC No. 16102-5249657-1.

Case No.8. **CHANGE OF TITLE OF M/S AAA HEALTH PHARMACEUTICALS LABORATORIES, PLOT NO. 9-A, STREET NO. N-5, RCCI, RAWAT UNDER DML NO 000871 (FORMULATION).**

M/s AAA Health Pharmaceuticals Laboratories, Plot No.9-A, Street No. N-5, RCCI, Rawat submitted the documents for change of title of the firm. The firm has deposited fee of Rs.75000/- for change of title. The detail is as under;

Previous Title	New Title AS PER Certificate of Incorporation
M/s AAA Health Pharmaceutical Laboratories, Plot No, 9-A, Street N-5, RCCI, Rawat.	**M/s Rite Bio Sciences (Pvt) Ltd,** Plot No,9-A, Street N-5, RCCI, Rawat.

Decision of the Central Licensing Board in 290th meeting

The Board considered and accepted for record the change of title of M/s AAA Health Pharmaceuticals Laboratories, Plot No.9-A, Street No. N-5, RCCI, Rawat DML No.000871 (By way of Formulation) as under

Previous Title	New Title AS PER Certificate of Incorporation
M/s AAA Health Pharmaceutical Laboratories, Plot No, 9-A, Street N-5, RCCI, Rawat.	**M/s Rite Bio Sciences (Pvt) Ltd,** Plot No,9-A, Street N-5, RCCI, Rawat.

Case No.9. **CHANGE OF MANAGEMENT OF M/S AAA HEALTHPHARMACEUTICAL LABORATORIES, PLOT NO. 9-A, STREET NO. N-5, RCCI, RAWAT UNDER DML NO 000871 (FORMULATION).**

M/s AAA Health Pharmaceuticals Laboratories, Plot No.9-A, Street No. N-5, RCCI, Rawat submitted the documents for change of management of the firm. The firm has deposited fee of Rs.75000/- for change of management. The detail is as under;

Previous Management	New Management as per Form-II
1. Mr. Mir Ghulam Khan S/o Muhammad Alam CNIC No. 17301-1094402-1. 2. Mr. Wahid Zaman S/o Mir Ghulam Khan CNIC No. 17301-0160315-7.	1. Mr. Muhammad Mehtab Mukhtar S/o Muhammad Mukhtar Ashrafi CNIC No. 42101-3137545-7. 2. Ms. Syeda Birjees Mehtab W/o Muhammad Mehtab Mukhtar CNIC No. 42101-7305924-8.

3. Mr. Muhammad Zahid Khan S/o Mir Ghulam Khan CNIC No. 17301-7977928-3. 4. Mr. Gohar Zaman Wazir S//o Mir Ghulam Khan CNIC No. 17301-5564374-7.	

Decision of the Central Licensing Board in 290th meeting:

The Board considered and accepted for record the change of management of M/s AAA Health Pharmaceuticals Laboratories, Plot No.9-A, Street No. N-5, RCCI, Rawat DML No.000871 (By way of Formulation) as under**;**

Previous Management	New Management as per Form-II
1. Mr. Mir Ghulam Khan S/o Muhammad Alam CNIC No. 17301-1094402-1. 2. Mr. Wahid Zaman S/o Mir Ghulam Khan CNIC No. 17301-0160315-7. 3. Mr. Muhammad Zahid Khan S/o Mir Ghulam Khan CNIC No. 17301-7977928-3. 4. Mr. Gohar Zaman Wazir S//o Mir Ghulam Khan CNIC No. 17301-5564374-7.	1. Mr. Muhammad Mehtab Mukhtar S/o Muhammad Mukhtar Ashrafi CNIC No. 42101-3137545-7. 2. Ms. Syeda Birjees Mehtab W/o Muhammad Mehtab Mukhtar CNIC No. 42101-7305924-8.

Case No. 10. CHANGE OF MANAGEMENT OF M/S MASS PHARMA (PVT) LTD, 17-KM, FEROZEPUR ROAD, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000444 BY WAY OF (FORMULATION).

M/s Mass Pharma (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore, DML No.000444 by way of formulation has submitted request for change in management of the firm as per SECP Form-29 with prescribed fee. The detail of management of the firm is as under: -

Existing management	New management
1. Ishfaq Ahmed (CEO), CNIC No. 35202-3705859-1 2. Khawaja Muhammad Akram (Director), CNIC No. 35202-3662275-5 3. Khawaja Muhammad Aslam (Director), CNIC No. 35202-9964519-3 4. Shahzeb Akram (Director), CNIC No. 35200-1509201-1 5. Iftikhar Javed (Director), CNIC No. 42000-0576240-7	1. Ishfaq Ahmed (CEO), CNIC No. 35202-3705859-1 2. Shahzeb Akram (Director), CNIC No. 35200-1509201-1 3. Jahanzeb Akram (Director), CNIC No. 35202-5525238-5 4. Iftikhar Javed (Director), CNIC No. 42000-0576240-7 5. Fazal-e-Rabbi (Director), CNIC No. 35202-7179768-7

Decision of the Central Licensing Board in 290th meeting:

The Board considered and accepted for record the change of management of M/S Mass Pharma (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore, DML No.000444 (By way of Formulation) as under**;**

Existing management	New management
1. Ishfaq Ahmed (CEO), CNIC No. 35202-3705859-1 2. Khawaja Muhammad Akram (Director), CNIC No. 35202-3662275-5 3. Khawaja Muhammad Aslam (Director), CNIC No. 35202-9964519-3 4. Shahzeb Akram (Director), CNIC No. 35200-1509201-1 5. Iftikhar Javed (Director), CNIC No. 42000-0576240-7	1. Ishfaq Ahmed (CEO), CNIC No. 35202-3705859-1 2. Shahzeb Akram (Director), CNIC No. 35200-1509201-1 3. Jahanzeb Akram (Director), CNIC No. 35202-5525238-5 4. Iftikhar Javed (Director), CNIC No. 42000-0576240-7 5. Fazal-e-Rabbi (Director), CNIC No. 35202-7179768-7

Case No. 11. CHANGE OF MANAGEMENT OF M/S UNEXOLABS (PVT) LTD, UNDER DRUG MANUFACTURING LICENSE NO. 000065 BY WAY OF (FORMULATION).

M/s Unexolabs (Pvt) Ltd, Lahore under Drug Manufacturing License No. 000065 by way of (Formulation) has submitted request for change in management of the firm along with prescribed fee. The detail of management of the firm is as under: -

Existing management	New management
1. Mr. Shafqat Ali Malik S/o Hakim Ali Malik (Director) CNIC No. 35202-2822932-9 2. Mr. Munib Shafqat Malik S/o Shafqat Ali Malik (Director) CNIC No. 35202-2822934-9	1. Mr. Munib Shafqat Malik S/o Shafqat Ali Malik (Director) CNIC No. 35202-2822934-9 2. Mrs. Tayyaba Munib Malik W/o Munib Shafqat Malik (Director) CNIC No. 35202-2657629-2

Decision of the Central Licensing Board in 290th meeting

The Board considered and accepted for record the change of management of M/s Unexolabs (Pvt) Ltd, Lahore under DML No.000065 (Formulation) as under

Existing management	New management

1. Mr. Shafqat Ali Malik S/o Hakim Ali Malik (Director) CNIC No. 35202-2822932-9 2. Mr. Munib Shafqat Malik S/o Shafqat Ali Malik (Director) CNIC No. 35202-2822934-9	1. Mr. Munib Shafqat Malik S/o Shafqat Ali Malik (Director) CNIC No. 35202-2822934-9 2. Mrs. Tayyaba Munib Malik W/o MunibShafqat Malik (Director) CNIC No. 35202-2657629-2

Case No. 12. **CHANGE OF MANAGEMENT OF M/S P.D.H LABORATORIES (PVT) LTD, 9.5-KM, SHEIKHUPURA ROAD, (KHAKI), LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000039 BY WAY OF (FORMULATION).**

M/s P.D.H Laboratories (Pvt) Ltd, 9.5-Km, Sheikhupura Road, (Khaki), Lahore, DML No.000039 by way of formulation has submitted request for change in management of the firm as per SECP Form-29 with prescribed fee. The detail of management of the firm is as under:-

Previous Management (Page 208-209/Corr)	New Management (Page 206-207/Corr)
1. Mr. Ayub Ahmed Siddiqui S/o Taseer Ahmed Siddiqui, CNIC: 42301-9182068-7, (Chief Executive Officer). 2. Ms. Zaineb Aleem Khan D/o Abdul Aleem Khan CNIC: 35201-6656509-0 (Director) 3. Mr. Abdur Rehman Khan S/o Abdul Aleem Khan CNIC: 35201-7643531-3, (Director) 4. Mr. Abdur Rafay Khan S/o Abdul Aleem Khan CNIC: 35201-7548436-3, (Director) 5. Mr. Abdul Khabir S/o Salim ud Din Akhtar CNIC: 35202-9376166-3, (Company Secretary)	1. Mr. Sajid Ullah Ghumman S/o Sana Ullah Ghumman Qadri, CNIC: 34601-8991701-1, (Chief Executive Officer). 2. Ms. Zaineb Aleem Khan D/o Abdul Aleem Khan CNIC: 35201-6656509-0 (Director) 3. Mr. Abdur Rehman Khan S/o Abdul Aleem Khan CNIC: 35201-7643531-3, (Director) 4. Mr. Abdur Rafay Khan S/o Abdul Aleem Khan CNIC: 35201-7548436-3, (Director) 5. Mr. Abdul Khabir S/o Salim ud Din Akhtar CNIC: 35202-9376166-3, (Company Secretary)

Decision of the Central Licensing Board in 290th meeting:

The Board considered and accepted for record the change of management of M/s P.D.H Laboratories (Pvt) Ltd, 9.5-Km, Sheikhupura Road, (Khaki), Lahore DML No.000039 (By way of Formulation) as under

Previous Management (Page 208-209/Corr)	New Management (Page 206-207/Corr)
1. Mr. Ayub Ahmed Siddiqui S/o Taseer Ahmed Siddiqui, CNIC:	1. Mr. Sajid Ullah Ghumman S/o Sana Ullah Ghumman Qadri, CNIC:

42301-9182068-7, (Chief Executive Officer). 2. Ms. Zaineb Aleem Khan D/o Abdul Aleem Khan CNIC: 35201-6656509-0 (Director) 3. Mr. Abdur Rehman Khan S/o Abdul Aleem Khan CNIC: 35201-7643531-3, (Director) 4. Mr. Abdur Rafay Khan S/o Abdul Aleem Khan CNIC: 35201-7548436-3, (Director) 5. Mr. Abdul Khabir S/o Salim ud Din Akhtar CNIC: 35202-9376166-3, (Company Secretary)	34601-8991701-1, (Chief Executive Officer). 2. Ms. Zaineb Aleem Khan D/o Abdul Aleem Khan CNIC: 35201-6656509-0 (Director) 3. Mr. Abdur Rehman Khan S/o Abdul Aleem Khan CNIC: 35201-7643531-3, (Director) 4. Mr. Abdur Rafay Khan S/o Abdul Aleem Khan CNIC: 35201-7548436-3, (Director) 5. Mr. Abdul Khabir S/o Salim ud Din Akhtar CNIC: 35202-9376166-3, (Company Secretary)

Case No.13 **CHANGE OF MANAGEMENT OF M/S AVICENNA LABORATORIES, 14-KM, FAISALABAD ROAD, BHIKHI, DISTRICT SHEIKHUPURA UNDER DML NO 000328 (FORMULATION).**

M/s Avicenna Laboratories, 14-Km, Faisalabad Road, Bhikhi, District Sheikhupura Under DML No 000328 submitted the documents for change of management of the firm. The firm has deposited fee of Rs.75000/- for change of management. The detail is as under;

Previous Management	New Management as per Form-29
1. Ms. Uzma Dilshad W/o Dilshad Muhammad CNIC No.17301-459134-4. 2. Mr. Dilshad Muhammad S/o Wali Muhammad CNIC No.17301-5381560-5.	1. Mr. Dilshad Muhammad S/o Wali Muhammad CNIC No.17301-5381560-5. 2. Mr. Muhammad Haris Dilshad Khan S/o Dilshad Muhammad CNIC No.17301-4515021-9.

Decision of the Central Licensing Board in 290th meeting:

The Board considered and accepted for record the change of management of M/s Avicenna Laboratories, 14-Km, Faisalabad Road, Bhikhi, District Sheikhupura DML No. 000328 (Formulation) as under**;**

Previous Management	New Management as per Form-29
1. Ms. Uzma Dilshad W/o Dilshad Muhammad CNIC No.17301-459134-4. 2. Mr. Dilshad Muhammad S/o Wali Muhammad CNIC No.17301-5381560-5.	1. Mr. Dilshad Muhammad S/o Wali Muhammad CNIC No.17301-5381560-5. 2. Mr. Muhammad Haris Dilshad Khan S/o Dilshad Muhammad CNIC No.17301-4515021-9.

Case No.14 **CHANGE OF MANAGEMENT OF M/S ZETA PHARMACEUTICALS, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000818 BY WAY OF (FORMULATION).**

M/s Zeta Pharmaceuticals, Plot No. 494-A, Sunder Industrial Estate, Lahore, DML No.000818 by way of formulation has submitted request for change in management of the firm along with partnership deed (reconstituted) and fee Rs. 75000/-. The detail of management of the firm is as under:-

Previous Management	Current Management
1. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. 2. Mr. Atiq Qamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5, 3. Mr. Zahid Masood Nasir S/o Basharat Ali CNIC No. 35202-5632630-7,	1. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. 2. Mr. Atiq Qamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5,

Decision of the Central Licensing Board in 288th meeting:

The Board observed that firm has not provided Form-D and the copy of the partnership deed is not readable. Hence the case is deferred for submission of original certified true copies.

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

Letter was issued to the firm dated 22nd November, 2022 for submission of documents. Now, the firm has replied and submitted above mentioned documents decided in 288th meeting of CLB held on 18th October, 2022.

Decision of the Central Licensing Board in 290th meeting

The Board considered and accepted for record the change of management of M/s Zeta Pharmaceuticals, Plot No. 494-A, Sunder Industrial Estate, Lahore under DML No. 000818 (Formulation) as under

Previous Management	Current Management
1. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. 2. Mr. AtiqQamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5, 3. Mr. Zahid Masood Nasir S/o Basharat Ali CNIC No. 35202-5632630-7,	1. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. 2. Mr. AtiqQamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5,

Case No. 15. **REVISION OF TITLE OF THE APPROVED SECTION FROM INJECTABL AMPOULE (STEROID) TO PLASTIC RASPULES SECTION OF M/S HUDSON PHARMA (PVT) LTD., KARACHI**

The Central Licensing Board in its 283rd meeting held on 28-10-2021 approved the new section namely "Plastic Ampule (Steroid)" of M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North West Industrial Zone, Port Qasim Authority Karachi under DML No. 000842 (Formulation).

The firm, M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North West Industrial Zone, Port Qasim Authority Karachi was applied for the change of title of licensed section as under;

Existing Name of Section	**New name of section**
Injectable Ampoule BF (Steroid)	Plastic Raspules Section

On the direction of Director (Licensing)/Chairman Central Licensing Board a letter was issued to FID, DRAP, Karachi to confirm whether same facility requires any changes / amendments or any equipment / part of equipment to remain from Injectable Ampoule BF (Steroid) to Plastic Raspules Section.

Now the FID, DRAP, Karachi has forwarded report which is re-produced as under;

> *"I have the honor to refer DRAP, Islamabad letter No.F.2-12/2010-Lic (Vol-II) dated 24th January 2023 on the subject cited and submit that undersigned pursued the documents of the firm submitted vide their letter No.HP/RA/016/23 dated 09th February, 2023 (Copies along with Annexure A to F enclosed). It is confirmed that the same facility does not require any changes / amendment or any equipment / part of equipment to manufacture Plastic Ampoule (Steroid Section) which is now named as Raspules (Steroid) section in compliance to the decision of 322nd Registration Board meeting."*

Decision of the Central Licensing Board in 290th meeting:

The Board considered and approved the change of title of the section from Injectable Ampoule BF (Steroid) to Plastic Repulse Section.

Case No. 16. **RENEWAL OF DRUG MANUFACTURING LICENSE & REGULARIZATION OF LAYOUT PLAN OF M/S ATCO LABORATORIES LTD, B-18, S.I.T.E., KARACHI.**

The Central Licensing Board in its 286th meeting held on 11th May, 2022 has considered and approved the renewal of Drugs Manufacturing License and regularization of Layout plan of M/s Atco Laboratories Ltd, B-18, S.I.T.E., Karachi. However, the section namely "Lotion Section (General-Second Floor Unit-2)" was mentioned in the evaluation report but not in the recommendation of the panel. Accordingly, a letter was issued to FID, DRAP, Karachi to clarify whether the renewal of section is approved or otherwise.

Now the FID, DRAP, Karachi has forwarded report which is re-produced as under;

"With reference to your letter No.F.2-5/85 Lic (Vol-II) dated 07th April, 2023 on the subject mentioned above undersigned visited the M/s Atco Laboratories Limited, Karachi situated at B-18, S.I.T.E., Karachi on dated 14th April, 2023 and following are observations of the visit.

M/s Atco Laboratories was last visited by the Panel on dated 09th March, 2021 for the grant of renewal of their DML and regularization of their existing approved Lay out Plan. The Paned had unanimously recommended the grant of renewal of their DML and also recommended the grant of regularization of their existing design to the board concerned, whereby their already approved & separately mentioned Lotion (G) Section in the approved design, had been left to write in final recommendation of the Panel although it is categorically mentioned in Evaluation Form.

The same is hereby verified during the current inspection of undersigned and found that the firm has approved section of Lotion (G).

Submitted for your kind information and further necessary action into the matter, please."

Decision of the Central Licensing Board in 290th meeting:

The Board considered and approved the grant of renewal DML for Lotion (General) Section for the period commencing on 11-04-2021 and ending on 10-04-2026 .

Case No. 17. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000428 (FORMULATION) OF M/S FLOW PHARMACEUTICALS (PVT) LTD, 17-KM SHEIKHUPURA ROAD, LAHORE.

M/s Flow Pharmaceuticals (Pvt) Ltd, 17-Km Sheikhupura Road, Lahore had applied for renewal of DML No. 000428 by way of formulation on 26-03-2021 for the period of 26-03-2021 to 25-03-2026. The application for the renewal of DML was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 1st July, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Late fee surcharge of Rs.75,00/-.
ii. Properly filled, signed & stamped Form-1A (as per format) along with its all annexures.
iii. Latest certified true copy of Form-29 duly attested by SECP (Original).
iv. Updated Nothing Due Certificate regarding CRF from STO, DRAP.
v. Detail of management, if any change, apply for the change of management.
vi. Duly attested CNIC copies of all Directors.

The firm did not reply and reminder was issued on 13th September, 2021 to the firm for submission of following documents: -

i. Late fee surcharge of Rs.75,00/-.
ii. Properly filled, signed & stamped Form-1A (as per format) along with its all annexures.
iii. Latest certified true copy of Form-29 duly attested by SECP (Original).
iv. Updated Nothing Due Certificate regarding CRF from STO, DRAP.

v. Detail of management, if any change, apply for the change of management.
vi. Duly attested CNIC copies of all Directors.

The firm has not replied and application for renewal of DML No. 000428 (Formulation) is still incomplete.

In the meanwhile, a Court Order No.1895-96/DC/Rawalpindi dated 13th December, 2022 received from Chairman Drug Court, Rawalpindi Division, Rawalpindi in the case No. 3995/Judl/Dc/RWP/2019 which is reproduced as under:

The Above mentioned case has been filed against Flow Pharmaceuticals (Pvt) Ltd and others on the charge of manufacturing and sale of substandard drug and for issuing false warranty. The accused firm and its officers being responsible for manufacturing and sale of substandard drug at the relevant time are being summoned by this court but their service has not yet been affected as they are intentionally hiding from the process of law. You are directed that if the said firm apply for the renewal/issuance of new DML, its license must not be renewed/issued and the firm be directed to approach this court in connection to Case No.3995/Judl/DC/RWP/2019 and their case of DML be kept pending till the decision of the case by this court.

Decision of the Central Licensing Board in 290th meeting

The Board in the light of direction of the Honorable Drug Court Rawalpindi vide Order No.1895-96/DC/Rawalpindi dated 13th December, 2022 in Case No.3995/Judl/DC/RWP/2019 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 Drug Manufacturing License No 000428 by way of formulation of M/s Flow Pharmaceuticals (Pvt) Ltd, 17-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.

CASE NO. 18. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000728 (FORMULATION) OF M/S. DERMA TECHNO PAKISTAN, PLOT NO. 528, SUNDER INDUSTRIAL ESTATE, LAHORE.

M/s. Derma Techno Pakistan, Plot No. 528, Sunder Industrial Estate, Lahore. DML No. 000728 (Formulation) Period: Commencing on 15-06-2021 & ending on 14-06-2026.	**06-12-2022**	**-**	1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller Punjab. 2. Dr. Syed Zia Husnain, FID, DRAP, Lahore. 3. Hafiz Sanaullah Babar, Assistant Director, DRAP, Lahore.

Observations & Recommendations of the panel:

Observations related to premises:

i. Experience of QA Manager is 4.5 years which is a violation of S.R.O 1460(1)/2019 which requires that QA Manager should have at least 06 years of experience.

ii. The documentation system of the firm was poor i.e. SOPs were missing and the SOPs that were available were not being adhered to. The documentation retrieval system was also poor.

iii. The facility was not designed as per layout plan approved by the division of Drugs Licensing DRAP Islamabad i.e. the firm had made new raw material stores, receiving bays, dispensing areas and liquid material store that were not approved by the concerned division.

iv. Specifications were not mentioned on the containers of API present in the Raw Material Store. Moreover, the API quarantine area was inappropriate which blocked the entrance of the cold storage area.

v. Sampling booth was not installed properly. There was space constraint. Common weighing balance was being used in both the dispensing booths and the sampling booth.

vi. There were huge gaps between the doors and the door closure system were also faulty that resulted in loss of differential pressure between the different sections. Doors also needs to be replaced.

vii. IPQC Lab in the steroidal cream section was incomplete. Only a weighing balance was provided the lab.

viii. There were no fixtures or change over facility provided in the male and female change room of the steroidal cream section.

ix. The firm had constructed a newly approved area i.e. Dry powder suspension (Macrolide). However, on inspection it was revealed that the firm had installed a liquid sachet filling machine and Tomato Ketchup labeled reel was fitted on the machine for packing. Panel suspected that the firm fill the tomato ketchup with that machine installed in dry powder suspension (macrolide) section (Pictorial evidence attached).

Observations related to the Quality Control Laboratory:

i. Quality control laboratory did not have appropriate equipment ie. Karl Fischer Titrey and Potentiometer were not available which are required for testing as per approved specifications of the registered products of the firm.

ii. No reference standard for test/analysis was present for any product. Moreover, the working standards were also derived from raw material of unknown source rather than the reference standard. No impurity testing for APIs was being conducted.

iii. Log books were not properly maintained and Quality control lab did not had any reagent balance sheet.

iv. Firm is not following official specifications for testing of products that are in official Pharmacopoeia.

v. Microbiology lab has only 02 buffers.

CONCLUSIONS

Panel has thoroughly evaluated the various documents in connection with production, Quality Control and Quality assurance systems of the unit. Panel also inspected the plant and discussed various technical aspects at length with the technical staff. After thorough evaluation of documents provided by the management and inspection of the unit panel was of the view that besides many other observations mentioned above firm has made major changes in the layout without approval of Licensing Division of DRAP. Moreover, Quality Control department was without the necessary equipment required for testing of registered products as mentioned above. Tomato Ketchup labeled reel was fitted on the machine for packing. Panel suspected that the firm fill the tomato ketchup with that machine installed in dry powder suspension (macrolide) section. Under the explained circumstances mentioned above in the report; panel was of the view to not recommend the facility at this stage for grant of renewal of Drug Manufacturing License to M/s. Derma Techno Pakistan Sunder Industrial Estate Lahore.

Decision of the Central Licensing Board in 289th meeting

The Board considered and decided to serve the Show cause notice to the firm and to stop the production activity till rectification of the observations made during inspection.

Proceeding of Licensing Division in compliance to Decision of the Central Licensing Board:

The show cause notice was issued to the firm on 03rd March, 2023.

The firm has submitted revised lay out plan for approval and CAPA in reply to show cause notice.

LOP committee discussed the proposed layout plan. The matter has already been discussed by CLB in the 289th meeting and the CLB has issued show cause to the firm. The firm has submitted the CAPA and revised LOP. The committee decided to refer the proposed LOP to the panel for verification and recommendation whether the proposed LOP *fulfills the requirement of Schedule-B in terms of men, material and process flow according to guidelines.*

Following panel is re-constituted by Chairman Licensing Board after transfer of Dr. Syed Zia Husnain, FID, DRAP, Lahore to Islamabad;

1. Chief Drugs Controller Punjab.
2. Dr. Akbar Ali, DD (QA/LT), DRAP, Islamabad.
3. Assistant Director, DRAP, Lahore.

The panel has inspected the firm on 14-04-2023 and recommendation of the panel is as under:

Recommendations:

Based upon the physical inspection of manufacturing and testing facility of the premises conducted, Technical people met and review of record/documents, for verification of improvements / expansions /amendments made by firm in already approved Lay Out Plan (LOP) submitted by firm and verification of CAPA generated by firm after the previous inspection conducted on 16-07-2022

for grant of Drug Manufacturing Licensing renewal. The panel reconstituted under rule 8(17) read with rule 10(1) and (2) of the drugs (licensing, Registration and Advertising) rules 1976 recommends the approval of revised/amended/extended LOP submitted by firm in Licensing division as it is more GMP complainant in terms of Schedule B regarding men-material and personal flow. The panel is also of the view that firm has fulfilled the observation through CAPA as pointed out in previous inspection for Grant of Drugs Manufacturing License therefore recommend for consideration of Licensing Board for DML renewal of M/s Derma Techno Pakistan, 528-Sundar Industrial Estate, Lahore, (DML No 000728) for following sections

i. Tablet (General) Section
ii. Capsule Section (General) Section
iii. Cream/Ointment (General) Section
iv. Topical Lotion (General)Section
v. Semi Solid (Steroidal) Section

Decision of the Central Licensing Board in 290th meeting

The Board considered and approved the grant of renewal of DML No. 000728 by way of Formulation in the name of M/s. Derma Techno Pakistan, Plot No. 528, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period of Commencing on 15-06-2021.

i. Tablet (General) Section.
ii. Capsule Section (General) Section.
iii. Cream/Ointment (General) Section.
iv. Topical Lotion (General)Section.
v. Cream/Ointment (Steroidal) Section.

Case No-19. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000259 OF M/S SIZA INTERNATIONAL (PVT) LTD, 18-KM, MAIN FEROZEPUR ROAD, LAHORE.

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

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

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

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

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

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12, Rule 16and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000259 by way of formulation of M/s Siza International (Pvt) Ltd, 18-KM, Main Ferozepur Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

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

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

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

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

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

Case No.20. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000228 OF M/S PHARMEDIC LABORATORIES (PVT) LTD, 16-KM, MULTAN ROAD, LAHORE.

M/s Pharmedic Laboratories (Pvt) Ltd, 16-KM, Multan Road, Lahore had applied for renewal of DML No. 000228 by way of formulation for the period of 07-04-2020 to 06-04-2025. 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 29th October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form 1A as per prescribed format.
ii. Classes of drugs & dosage form of drugs.
iii. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
iv. Latest Certified true copy of Form-29 (Attestation by SECP).
v. Attested CNIC's copies of all Directors.
vi. Detail of premises including layout plan.
All documents should be duly attested.

The firm submitted their reply on 24th December, 2020. After evaluation of the submitted documents, final reminder was issued on 5th April, 2021 to the firm with following shortcomings:-

For Renewal of DML.

i. Form 1A as per prescribed format.
ii. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
iii. Latest Certified true copy of Form-29 (Attestation by SECP).
iv. Attested CNIC copies of all Directors.
v. Detail of premises including layout plan.
All documents shall be duly attested.

However, the application of Renewal of Drug Manufacturing License is still deficient for following documents: -

i. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
ii. Latest Certified true copy of Form-29 (Attestation by SECP).

The case was placed before the Central Licensing Board in its in 285th 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000228 by way of formulation of M/s Pharmedic Laboratories (Pvt) Ltd, 16-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 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 26/05/2022.

The firm replied in response of Show Cause Notice which is reproduced as under

"In regard to the decision of CLB in its 285th meeting to serve show cause notice to M/s Pharmedic Laboratories as to why its DML should not be suspended or cancelled, we hereby state that we have tried to submit attested copy of Form-29 but

the DRAP has refused to accept the copy as SECP has stated on the attestation the following words: "Certified to be true copy. however, this office accepts no responsibility as to the correctness of the details given in the document". We have been told by officials at DRAP that the stamp should just contain the words: "Certified To Be True Copy".

The board may kindly note that as per the version of the SECP, the department uses these words in such a case where the company has a litigation pending in any court of law. Currently their is no outstanding litigation against the company or involving any of its directors however since the litigation has just recently ended the SECP, as we have been informed, shall only revert back to the standard attestation after the filing of the next Form-29 by the company.

We are engaged with the SECP in efforts to obtain the document as is required by DRAP. In case the SECP refuses to entertain our request we shall submit the same after the next filing of the Form-29. The company accepts full responsibility to the correctness of the Form-29."

The firm submitted from-29 Form-29 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"

However, the firm did not rectify above mentioned shortcoming.

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. Shahid Iqabl and Mr. Hassan Javid representative of the firm appeared before the Board. They contended that the case was under litigation at SECP and the case has been resolved/decided. They further contended that they will provide/submit updated Form-29 attested as true copy (in original) without disclaimer/qualification within a week. The Board decided to accept firm's request and decided that the firm shall submit Form 29 within 15days and the case be placed before the Board in its upcoming meeting for its consideration.

M/s Pharmedic Laboratories (Pvt) Ltd, 16-KM, Multan Road, Lahore, has submitted attested Form-29 in response to this Division's letter dated 17th November, 2022 for renewal of Drug Manufacturing License. The application for renewal of Drug Manufacturing License No. 000228 for the period from **07-04-2020 to 06-04-2025** is now complete. The case may be placed in agenda of next meeting of Central Licensing Board for revocation of Show Cause Notice issued to the firm on 26th May, 2022.

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

The Board while considering the facts on the record decided to revoke the show cause notice issued to the firm.

Case No. 21. SITE VERIFICATION OF M/S INCEPTA PHARMA, TAXILA.

M/s Incepta Pharma, Plot No.17-A, Punjab Small Industrial Estate, Taxila applied for site verification of proposed plot. After application was completed by the firm, FID 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 Ms. Tehreem Sara, FID-IV, DRAP, Islamabad and the recommendations of the inspection report are as under: -

1.	**Location**	**:**	The premises of M/s Incepta Pharma, Plot No.17-A, Punjab Small Industrial Estate, Taxila is located in the industrial Area approved by Punjab Small Industrial Estate. The site is away from residential and commercial area.
2.	**Surrounding**	**:**	Premises/Plot (at present) is situated in an industrial area & open environment surrounded by other industries which is **marble** and **Granite** which produces large quantities dust (causing unsuitability of surrounding), may result in contamination if the drugs will be manufactured or adversely affect its quality. The firm is responsible in future for the environmental control of their manufacturing unit
3.	**Size**	**:**	Total area of the plot is18000 square feet = 04 kanals (as reported by Regional Director, Punjab Small Industries Corporation, Rawalpindi.
4.	**Recommendations**	**:**	The location under consideration is "**Not Suitable**" for a pharmaceutical unit as per requirements laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(1)/98 dated 15-5-1998 under rule 16 (a) of the Drugs (Licensing, Registering and Advertisement) Rules, 1976 with reference to the **Surroundings & Size** requirement in the above stated Rules.

5. Other Observations noted by the inspector(s):

5.1 At present, the details are as under:

a) in-front of the site there is a street road.

b) At the back there is storage area of tough tiles.

c) On the left is **Granite industry.**

d) Right side. There is a **Marble industry**.

5.2 The firm has already approved Health and OTC unit from DRAP having appox.70 enlisted products which covered the approx. 2 kanals of the total area of plant.

5.3 Mr. Jawad Naeem (Managing Partner) of M/s Incepta Pharma, Plot No. 17-A, Punjab Small Industrial Estate, Taxila was present at the site and accompanied during the visit.

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

The Board while considering the facts on the record decided to give an opportunity of Personal hearing to the firm in upcoming meeting of the Central Licensing 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 20th April, 2023.

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

Mr. Jawad Naeem Director of the firm appeared before the Board. He contended that Marble and granite are using wet cutting technology which produces less air pollution and the firm will install efficient HVAC to ensure the manufacturing of quality medicine under controlled environment.

The Board considered the request of the firm and decided as follows:

a. to re-inspect the premises by panel comprising of Deputy Director Licensing Division and representative of QA/LT (other than FID).
b. to seek the report/recommendation from relevant Environment agency.

Case No. 22 APPROVAL FOR ENEMA MANUFACTURING IN LOTION (TOPICAL) SECTION OF M/S ATCO LABORATORIES LTD, B-18, S.I.T.E., KARACHI.

The firm M/s Atco Laboratories Ltd., B-18, S.I.T.E., Karachi has submitted request for approval of Enema manufacturing in their already approved Lotion (Topical) Section. The firm has submitted that they have updated its manufacturing facility as per Current GMP requirements and in this regard, they have developed a multistory new building which has all advance resources to manufacture different pharmaceutical dosage forms e.g. OSD, Oral Liquid, Topical, Liquid Injectable and Eye/Ear/Nasal Drops etc. All sections have been approved by DRAP and successfully shifted to new building namely Unit-II. But, manufacturing of Microenema solution is still continued in old building because the firm have no DRAP approval to manufacture Microenema in new building.

The firm further informed that as per their estimation, Lotion and Microenema manufacturing requirements are same in terms of equipments as well as process flow. Therefore, it is requested to allow us the manufacturing of Microenema Solution in our already approved "Lotion Section" either in Routine basis or as per Campaign policy. The firm has also attached comprehensive Risk Assessment report for both Routine and Campaign manufacturing of Microenema Solution in Lotion section.

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

The Board while considering the facts on the record decided to defer the case for further deliberation. The Board further decided to constitute the working group comprising of representatives of Divisions of QA&LT, Licensing and PE&R Divisions, DRAP and from PPMA and Pharma Bureau (observer) to bring forth recommendations regarding permission to manufacture the Enema in Lotion (Topical) Section or otherwise.

QUALITY ASSURANCE CASES

(GMP NON-COMPLIANCE)

INDEX

Item No. I **ITEM NO. I cGMP NON-COMPLIANCE MATTERS**

Case No. I: - **M/S. WELWINK PHARMACEUTICALS, G.T. ROAD, INDUSTRIAL ESTATE, GUJRANWALA CANTT, GUJRANWALA.**

BACKGROUND

1. QA received letter No. 17364/2019-DRAP(L-III) dated 31.12.2019 from the Area FID DRAP, Lahore. Enclosed is the GMP inspection report of the firm M/s. Welwink Pharmaceuticals, G.T. Road, Industrial Estate, Gujranwala Cantt, Gujranwala conducted by following panel on 11.10.2019 to check the GMP compliance.

i. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore
ii. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore
iii. Ms. Maham Misbah, AD, DRAP, Lahore

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

Change Rooms: -

i. Improve the cleanliness of workers change rooms.

Storage Areas: -

i. Firm has not provided exterior solvent storage area and drums of solvents i.e. IPA were placed in receiving bay.
ii. HVAC was not provided in RM dispensing room.
iii. Sampling booth was not provided.

Production Areas:

Tablet Section: -

i. Differential pressures of rooms were not proper, manometers in drying room were not working and glass of windows was broken at some places.

Capsule Section: -

i. Differential pressure of filling room was not appropriate.

Sachet Section: -

i. Differential pressure of filling room was not appropriate.

Liquid Injectable Section: -

i. Ampoule / vial washing room was having a door directly opening in water treatment system room (Uncontrolled area) without any buffer.
ii. Epoxy flooring was damaged at various places.

iii. In filling room pressure gradient was not appropriate as per manometers. HVAC ducting was not appropriate both air supply and air return ducts were in the ceiling, suggesting inadequate air flow and supply in the filling room.
iv. Doors and windows were made of aluminum and glass, were not smooth / flushed, not being closed properly, gaskets were broken / damaged at many places having edges and recesses for accumulation of dirt and dust. Such doors and windows were not appropriate for sterile manufacturing area.
v. Buffers at entrance were not appropriate, pressure differentials were not adequate, doors were not being closed properly.
vi. There was no provision for supply of purified water for manufacturing, management informed that they carry purified / WFI form water purification system in buckets.

Dry Powder Injectable Section: -

i. Ampoule / vial washing room was having a door directly opening in water treatment system room (Uncontrolled area) without any buffer.
ii. Epoxy flooring was damaged at various places.
iii. In filling room pressure gradient was not appropriate as per manometers. HVAC ducting was not appropriate both air supply and air return ducts were in the ceiling, suggesting inadequate air flow and supply in the filling room.
iv. Doors and windows were made of aluminum and glass, were not smooth / vialflushed, not being closed properly, gaskets were broken / damaged at many places having edges and recesses for accumulation of dirt and dust. Such doors and windows were not appropriate for sterile manufacturing area.
v. Buffers at entrance were not appropriate, pressure differentials were not adequate, doors were not being closed properly.

Sanitation and Hygiene: -

i. Improve the general cleanliness of RM store, receiving bay and workers change rooms.

Qualification and Validation: -

i. Process and cleaning validations were not being carried out as per SOPs and no record for cleaning validation was provided.
ii. Media fill test for aseptic filling processes was not performed.

Complaints: -

i. No records were maintained and shown.

Product Recalls: -

i. The firm has not developed a proper SOP for product recall only a very rudimentary procedure was available. The firm was advised to upgrade the SOP and perform a mock recall to evaluate the effectiveness of the recall system.

Personnel: -

i. The firm has not hired adequate number of qualified persons. In addition to production manager, in production department there was only one Pharmacist despite the fact that firm has 5 manufacturing sections.
ii. Strengthen the production and QA sections by hiring adequate technical staff.

Equipment & Machinery: -

i. At the time of inspection FTIR was not present, the management informed that it was out of order and sent for maintenance.
ii. Karl Fischer was not available.
iii. Dissolution and Disintegration apparatuses required upgradation as their glass has become hazy / blurred.
iv. Digital Polarimeter was not provided.

Materials: -

i. Improve the material management system.
ii. The labels were not having complete information of the product as required to be.
iii. Maintain the storage conditions of stores as at the time of inspection, temperature and humidity of the PM store, where aluminum foils etc. were placed, was found out of specification.

Documentation: -

i. It was noted that BMRs in tablet section were not being filled appropriately with real time entries.
ii. Log books for QC instruments were not maintained.
iii. Log books for production machinery were not maintained.

Good Practices in Production: -

i. Workers were seen wandering outside the production area in uniform.
ii. In in-process quarantine of the tablet section a number of different products in different manufacturing stages were placed in poly bags / empty and dirty drums of raw materials without proper labelling and storage conditions.
iii. Real time entries of manufacturing procedure were not being made in BMR.

Good Practices in Quality Control: -

i. It was found that the log books were not being maintained properly. The SOPs were not being implemented in true letter and spirit. Deviations from standard procedures were observed.
ii. For most of the products firm was using in-house testing procedures (which were even not validated) in spite the fact that these products were included in official monographs of compendial books.
iii. The firm was using in house working standards for testing and was advised to purchase reference standards.

iv. No microbial cultures were available in microbiology lab. Firm was not performing growth promotion test for media.

Utilities:

Water Purification System; -

i. It was noted with grave concern that the firm has not provided loop system for supplying the purified water to manufacturing sections even no water transfer pipes were provided. Firm was carrying purified water to manufacturing section, even in sterile manufacturing areas, through buckets. It was also noted that firm was many times asked to install loop system for transferring purified water but no avail.

ii. *Fir has not validated its water purification system. The firm has not developed procedure for sanitization of water purification system.*

HVAC System; -

i. *It seemed to be in adequate in injectable sections as both air supply and return ducts were in ceiling, suggesting it to be incapable to provide class A/B for aseptic processing area. Manometers were not installed in some areas. In oral solid dosage sections pressure differentials needed to be adjusted properly as pressure gradients were not appropriate in different sections.*

ii. *It was also noted that there was no electricity generator as a backup in electricity shut down, this also put the manufacturing process in high risk especially the aseptic and sterile manufacturing processes.*

Conclusion: -

"Based on the areas inspected, the people met and considering the findings of inspection, the panel was of the opinion that at the time of inspection, the firm was:

i. ***Not complying*** *with the GMP requirements as required under the Drug (Licensing, Registering and Advertising) Rules, 1976 with reference to* ***Liquid Injectable and Dry Powder Injectable Sections.***

ii. Operating at a satisfactory level of compliance with the GMP requirements as required under the Drug (Licensing, Registering and Advertising) Rules, 1976 with reference to Tablet, Capsule and Sachet sections."

Recommendations: -

"In the light of conclusion, the panel recommends that the firm may be directed to stop production in liquid injectable and dry powder injectable sections. Rectify the deficiencies and submit CAPA."

Keeping in view the observations noticed and conclusion by the FID, it is proposed that we may issue **Explanation Letter / Suspension of Production Activities in Liquid Injectable and Dry Powder Injectable Sections** to the firm for giving reasons of such violations and to submit compliance report of the rectification of the observations.

2. Whilst the case was under processing for issuance of the above said letters the firm vide letter dated 06.01.2020 stated that the firm disagrees the report; the matter was placed before the Director QA&LT, accordingly a panel of experts was constituted by the Director QA&LT.

3. QA received letter vide No. 5045/2020-DRAP (L-VI) dated 13-4-2020 from Additional Director DRAP Lahore, enclosed was the panel re-inspection report of M/s Welwink Pharmaceuticals, G.T. Road Industrial Estate Gujranwala Cantt, Gujranwala.The inspection was conducted by following panel on 25-02-2020 to verify GMP compliance of the firm;

i. Mr. Abdul Rashid Sheikh FID, DRAP Lahore.
ii. Mr. Shoaib Ahmed FID DRAP Lahore.
iii. Ms. Anam Saeed AD, DRAP Lahore.

The panel made following advises and observations in the report;

Change Rooms

i. The firm was advised to install hand sanitizer and provide lockers for the workers to keep their belongings.

Storage Area:

ii. Provide exterior solvent storage area to store solvents/liquids.
iii. Provide HVAC ducting in dispensing room.
iv. Ensure availability of sampling booth.
v. Provide separate rejected area.
vi. Monitor temperature humidity of store because capsule shells were found stored inside Raw Material Store where humidity was 92% at the time of visit.
vii. Provide separate recalled / returned area.
viii. Improve labels.

Tablet Section:

ix. It was noted that differential pressures of rooms were not proper, manometer was not installed in mixing room. It was advised to maintain the differential pressure and install manometers in all rooms.

Capsule Section:

x. Differential pressure of filling room was not appropriate. It was advised to adjust the differential pressures.

Sachet Section:

xi. Differential pressure of filling room was not appropriate and humidity was found 65% at the time of visit.

Injectable Section:

xii. The firm was having a single autoclave which was used for sterilization of filled liquid vials as well as for sterilization of uniforms and utensils.
xiii. One side of autoclave was opened in vial washing room and other side was in cooling room (between liquid injectable filling room and dry powder injection filling room).

xiv. Ampoule / vial washing room was having a door directly opening in water treatment system (uncontrolled area) without any buffer. The firm informed that the door is not in use but it was advised to close it permanently.

xv. Firm was advised to validate HVAC system as differential pressures were not proper in many areas.

xvi. HVAC ducting in some rooms were not appropriate as both air supply and air return ducts were in the ceiling, suggesting inadequate air flow and supply in those areas. It was advised to make proper ducting.

xvii. Firm was advised to make doors and windows smooth/flushed with proper door closures.

xviii. Firm was advised to install air supply and air return ducts in all buffers as returns were not provided in some buffers and air supply ducts were missing in some buffers.

xix. It was advised to provide proper loop system because a paste cooking vessel was modified as a storage tank of WFI in water treatment as well as for supply of WFI in manufacturing areas which was not found appropriate.

xx. It was advised to provide cooling trolley with HEPA filter in the cooling zone.

xxi. It was advised to provide supply of RO water in solution preparation room.

xxii. It was advised to arrange separate autoclave for sterilization of uniform and utensils.

xxiii. It was advised to calibrate temperature and pressure gauges of the solution preparation tanks and install heat exchanger in solution preparation room.

xxiv. It was advised to replace screens of optical checking and ensure availability of Lux meter.

xxv. It was advised to perform media fill trial.

Quality Control

xxvi. HVAC ducting was not appropriate in microbiology laboratory and its buffers.

xxvii. Improve LFC in sterility room as it was not working properly at the time of inspection.

xxviii. Ensure the availability of air sampler and improve area monitoring reports as advised.

xxix. Purchase reference standards

xxx. Perform media fill trial.

xxxi. Ensure the availability of FTIR, Karl Fischer and Digital Polarimeter.

xxxii. Upgrade Dissolution and Disintegration apparatus.

xxxiii. Ensure the availability of cultures in microbiological laboratory.

xxxiv. Perform growth promotion test for media.

Personnel:

xxxv. Only 1 pharmacist in addition to production pharmacist was working despite the fact that firm had 5 manufacturing sections. The firm had one QC Manager who was M.Sc. Chemistry and one pharmacist who was working as microbiologist. In QA there was only one pharmacist who was a fresh graduate. The firm was advised to strengthen the Production and Quality Assurance Departments.

Water Purification System:

xxxvi. The system was not functional at the time of visit and also found inappropriate. Firm had also not validated its water purification system and not developed procedure for sanitization of water purification system.

xxxvii. Provide proper storage tank for WFI with a proper loop system.

xxxviii. Validate water purification system.

xxxix. Develop procedure for sanitization of water purification system.

HVAC System:

xl. Both air supply and return ducts were found in ceiling, inside some areas of injectable sections, suggesting it to be incapable to provide class A/B for aseptic processing, areas. Manometers were not installed in some areas. Differentials pressures required adjustments as pressure gradient were not appropriate in different sections. Firm was asked to provide HVAC validation data but the firm could not provide the same to the panel.

xli. It was also noted that there was no electricity generator as a backup in electricity shut down, this also put the manufacturing process in high risk especially the aseptic and sterile manufacturing processes.

The Conclusion of report is reproduced below;

"Based on the areas inspected, the people met and considering the findings of inspection, the panel is of the opinion that the firm was operating at satisfactory level of GMP compliance for all sections ***except Liquid Injectable Section*** *because of absence of proper loop system and others observations pointed out above in the different areas as well, As the improvements of the system is a continuous process."*

Keeping in view the critical observations noticed, noncompliance behavior of the firm and conclusion by the panel, it is proposed that we may issue **Show Cause Notice** to the firm M/s Wellwink Pharmaceuticals Gujranwala for the observations noted by the panel in the general production area and specifically in Liquid Injectable Section, for giving reasons of such violations and to submit compliance report of the observations noted by the panel. Accordingly, DFA was placed on file for approval; however, the Director QA&LT pointed out that the panel had rated the compliance level of the firm as satisfactory with critical observations hence clarification was sought from the panel vide letter dated 15.05.2020.

4. QA received the letter No. 11592/2020-DRAP (L-VI) dated 18-08-2020 in response to this office letter of even No. dated 15-05-2020 wherein directions of the Director QA&LT were communicated to following panel to give clarification on critical points in their report dated 25-02-2020;

i. Mr. Abdul Rashid Sheikh FID, DRAP Lahore.
ii. Mr. Shoaib Ahmed FID DRAP Lahore.
iii. Ms. Anam Saeed AD, DRAP Lahore.

The panel has given following reply;

"As GMP is ongoing improvement process, whereas the firm also addressed some points which were already mentioned. However, as there were no such critical observations in the recommended sections as per the view of the panel. The panel did not recommend the "liquid injectable section" of the firm. Since there were no critical observations in the remaining sections other than liquid injectable section. So, the panel keeping in view the major and minor observations, recommends their other approved sections, except ***liquid injectable section.*** *The panel is of the opinion that firm was operating at satisfactory level of GMP at the time of inspection."*

In light of above, firm was informed vide letter dated 07.09.2020 that Production in liquid injectable section shall remain suspended till submission of compliance report, verification by panel and subsequent approval from competent authority as panel did not recommend the liquid injectable section.

5. The firm vide letter dated 22.09.2020 challenged the GMP inspection report conducted by panel of experts on 25.02.2020. The matter was placed before the CEO (DRAP) who approved that the matter may be placed before the CLB in the forthcoming meeting. Subsequently, the matter was placed in the 277th and 278th meeting of the CLB; after giving the opportunity of being heard the Board decided that: -

i. To direct the firm to submit compliance report on the observations noted in panel inspection reports dated 11.10.2019 & 25.02.2020.
ii. Production in Sterile Area (Liquid Injectable) of the firm M/s. Welwink Pharmaceuticals, Gujranwala shall remain suspended.
iii. The Additional Director (QA & LT) shall decide the matter accordingly.

6. The firm did not submit compliance report however, inspection of M/s Welwink Pharmaceuticals, G.T Road Industrial Estate, Gujranwala Cantt, Gujranwala, conducted on 28.07.2022 by Dr. Syed Zia Husnain, FID, DRAP, Lahore and Mst. Maham Misbah, Assistant Director, DRAP, Lahore for grant of GMP certificate was received in QA section. The panel has rated the firm on the Schedule B-II proforma as under:

- Good Compliance (Needs improvement) =86

- Fair Compliance (Needs active improvement) =131
- Poor Compliance (Needs active improvement & stoppage of production) = 49

The Panel had concluded *"The inspection of M/s Welwink Pharmaceuticals, GT Road, Gujranwala was conducted on 28-7-2022 for verifying compliance to cGMP. The details of the findings of the panel are given in the report above. As cGMP is a continuously evolving process and consistent day to day effort by the firm, the panel was of the pinion that the firm had fair compliance of GMP in the following three sections, at the time of inspection: Tablet (General), Capsule (General), powder Sachet (General).*

The production in Liquid Injectable section (General) had not been resumed. Matter of resumption of production in Liquid injectable is already under process at Directorate of QA &LT, DRAP, Islamabad. Moreover, the firm's representatives were given several advices to upgrade the manufacturing facility and quality monitoring of Dry Powder injection section (General) and Liquid injectable section (General). Details are noted in the checklist above. On the basis of risk-based approach, the panel is of the opinion that firm shall submit CAPA against the observations noted above as well as previously pointed out and re-inspection of both injectable sections may be conducted, accordingly"

REPLY OF THE FIRM

The firm submitted reply vide letter No. Nil dated 6th February 2023 bearing subject **"Submission of CAPA".** Wherein Rana Taimoor, Regulatory Manager of the firm had informed that deficiencies on serial No. 1-7 have been rectified adequately. Deficiencies pertaining to the Dry Powder Injection Section on serial No. 8-11 have been challenged as the firm has stated in their reply that the **disagree** with the deficiency pertaining to the absence of Automatic filling and sealing machine.

EVALUATION OF THE REPONSE

Deficiency pertaining to the Liquid Injectable section on serial No.13-20 of the CAPA submitted by the firm; too have been challenged with proclaimed reason of legacy product and construction being as per approved layout plan. Similarly, deficiencies on serial No. 21-25 have been claimed to be rectified. Summarizing the above, 12 out of the 25 deficiencies have been challenged as the firm does not agree with the deficiencies made; 13 deficiencies have been claimed to have been rectified, no evidence of rectification has been provided by the firm. Hence, CAPA submitted by the firm is not satisfactory as the firm had challenged the deficiencies pointed out in injectable sections instead of rectifying the same.

RECOMMENDATION FROM QA&LT

In view of the scenario detailed above the QA&LT Division recommends that, since the firm is disagreeing to accept all /any observation made by panel of experts deputed by the Directorate of QA&LT, despite the fact that three inspections having different panel members have identified similar observations pertaining to the Sterile manufacturing facilities of the firm, reflect that the firm's claims regarding the panel of experts are biased towards the firm are false and baseless. **Therefore, under rule 12 of the Drugs (Licensing Registering and Advertising) Rules 1976; the proceeding for Cancellation or Suspension of Licenses may be initiated under 12 (1)** *If licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, …, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates*. **Through formal procedure under rule 12 (2)** *The Central Licensing Board shall, before cancelling or suspending a license under sub-rule (1), provide an opportunity of being heard to the licensee*.

In view of the case history such situations may pose a great risk on consumers of these products.

PROCEDING 290TH MEETING OF CLB: -

During the detailed deliberation on the reply of the firm regarding the Dry Powder Injection Section of the firm, wherein the firm had disagreed with the observation ***"Automatic filling and sealing machine as manual machines have high risk of contamination; immediate replacement required"*** *of the panel from last inspection, as they claim* ***"In last 10 years we have manufactured around 1 million injectable products during last 10 years, we have never been declared sub-standard in injectable section product. So there's no such cross contamination in this case. Despite of this, for the upgradation we shall soon upgrade our machines to fully automatic."***

The Board observed that since the recent Good Manufacturing Practices guidelines 1st Edition published by DRAP refer to the Annex-1: Manufacture of sterile medicinal products and Guide to Good Manufacturing Practices for Medicinal Products' published by Pharmaceutical Inspection Co-operation Scheme (PIC/S) (Doc. No. PE 009-16, 1 February 2022). Therefore, the matter for use of manual/semi-automatic powder filling machines (generally used for filling of oral powder and not suitable for aseptic filling of powder in injectable section) needs to be evaluated by a working group comprising of representatives of Divisions of QA&LT, Licensing of DRAP and from PPMA and Pharma Bureau. The working group shall bring forth recommendations regarding the use of manual/semi-automatic filling and sealing machines in light of the above mentioned guidelines in the next meeting of CLB, so that harmonized decision making may take place regarding these critical operations.

DECISION OF 290TH MEETING OF CLB: -

The Board after thorough deliberation on the facts of the matter; concluded that since firm has violated Section 23(1)(b) of the Drug Act, 1976 read with DRAP Act, 2012 and Rules framed thereunder, therefore decided as under;

i. *To issue Show Cause Notice to firm along with providing opportunity for personal hearing.*
ii. *Production activities in the Liquid injectable and dry powder injectable sections of the firm shall remain suspended until the verification of rectifications made by the firm and subsequent processing through the Directorate of QA&LT.*
iii. *Director QA&LT Division to constitute the working group comprising of representatives of Divisions of QA&LT, Licensing of DRAP and from PPMA and Pharma Bureau (observer) to bring forth recommendations regarding the use of manual/semi-automatic filling and sealing machines in aseptic filling area of dry powder injectable sections in next meeting of CLB.*

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

BACKGROUND

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

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

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

Premises entrance

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

Stores (Raw material store and Packing material store)

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

v. The API of product in question i.e. Linzolid was also checked by the panel. Firm provided ADC clearance of 25 Kgs of Linezolid from DRAP Lahore office however, firm had 17kgs out of 25kgs present in their store at the time of inspection. Management of firm claimed that they had only made 03 batches of Linzonov injection however on scrutiny of record it was suspected that firm had made more than 03 batches of product Linzonov infusion of which the BMRs were not present at the time of inspection. On enquiry, the management of firm replied that they had made 02 or 03 more batches of product Linzonov infusion but could not show the record of those batches during visit of the panel.
vi. There were un-identifiable and un-labelled cartons having packing materials and glass vials along with un-labelled bags suspected to contain active pharmaceutical ingredients were present in the packaging material store. The unlabeled bags and cartons were seized by the area Provincial Drug Inspector.

Finished goods store

i. There was no quarantine area and recalled/returned stocks area present in the store.
ii. Samples of product Linzonov Infusion were taken from the retained sample store for the purpose of test/analysis by the Provincial Drug Inspector.
iii. Syrup Section
iv. Doors of the syrup section were damaged, HVAC was not working and the pressure gauges were out of order.
v. The paint on the walls was flaking and the epoxy flooring was damaged that exposed the floor beneath.
vi. Packing material for Linzonov Infusion was stored in the quarantine are of the syrup section.
vii. Firm staff was washing glass infusion bottles in the syrup section. Broken glass shards were scattered all over the bottle washing machine and the floor of syrup section.

Injectable Section

i. Doors of the injectable section were damaged and HVAC was turned off. The pressure gauges were out of order
ii. The buffers were not maintained i.e. the buffer doors were open while sterile filling was being done in the filling section. There was no interlocking of buffers present.
iii. Lights were out of order, paint on the walls was flaking, floor epoxy was damaged reveling the floor below and there was liquid spillage on the floor in the corridors and filling area of sterile section.
iv. Sterile filling was being conducted in an un-controlled area and through an open stainless steel container and the material present in the container (claimed to be paracetamol IV solution) was being filled in the glass infusion

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

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

Tablet section

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

Quality Control

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

Quality Assurance

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

Documentation

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

ACTION TAKEN BY QA&LT

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

REPLY OF THE FIRM

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

EVALUATION OF THE REPONSE

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

RECOMMENDATION FROM QA&LT

In view of the scenario detailed above and the fact that the instant inspection was conducted in response to the **Cluster of serious adverse events with inj linzonov 600 mg (Linezolid) Batch No. LN003**, and the initial investigation report; the QA&LT Division recommends that, under rule **12 of the Drugs (Licensing Registering and Advertising) Rules 1976; the proceeding for Cancellation or Suspension of Licenses may be initiated under 12 (1)** *If licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, …, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates*. **Through formal procedure under rule 12 (2)** *The Central Licensing Board shall, before cancelling or suspending a license under sub-rule (1), provide an opportunity of being heard to the licensee. Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 28.04.2023.*

Representative of the firm M/s. Novartana Pharmaceutical, Lahore has been called upon for personal hearing

PROCEDING 290TH MEETING OF CLB: -

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

DECISION OF 290TH MEETING OF CLB: -

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

Case No. III: - M/S. MEDHOUSE PHARMACEUTICAL 1 KM OF 16 KM SARGODHA ROAD MANGOWAL, GUJRAT.

BACKGROUND

1. QA received Letter No.11023/2022-FID(L-II) dated 20.11.2022, received in this office on 25.10.2022 titled **"Seizure of Stock under section 18(1) of the Drugs Act, 1976-from M/s Medhouse Pharmaceuticals 1-K.M. off 16-K.M. Sargodha Road., Mangowal Gujrat"**. Wherein Dr. Syed Zia Hasnain, FID-II, Lahore had reported that he along with Drug Controller Gujranwala, Deputy Drugs Controller Gujranwala, Secretary DQCB Gujranwala, Drug Controller Sare-e-Alamgir, DDC Kahrian and DI Pasrur inspected the premises of M/s Medhouse Pharmaceutical, Mangowal Gujrat on 19.10.2022. Production In-Charge Ms. Madiha Iqbal, QC In-Charge Mr. Rahat Khan and Mr. Farrukh Mushtaq Director Operation were present. Mr. Rohail Aslam (Purported to be CEO by the above mentioned persons) was not available.

2. The inspection team reported that at the time of inspection following products/ items were found in your firm stored in finished goods store/packing store having fake and fictitious product registration and DML number:

Sr. No.	Name Drugs/Reg. No.	Batch No.	Mfg. date	Exp. date	Mfg by	Quantity	Reason for Seizure
1.	Inner Label of CiproMed Veterinary Oral Liquid DRAP Enlistment No. 00807 with label Claim of Ciprofloxacin 200g/1000ml	-NA-	-NA-	-NA-	DRAP Enlistment No. 00807	2 Bundles	All above products / drugs are manufactured by M/s Medhouse Pharmaceuticals (Pvt) Ltd. 1 km off 16 km Sargodha Road mangowal, Gujrat and placed in finished good store (item 04 to 06). Packing material store items (Sr 01 to 03)

							intended to used for manufacturing of un-registered drugs. Products at Sr. 04 to 06 were suspected to be without valid registration and labels also bear Licensing No., Form 6 Number wrongly which are violation of DRAP Act 2012 and Drugs Act 1976.
2.	Inner Label of Ciprofloxacin Med Veterinary Oral Liquid, DML No. 00949 with label Claim of Ciprofloxacin 200g/1000ml:	-NA-	-NA-	-NA-	M/s Med-house Pharmaceuticals (Pvt) ltd., 1 K.M off 16 K.M Sargodha Road, Mangowal Road, Gujrat	1 Bundle	--do--
3.	Outer Carton of Tilphyllin-B Veterinary Oral Liquid 01 Liter, DML No. 000949, Reg. No 165936.	-NA-	-NA-	-NA-	M/s Med-house Pharmaceuticals (Pvt) ltd., 1 K.M off 16 K.M Sargodha Road, Mangowal Road, Gujrat	05 Bundles	--do--

4.	Broncho Dell Veterinary Oral Liquid, Reg. No. 102313.	-NA-	Sep 2022	Sep 2024	M/s Med-house Pharmaceuticals (Pvt) ltd., 1 K.M off 16 K.M Sargodha Road, Mangowal Road, Gujrat	02 Carton x 12 Bottles	--do--
5.	Ultramol DS Powder Reg. No. 189632.	ULDF 008	May 2022	2024	DML No. 00807	01 Carton x 12 Bottles	--do--
6.	Med-Dine Powder 1kg. Reg. No. 136986.	MDD F003	May 2022	May 2024	DML No. 00807	01 Carton x 12 Bottles	--do--
7.	Ultrmol DS Powder (1kg)	ULDF 007 and ULDF 008	May-2022	May-2024	-NA-	09 Cartons x 12 Bottles and 05 Bottles	Products/drugs at serial 7-12 were placed in finished goods store and suspected to be manufactured by M/s Medhouse Pharmaceuticals (Pvt) Ltd., 1 km off 16 km Sargodha Road, Mangowal West, Gujrat without valid registration and labels bear License No./ form 6 number wrongly.
8.	Broncho Dell Veterinary Oral Liquid Reg. No 102313	-NA-	Sep-2022	Sep-2024	Manufactured by M/s Medhouse Pharmaceuticals (Pvt)	55 Bottles x 1 Liter	---do--

					Ltd., off 16 K.M Sargodha Road, Mangowal Road West, Gujrat		
9.	Macrodox-N Vet Oral Powder, Pack Size 1 Kg	MDNI 009	Aug-2022	Aug-2024	Manufactured by M/s Medhouse Pharmaceuticals (Pvt) Ltd., off 16 K.M Sargodha Road, Mangowal Road West, Gujrat	35 Bottles	---do--
10.	Virol Oral Powder Pack Size 1 Kg	-NA-	Aug-2022	Aug-2024	DML No. 00807	05 Cartons x 12 Bottles	---do--
11.	Med-Dine Powder, pack size 1 Kg, Reg 136986	--NA--	May-2022	May-2024	DML No. 00807	23 Bottles	---do--
12.	Tilphyllin-B vet oral liquid outer-carton Reg. No.165936	-NA-	-NA-	-NA-	DML 000949	05 Bundle	Suspected to be used for manufacturing of un-registered drugs.
13.	Label Floromed 23% DML 000949 Reg No. 102696	-NA-	-NA-	-NA-	DML 000949	03 Bundle	--do--

14.	Cipromed Oral Liquid inner label DRAP Enlistment No.00807	-NA-	-NA-	-NA-	DML No. 00807	01 Bundle	--do--
15.	Tilphyllin-B liquid inner label	-NA-	-NA-	-NA-	-NA-	02 Bundle	--do--
16.	Inner Label of Broncho Del Oral Liquid	-NA-	-NA-	-NA-	-NA-	01 Bundle	--do--
17.	Inner label of Floromed 23% oral Liquid	-NA-	-NA-	-NA-	-NA-	01 Bundle	--do--
18.	Inner label Ultramol DS powder	-NA-	-NA-	-NA-	-NA-	01 Bundle	--do--
19.	Aminophyllin e API (Purported)	-NA-	-NA-	-NA-	-NA-	03 Kg	Purported APIs seized were suspected to be used in manufacturing of un-registered drugs.
20.	Doxycycline Hyclate (Purported)	-NA-	-NA-	-NA-	-NA-	245 gm	--do--

3. The FID seized above products/items as an evidence of illegal manufacturing on Form 2 under Section 18(1)(f) of the Drugs Act, 1976 and Schedule V of the DRAP Act, 2012.

ACTION TAKEN BY QA&LT

The firm was issued Show cause notice on 22.03.2023, with information regarding the opportunity to be heard in person also communicated vide same letter. Subsequently, Reminder-I with information to nominate a representative to appear in person before the Central Licensing Board was communicated on 18.04.2023.

REPLY OF THE FIRM

The firm submitted reply has vide Letter No. Nil dated 3rd April, 2023; received in this office on 19.04.2023, wherein they have claimed that the seized products/drugs were manufacture in ***small quantities for clinical trial examination, test, analysis or personal use under Paragraph (2) of schedule-II of DRAP Act 2012***.

EVALUATION OF THE REPONSE

The firm has claimed to have manufacture the product/drugs in *small quantities for clinical trial examination, test, analysis or personal use under Paragraph (2) of schedule-II of DRAP Act 2012*; **No evidence for clinical trial or its approval from the Directorate of Pharmacy Services Division has been provided for review. The response is inadequate and unsatisfactory.**

RECOMMENDATION FROM QA&LT

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

Representative of the firm M/s. Medhouse Pharmaceutical, Gujrat has been called upon for personal hearing

PROCEDING 290TH MEETING OF CLB: -

The case was presented before the Board; Mr. Farrukh Mushtaq (Director Operations) on behalf of the firm appeared before the Board and reiterated the firm's version as narrated in written reply in the defense. The Board after detailed deliberations, reviewing the findings of inspection and statement of the firm was of the opinion that firm was found guilty of offences levelled against firm by the inspector for manufacturing of drugs without registration which is prohibited under section 23(1)(a)(vii) of Drugs Act, 1976 read with Schedule-VI of DRAP Act, 2012 and punishable under Section 27(1)(a) read with Schedule-VI of DRAP Act, 2012.

DECISION OF 290TH MEETING OF CLB: -

The Board after thorough deliberation decided as under;

i. *To suspend the Drug Manufacturing License (DML) of the firm for a period of One (01) year to the extent of two manufacturing sections only as follows:*
    a. *Oral Powder Section (General) Veterinary and,*
    b. *Oral Liquid Section (General) Veterinary".*
ii. *To direct the FID to lodge case in the Drug Court for prosecution.*

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

BACKGROUND

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

Change Rooms: -

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

Storage Areas: -

i. The firm has provided receiving bay for the incoming raw/ packing materials. However, receiving bay was found poorly maintained. No cleaning equipment was found for dusting / cleaning of incoming materials.
ii. No quarantine area was found / marked in ware house.
iii. No sampling booth facility is available.
iv. Rejection / Recall area is being used as quarantine area.
v. In the raw material approved area temperature / humidity needs to be properly maintained with supporting data / record.
vi. In the dispensing area, dispensing booth is not provided with proper air supply. The same dispensing booth is used for sampling of raw materials.

Tools for raw material dispensing also need to be properly labelled after cleaning.

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

viii. Empty Ampoules and vials storage area;

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

Production areas: -

Liquid Ampoules / Infusion Section: -

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

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

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

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

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

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

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

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

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

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

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

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

Dry Powder Vial Injection: -

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

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

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

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

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

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

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

Quality Control: -

i. The firm management has procured Liquid Particle Counter in the year 2020 but it was never functional.

ii. Similarly, Total Organic Carbon analyzer was also procured by the firm Management in 2020 but it was never functional.

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

Quality Assurance: -

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

Personnel: -

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

Allied facilities: -

i. The firm has not provided satisfactory loop distill water system along with proper monitoring as required for injectable areas as well as liquid injection manufacturing.
ii. Ancillary areas are also not up to the mark.

Conclusion

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

ACTION TAKEN BY QA&LT

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

REPLY OF THE FIRM

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

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

During FID visit the firm was already out of production from 2nd August, 2021. FID has visited and witnessed by himself and checked all areas and records there was noproduction at all.

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

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

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

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

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

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

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

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

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

Dear Sir,

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

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

CORRESPONDENCE BY QA&LT & ITS REPONSE

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

The firm submitted a detailed reply vide letter No. PRP/DRAP/2021 dated 01.10.2021 wherein they have stated that they are working on rectifying deficiencies pointed out by the FID. Furthermore, they have stated that rectification of most of the observations is associated with civil work. The civil work is associated with regularization of LOP, for which, they have applied.
The matter was placed before the Central Licensing Board in its 283rd meeting.

PROCEEDINGS OF 283RD MEETING OF CENTRAL LICENSING BOARD;

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

DECISION OF 283RD MEETING OF CENTRAL LICENSING BOARD;

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

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

b. Area FID DRAP Peshawar.
c. Area Assistant Director DRAP Peshawar.

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

PANEL INSPECTION REPORT

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

Change Rooms

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

Storage areas

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

Production Areas (Liquid Ampoules/ infusion section)

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

Dry Powder Vial Injection

The firm has improved area limited to paint/epoxy flooring and similar civil work, however, technical observations mentioned under the inspection report

dated 05th-06th August, 2021 were not addressed in letter and spirit nor any documentary evidence has been generated for any review.

Quality Control

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

Quality Assurance

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

Allied Facilities

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

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

RECOMMENDATION FROM QA&LT

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

Representative of the firm M/s. Pak-Risen Pharmaceutical, Hattar has been called upon for personal hearing.

PROCEDING 290TH MEETING OF CLB: -

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

DECISION OF 290TH MEETING OF CLB: -

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

Case No. V: - M/S IPP, 34-INDUSTRIAL TRIANGLE KAHUTA ROAD ISLAMABAD

BACKGROUND

The firm was selected for Risk based inspection for 2023, intimated vide Letter NO. F.6-27/2022-QA dated 21.012.2022, One of the purported Directors of the firm Mr. Nadeem Jawaid telephonically informed the Lead Auditor/ Area FID that due to some internal matters the production activities of the firm had been suspended by them to some internal matters the production activities of the firm had been suspended for some time and that the same had been communicated in writing to FID office. The FID on perusal of the record concluded that the firm had not informed neither the FID nor the Licensing Division regarding the halt of production activity. Subsequently, a team comprising of the following officers inspected the firm on 28.12.2022 to evaluate the veracity of the statement and GMP compliance of the firm: -

- Mst. Saadia Mahwish, FID-I, Islamabad.
- Mr. Muhammad Umar Latif, the then Assistant Director-II (QA)

The Panel made the following observations: -

i. Sampling or dispensing booths were not available in the RMS.
ii. HVAC was non-functional.
iii. Water treatment system was only an old domestic type filter.
iv. Lack of QC testing.
v. Absence of QC In-Charge.
vi. Lack of QA Manager, microbiologist.
vii. Lack of microbiology section.
viii. Lack of any documentation including BMR, logbooks, Certificates of analysis.
ix. Complete lack of QC analysis.
x. Complete lack of particulate / microbial area maintenance etc.
xi. Equipment were un-calibrated.
xii. FTIR & HPLC not available.

The panel has conducted sampling of the available products, and ordered not to dispose of API and excipients in the RMS. The panel has concluded that the *"panel unanimously decided to forward the case to Central Licensing Broad for suspension of production till rectification of all above mentioned deficiencies"*

ACTION TAKEN BY QA&LT

Keeping in view the observations noticed and conclusion of report by the FID, **Show Cause Notice / Order of Suspension of Production Activities in all Sections** was issued to the firm M/s. IPP, Plot 34, Industrial Triangle Kahuta Road Islamabad vide No. F.4-33/98-QC dated 17.01.2023 and subsequent Reminder was issued on 20.04.2023

REPLY OF THE FIRM

The firm did not submit response to the Show Cause Notice and subsequent Reminder.

RECOMMENDATION FROM QA&LT

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

Representative of the firm M/s. IPP, Kahuta Triangle Islamabad has been called upon for personal hearing

PROCEDING 290TH MEETING OF CLB: -

The case was presented before the Board; Mr. Nadeem Jawaid (Director) and Mrs. Rukhsana Jawaid appeared before the board on behalf of firm and presented the firm's stance. During the detailed deliberation on the case the Board observed that since the firm has not submitted any CAPA neither reply to show cause notice. The Board directed the QA&LT Division to ask the firm to submit CAPA and rectify all the deficiencies as pointed out by the inspector during inspection for compliance to DML conditions and GMP requirements. The Director QA&LT shall constitute a

panel of experts to verify the claim of the firm and the Division may place the outcomes of the inspection before the CLB for assisting the Board in decision-making.

DECISION OF 290TH MEETING OF CLB: -

The Board after thorough deliberation on the facts of the matter; decided that the Drug Manufacturing License of the firm shall remain suspended till the firm rectify all the deficiencies according to CAPA plan and the compliance is verified by follow-up panel inspection.

Case No. VI: ILLEGAL IMPORT OF RAW MATERIAL WITHOUT CLEARANCE FROM DRAP BY M/S. EG PHARMCEUTICALS 13-A INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

BACKGROUND

Federal Inspector of Drugs-I Islamabad inspected the premises of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad on 25th January 2022 to investigate PM portal complaint regarding the import of illegal raw material, lack of qualified persons and non-compliance of GMP by M/s. EG Pharmaceuticals Islamabad. During the inspection following Raw Material was recovered from the Raw Material Store (RMS) of the M/s EG Pharmaceutical Islamabad without import documents/NOCs issued by DRAP R&I Section as well as evidence of purchase:

S.	Name of Drug	Batch No.	Quantity	Mfg. by
01.	Amlodipie Besylate powder	AMB/057/03/21	0.29kg	M/s. Prudunce Chemical
02.	Diclofenac Potassium	20190810	109.125	M/s. Zanghai Gindjiuzhou Pharma Henan Dongtai Pharma Co Ltd
03.	Diclofenac Sodium	20200520	3.135	N/A
04.	Tizanidine powder	N/A	2.50	N/A
05.	Ketorolac Trtonetamol/ Tronethamine	0361220	0.800	M/s. Satyalidivis Pharma
06.	Lidocaine HCl	N/A	0.804	N/A
07.	Metronidazole		13.000	N/A
08.	Paroxetine Calcium		1.000	N/A
09.	Rosuvastatine Calcium		36.0 gm	N/A

10.	Vitamin B3		3.10gm	N/A
11.	Valsartan		0.36	N/A
12.	Metformin	MEF/1010233	598.950	AARTI Begus Ltd India
13.	Loratidine	NRHB0534	5.000	Morepan Lab India
14.	Sitagliptin		3.734	N/A

ACTION TAKEN BY QA&LT

The mentioned raw materials were ordered "Not to Dispose of" on Form-1 dated 25-01-2022 under Schedule-V Section (l)(i) of DRAP Act 2012. Permission in order not to dispose of was granted to FID I Islamabad vide letter F.03-05/2021-QC dated 21st February 2022.

M/s. EG Pharmaceuticals Islamabad was directed by FID I to submit import documents/NOCs issued by the DRAP I&E Department or as well as evidence of purchase of the above-mentioned raw materials vide letter No. F. 03-07/2004-FID-I(ISD) dated 31st January, 2022 with subsequent reminders on 17th March 2022 and 13th April 2022.

REPLY OF THE FIRM

The firm replied vide letter dated 12th April 2022 and admitted that they are obtaining raw material on loan from the local manufacturers/local markets as they are producing their products in small quantities to fulfill institutional commitments and to avoid market shortage and hence small amount required did not warrant import. Furthermore, Reference to the letter No. F.03-07/2004-FID-1(ISD) dated 13th April 2022, M/s EG Pharmaceuticals through its letter dated 12th April 2022, stated, "we have to get locally either because of their equipment in very low quantity, hence not possible to import, or we had to get them to avoid shortage in the market. As you know that because of International scenario, consignments now a days are delayed and even cancelled. Almost all Pharmaceutical companies do this in Pakistan and Internationally."

CORRESPONDENCE BY QA&LT & ITS REPONSE

In light of the firm's response, FID I Islamabad directed the firm vide letter No. F.03-07/2004-FID-I(ISD) dated 25th April 2022 to disclose the sources from which they had procured the above-mentioned raw material on loan in order to identify the culprits & to discourage such practices since it is violation of Import & Export rules 1976 & Section 23(l)(e) and punishable under Section 27(c) of the Drugs Act, 1976. The firm was further directed to provide complete information regarding batch sizes of the aforementioned items as well as the institutional orders placed with the firm. The firm has failed to respond till date and verbally the representatives of the firm refused to provide further cooperation in this matter.

Considering the circumstances mentioned above, FID-I Islamabad has concluded that the firm is in violation of Import & Export rules 1976 & Section 23(1)(e) of the Drugs Act, 1976 read with Schedule-II(1)(A)(x)(e) punishable under Section 27(c) of the Drugs Act, 1976 read with Schedule-III(l)(c) of the DRAP Act, 2012 and cognizable under Section 30(1)(a) of Drugs Act,1976 read with Schedule-lV (l)(a) of the DRAP Act, 2012, and has requested as under:

i. Cancellation of Registration of the above-mentioned products
ii. Cancellation of DML of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad
iii. Grant permission for prosecution M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad through its CEO Mr. Shaukat Hayat Khan and its QC manager Mr. Ihtisham-ul-Haq.

In light of above the firm has violated Section 23(1) of Drug Act 1976 punishable under section 27 of Drug Act 1976 and violated the section 6 of Schedule B-II of Drugs (LR&A) rules 1976.

DECISION OF 289TH CLB MEETING

The case was discussed and deliberated in detail and the Central Licensing Board directed the Division of Quality Assurance & Laboratory Testing (QA&LT) to issue show cause notice and personal hearing to M/s EG Pharmaceutical, 13-A Industrial Triangle Kahuta Road Islamabad, regarding illegal import/storage of raw materials without Drug Import Licence (Form-5) and clearance certificate from DRAP.

In light of the decision of 289th CLB meeting, M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad was issued show cause notice and personal hearing.

RECOMMENDATIONS

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

Representative of the firm M/s. EG Pharmaceuticals, Kahuta Triangle Islamabad has been called upon for personal hearing

DECISION OF 290TH MEETING OF CLB: -

The Board after thorough deliberation on the facts of the matter; after hearing the stance of Mr. Ihtischam-ul-haq (QC In-charge) on behalf of the firm, concluded that frim has contravened the Section 23(1)(b) of the Drug Act, 1976 read with DRAP Act, 2012 and Rules framed thereunder and decided as under;

i. *Destruction of raw material, which were ordered not to dispose of on Form-2 by the FID, as per the guidelines issued by the Division of QA&LT.*
ii. *Refer the matter to the Registration Board with the recommendation to suspend the Registration of all the products, the formulation of which contains above-mentioned illegally procured raw materials, for a period of not less than 18 months.*

Case No. VII: ILLEGAL IMPORT OF RAW MATERIAL WITHOUT CLEARANCE FROM DRAP BY M/S HAWK BIO PHARMACEUTICALS (PVT) LTD, PLOT NO. 10, S-6, NIZ, RCCI RAWAT, ISLAMABAD.

BACKGROUND

M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No. 10, S-6, NIZ, RCCI Rawat, Islamabad's Inspection was conducted by Federal Inspector of Drugs-III Islamabad on 14th October, 2019. The FID has reported that 07 raw materials stored in Raw Material Store were not purchased directly from producer or established supplier. The firm failed to produce any evidence for import or local purchase such as invoice or any other purchase documents for these raw materials. List of raw materials is as follows:

S.	Name of Drug	Batch No.	Quantity	Mfg. by
01.	Invermectin	201808021	1.7Kg	Unknown
02.	Bismuth Subnitrate	19030211	4.1Kg	-do-
03.	Ferrous Sulphate	00118-060	22.250Kg	-do-
04.	Copper Sulphate	RLFX-873-18	19.90Kg	-do-
05.	Zinc Sulphate	JXBHB2019-014	17.7Kg	-do-
06.	Magnesium Sulphate	Not know.	50Kg	-do-

07.	Manganese Sulphate MnSo4	10819-019	2.4Kg	-do-

ACTION TAKEN BY QA&LT

M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No. 10, S-6, NIZ, RCCI Rawat, Islamabad's was issued show cause notice and personal hearing.

PROCEEDINGS AND DECISION OF 297TH,307thand 324th MEETING OF REGISTRATION BOARD:

Decision of 297th meeting of Registration Board: -

"The Board after detailed deliberations and considering the facts of the case decided to issue show cause notice for cancelation/suspension of products to the accused."

In compliance to the decision of Registration Board, the accused was issued a showcause notice vide No. F. 03-56/2021-QC (Pt-I) (297-RB) dated 05-04-2021. The accused has replied vide ref. No. HBP 4 / 2021 dated 15-04-2021 which is given as under:

"This refer to your letter no. F.03-56/2021-QC(Pt-I) (297-RB) dated April 05,2021 via ums services, which we received on dated April 12,2021 on Subject cited above.

• Please provide us an opportunity to be heard in person in response to above show cause notice.

• We want to submit justification / clarification in person."

Keeping in view of above-mentioned reply, the representatives of the firm are called before the Board for personal hearing.

Decision of 307th meeting of Registration Board:

Dr. Javed Saeed (CEO M/s. Hawk Bio Pharma, Islamabad) along with QC Manager, Mr. Ajmal and Production Manager, Mr. Zia Hussain appeared before the Board for Personal hearing. They pleaded that they have submitted evidence to FID that their imports were done as per legal procedures. They submitted a written reply and supporting documents. The Board after considering the facts of the case and thorough deliberations decided as follows:

i. Refer the case back to area FID for complete investigation.
ii. ii. Suspend all registered products of the firm (as identified by area FID) that were manufactured by the raw materials in question

Decision of 324th Meeting of Registration Board:

Registration Board after discussion, considering the facts of the case decided as under: i. Import and export of raw materials does not fall under the mandate of Registration

Board. Hence, the case is referred back to QA< Division to decide the case under the Drugs (import & Export) Rules, 1976 under Drugs Act, 1976. Till that decision, registration of all products shall remain suspended as per decision of the 307th meeting of Registration Board communicated vide letter No. No.F.03-15/2021-QC (307-RB) (Pt-I) dated 03-08-2021.

RECOMMENDATIONS

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

Representative of the firm M/s. Hawk Bio Pharmaceuticals, National Industrial Zone Rawat, Islamabad has been called upon for personal hearing.

DECISION OF 290TH MEETING OF CLB: -

The Board after hearing the stance of Dr. Javed Saeed (CEO) and Ms. Zia Hussain (Production In-charge) before the Board on behalf of the firm and thorough deliberation on the facts of the matter; concluded that frim has contravened the Section 23(1)(4) of the Drug Act, 1976 read with DRAP Act, 2012 and Rules framed thereunder and decided as under;

i. *Destruction of raw material, which were ordered not to dispose of on Form-2 by the FID, as per the guidelines issued by the Division of QA&LT.*
ii. *Refer the matter to the Registration Board with recommendation for revocation of Suspension of Registration of the suspended products issued vide letter dated i.e. 3rd August 2021.*
iii. *Issuance of warning letter to M/s Hawk Bio Pharmaceuticals (Pvt) Ltd. by the Division of QA&LT.*

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

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

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

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

1. Additional Director (E&M), DRAP, Karachi.
2. Area Federal Inspector of Drugs, DRAP, Karachi.

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

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

Followings are the outcome of the inspection by the panel.

i. As per the details provided and the same was verified from the management of the firm that firm is possessing Manufacturing Enlistment No.00265 under H&OTC Rules and also possessing necessary Form-7 for COS-CH syrup E.No.0265680138.
ii. The firm also possessing DML No.000784 (By way of formulation) at the same premises for some general sections like tablets, Capsules, Liquid Syrup at ground floor, whereas H&OTC Nutraceutical separate facilities are kept as first floor for tablets, capsules and liquid syrups.
iii. During the detail inspection of the entire facilities it was dawned upon that the firm is manufacturing their all H&OTC products in their liquid Pharma section which was verified

from respective log books. H&OTC facilities were seen un-operational at the time of inspection. From dispensing to packing all production activities for Nutraceutical products are carried out in their Pharma sections (records pertaining to these activities were taken into custody and copies are enclosed for your kind perusal).

iv. As evident from machine log books prior to COS-CH syrup various Pharma products like Famotidine, Ibuprofen and Paracetamol were manufactured inside the Pharma liquid section and on the same machines which might have caused cross-contamination into the H&OTC product, hence sample of the same batch was taken on form-3 for further confirmation of these impurities into the product form 4 enclosed.

v. The samples were sent to CDL for further testing and confirmation.

vi. The records taken further potentiated that the nothing was tested on semi-finished and finished goods like potency of active, identification & most critical the microbial bio-burden of the syrup and that may have caused the syrup hazardous and ineffectiveness.

vii. The management further provided a statement whereby confirming that their H&OTC products were being manufactured in their Pharma liquid sections.

viii. Keeping in view of the above stated observations it was concluded that besides provisions of H&OTC Enlistments & respective sections the firm had not to manufacture those products in their Pharma section and could tantamount to an offence of manufacturing an un-registered product with the most possibilities of cross-contamination hence their both the liquid sections (Neutra & Pharma) were ordered to be locked-sealed on form-1 under section 18(1) h of the Drugs Act 1976.

4. **Recommendation of the Panel**

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

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

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

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

The meeting ended with vote of thanks to and from the Chair.