MINUTES OF 294th MEETING OF CENTRAL LICENSING BOARD HELD ON 27th DECEMBER, 2023

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294th meeting of the Central Licensing Board (CLB) was held on 27th December, 2023 in the Committee Room, , Ground Floor, NCLB, Drug Regulatory Authority of Pakistan (DRAP) National Institute of Health (NIH), Chak Shahzad, Islamabad. Dr. Muhammad Akhtar Abbas Khan, Director (Licensing), Drug Regulatory Authority of Pakistan, Islamabad Chaired the meeting. Following members attended the meeting: -

S.No	Name & Designation	Status
1.	Mr. Babar Khan 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. Abdul Hafeez Tunio, Chief Inspector of Drugs , Government of Sindh, Karachi	Member
6.	Mr. Abid Ali, Deputy Draftsman, Ministry of Law & Justice Division, Islamabad	Member
7.	Ms. Mahvish Ansari, Additional Director, representative from QALT, DRAP	Member

Mr. Babar Khan Additional Director/Secretary Licensing Board presented the agenda before the Board. Mrs. Ume Liala Deputy Director (Lic), Mr. Mubashir Iqbal, Deputy Director (Lic), Mr. Yaqoob Kakar, Assistant Director (Lic), Abdullah, Assistant Director (Lic), Mrs. Zunaira Faryad Assistant Director (Lic) assisted the S ecretary, Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 293nd MEETING**

All members of the Central Licensing Board (CLB) formally confirmed the minutes of its 293rd meeting of Central Licensing Board which was held on 20th November, 2023.

OPERATIONAL DECISIONS

The manufacturer/applicant intended to establish a pharmaceutical unit, submitted an application for site approval, and the site got approved according to para 1.1 of the Schedule B of Drugs (Licensing, Registering, and Advertising) Rules, 1976. However, the Board raised concerns about the lack of clarity or provisions for granting licenses to manufacturers who use rented land (plots or buildings). Many firms request site verification for building their manufacturing units on rented land. Recently, an incident was reported where a manufacturing unit was set up on rented land, and the landowner filed a court case for vacation. These incidents have presented a regulatory challenge.

Additionally, the Board noticed that numerous firms apply for site verification for plots situated in unclassified, agricultural or industrial areas. This aspect is not clearly mentioned in the Drugs (Licensing, Registering, and Advertising) Rules, 1976. Consequently, firms do not specify the duration within which layout approval should be granted, leading to delays in construction for undisclosed reasons (these delays could be due to personal interests or intended purposes). Furthermore, changes in the surroundings and environment over time may render these sites unsuitable for pharmaceutical units.

Similarly, layout plans for manufacturing units/sections are approved in accordance with approved SOP, and this layout approval is valid for one year. However, firms delay construction for several years, causing changes in requirements due to updates in cGMP and other regulatory standards.

Moreover, the Board noted that a panel of experts or inspectors is constituted/approved for inspecting premises, but firms do not make arrangements for carrying out inspections within the specified time. The timeframe for conducting inspections for granting new licenses, adding additional sections, or renewing existing ones is also not clearly defined.

Decision:

The Board after threadbare discussion decided as under.

1. The proposals/applications to establish a pharmaceutical unit on the rented premises shall not be entertained. At least one of the owners of the plot should be part of management of the firm as a director/partner/owner.

2. The site verification of unclassified/agricultural area/premises shall be valid only for one year and for sites in industrial zones for 2 years. The firm shall apply afresh for approval after the lapse of the period.

3. The approval of lay out plans shall be for one year for additional section and 2 years for a new unit. If the firm do not complete the construction and installation of the machines and equipment, then firm shall apply afresh for the purpose.
4. The panel for inspection of new units/ additional sections/ renewal shall be valid for 6 months. If the panel doesn't conduct the inspection within the time frame, same or fresh panel shall be constituted by the Chairman CLB.
5. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

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

The respective panels of experts have forwarded following cases for grant of Drug Manufacturing License. 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 Nahal Pharmaceuticals, Plot No. 2, Street No. SS-4, Industrial Estate, Rawat. Sections (06): 1. Dry Powder Suspension (Cephalosporin) Section. 2. Capsule (Cephalosporin) Section. 3. Dry Powder Injection (Cephalosporin) Section. 4. Dry Powder Suspension (Penicillin) Section. 5. Capsule (Penicillin) Section. 6. Dry Powder Injection (Penicillin) Section. Evaluator: - Ume Laila (DD-Lic)	07-12-2023	Good	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP (QA/LT) DRAP, Islamabad. 2. Mrs. Tehreem Sara, FID, DRAP, Islamabad. 3. Mr. Akbar Ali, Deputy Director (QA/LT), DRAP, Islamabad.

	Production Manager	Mr. Amjad Ikram (B-Pharm)		
	QC Incharge	Mr. M. Yousuf Qureshi (M.Sc. Chemistry)		
	Recommendations of the panel: *"In view of the inspection conducted, reviewing the documents, interview of technical team, intent of the management and verification of manufacturing and testing facility such as FTIR, HPLC, Spectrophotometer, Dissolution Apparatus, Potentiometer, LFC, Polarimetry, ultrasonic bath, and other QC equipment along with 2 stability chambers, the panel unanimously* ***recommends*** *the Grant of Drug Manufacturing License by way of Formulation to M/s Nahal Pharmaceuticals (Pvt) Ltd, Plot No. 2, Street No. SS-4, Industrial Estate, Rawat, Islamabad for the following six (06) sections along with Quality Control, Microbiology and R&D Lab as under.*" i. Dry Powder Suspension (Cephalosporin) Section. ii. Capsule (Cephalosporin) Section. iii. Dry Powder Injection (Cephalosporin) Section. iv. Dry Powder Suspension (Penicillin) Section. v. Capsule (Penicillin) Section. vi. Dry Powder Injection (Penicillin) Section. **Decision of the Central Licensing Board in 294th meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Nahal Pharmaceuticals, Plot No. 2, Street No. SS-4, Industrial Estate, Rawat on the recommendations of the panel of experts for the following sections: - i. Dry Powder Suspension (Cephalosporin) Section. ii. Capsule (Cephalosporin) Section. iii. Dry Powder Injection (Cephalosporin) Section. iv. Dry Powder Suspension (Penicillin) Section. v. Capsule (Penicillin) Section. vi. Dry Powder Injection (Penicillin) Section			
2	M/s Pharmonix Pharmaceuticals, Plot No. 28, Street No. SS-2, National Industrial Zone, Rawat. Sections (03): 1. Dry Powder/Granules/Pellets Section (Vet). 2. Injectable Section (Vet).	19-12-2023	Good	1. Dr. Qurban Ali (Vet Expert), Islamabad 2. Dr. Ghazanfar Ali Khan, Additional Director, DRAP (QA/LT) DRAP, Islamabad. 3. Mrs. Tehreem Sara, FID, DRAP,

	3. Oral Liquid Section (Vet) Evaluator:- Ume Laila (DD-Lic)			Islamabad.
	Production Incharge	Mr. Muhammad Ishaq (B-Pharm)		
	QC Incharge	Mr. Muhammad Ayaz (M.Sc. Chemistry)		
	Recommendations of the panel: *"The panel based on the available equipment/machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management* ***recommends*** *the grant of drug manufacturing license to M/s* Pharmonix Pharmaceuticals, Plot No. 28, Street No. SS-2, Industrial Estate, Rawat, for the following sections." i. Dry Powder/Granules/Pellets Section (Vet). ii. Injectable Section (Vet). iii. Oral Liquid Section (Vet) **Decision of the Central Licensing Board in 294th meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Pharmonix Pharmaceuticals, Plot No. 28, Street No. SS-2, Industrial Estate, Rawat on the recommendations of the panel of experts for the following sections: i. Dry Powder/Granules/Pellets Section (Vet). ii. Liquid Injectable Section General (Vet). iii. Oral Liquid Section General (Vet)			
3	M/s Medisynth Pharmaceuticals, Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, Distt. Rawalpindi. Sections (04): i. Tablet (General) Section ii. Capsule (General) Section iii. Cream/Ointment (General) Section	19-12-2023	Good	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP (QA/LT) DRAP, Islamabad. 2. Mrs. Tehreem Sara, FID, DRAP, Islamabad. 3. Ms. Ume Laila, Deputy Director

	iv. Oral Powder for Sachet (General) Section Evaluator:- Ume Laila (DD-Lic)			(Lic), DRAP, Islamabad..
	Production Incharge:	Mr. Qaiser Khan (Pharm-D)		
	QC Incharge:	Mr. Kashif Alam (Pharm-D)		

Recommendations of the panel:

"In view of the inspection conducted, reviewing the documents, interview of technical team, intent of the management and verification of manufacturing and testing facility such as HPLC, Spectrophotometer, Dissolution Apparatus, LFC, Polarimetry, ultrasonic bath, and other QC equipment along with 2 stability chambers, the panel unanimously ***recommends*** *the Grant of Drug Manufacturing License by Formulation to M/s Medisynth Pharmaceuticals, Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, Distt. Rawalpindi, for the following six (06) sections along with Quality Control, Microbiology as under*."

i. Tablet (General) Section
ii. Capsule (General) Section
iii. Cream/Ointment (General) Section
iv. Oral Powder for Sachet (General) Section

As per inspection report, FTIR is non-functional at the time of inspection. However, the establishment has submitted the undertaking for making it functional at the time of start of production.

The firm has requested to cancel previous license mentioned at old address Plot No.55, Street S5, National Industrial Zone, Rawat, Islamabad.

Decision of the Central Licensing Board in 294th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Medisynth Pharmaceuticals, Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, Distt. Rawalpindi on the recommendations of the panel of experts for the following sections subject to verification of testing equipment (in the light of decision M-290th CLB). The Board also cancelled the license previously granted at **Plot No.55, Street S5, National Industrial Zone, Rawat, Islamabad.** The same license number 000718 shall be allotted to the firm at new premises. This approval shall not absolve company from its previous/pending liabilities/obligations of what soever nature.

i. Tablet (General) Section
ii. Capsule (General) Section
iii. Cream/Ointment (General) Section
iv. Oral Powder for Sachet (General) Section

<table>
<tr><td rowspan="4">4</td><td>M/s Archard Pharmaceuticals (Pvt) Ltd., Plot No.27-28/B, Small Industrial Estate, Bhimber AJK.

<u>Sections (13)</u>:

Ground Floor:

i. Oral Powder-I (General) Vet
ii. Oral Powder-II (General) Vet
iii. Oral Liquid-I (General) Vet
iv. Oral Liquid-II (General) Vet
v. Liquid Injectable (General) Vet
vi. Liquid Injectable (Steroid) Vet
vii. Tablet Bolus (General) Vet
viii. Quality Control Laboratory & Microbiology
ix. Warehouse (General)

First Floor:

i. Liquid Injectable (Penicillin) Vet
ii. Dry Powder Injectable (Penicillin) Vet
iii. Oral Powder (Penicillin) Vet
iv. Warehouse (Penicillin) – Vet

<u>Evaluator: - Muhammad Yaqoob (AD-Lic)</u></td><td>22-12-2023</td><td>Good</td><td>1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP (QA/LT) DRAP, Islamabad.

2. Mr. Muhammad Arif, Additional Director (CD), DRAP, Islamabad.

3. Mr. Abdullah, Assistant Director (Lic), DRAP, Islamabad.</td></tr>
<tr><td>Production Incharge:</td><td colspan="3">Farhat Ali Pharm-D</td></tr>
<tr><td>QC Incharge:</td><td colspan="3">Robina Kausar B-Pharm</td></tr>
<tr><td colspan="4"><u>Recommendations of the panel:</u>

“The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, TOC, LPC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and</td></tr>
</table>

	commitment of the management recommends the grant of drug manufacturing license (DML) to M/s Archard Pharmaceuticals (Pvt) Ltd., located at Plot No.27-28/B, Small Industrial Estate, Bhimber AJK for following sections along with microbiology, QC laboratory and warehouse as per approved lay out plan: ” **Ground Floor**: i. Oral Powder-I (General) Vet ii. Oral Powder-II (General) Vet iii. Oral Liquid-I (General) Vet iv. Oral Liquid-II (General) Vet v. Liquid Injectable (General) Vet vi. Liquid Injectable (Steroid) Vet vii. Tablet Bolus (General) Vet **First Floor**: viii. Liquid Injectable (Penicillin) Vet ix. Dry Powder Injectable (Penicillin) Vet x. Oral Powder (Penicillin) Vet **<u>Decision of the Central Licensing Board in 294th 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 Archard Pharmaceuticals (Pvt) Ltd., Plot No.27-28/B, Small Industrial Estate, Bhimber AJK on the recommendations of the panel of experts for the following sections subject to verification of testing equipment (M-290th CLB): **Ground Floor**: i. Oral Powder-I (General) Vet ii. Oral Powder-II (General) Vet iii. Oral Liquid-I (General) Vet iv. Oral Liquid-II (General) Vet v. Liquid Injectable (General) Vet vi. Liquid Injectable (Steroid) Vet vii. Tablet Bolus (General) Vet **First Floor**: viii. Liquid Injectable (Penicillin) Vet ix. Dry Powder Injectable (Penicillin) Vet x. Oral Powder (Penicillin) Vet

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 Hilton Pharma (Pvt) Ltd., Plot No.13&14, Sector 15, Korangi Industrial Area, Karachi. **Section (01)**: i. Tablet (Biotech) Section Evaluator:- Mubashir Iqbal (DD-Lic)	21-12-2023	Good	1. Mr Abdul Rasool Sh. Additional Director, DRAP, Karachi. 2. Dr. Shoaib Ahmed, FID-III, DRAP, Karachi. 3. Dr. Abdul Waheed, Assistant Director, DRAP, Karachi.

Recommendation of the Panel:

Based on the observations stated herein the panel found the dedicated Tablet (Bio-Tech) facilities complaint as per current GMP requirement with respect to premises, personnel, procedures, equipment and necessary documents are also developed, and is of the opinion to recommend the grant of additional section of Tablet (Bio-Tech) under DML No.000136 (Formulation).

The firm has submitted that initially Semaglutide Tablet will be manufactured in Tablet (Biological section) and later other biological tablets.

Decision of the Central Licensing Board in 294th meeting:

On the recommendations of the panel of experts, the Board considered and approved the grant of following section in the name of M/s Hilton Pharma (Pvt) Ltd., Plot No.13&14, Sector 15, Korangi Industrial Area, Karachi under DML No. 000136 (Formulation) subject to verification of testing equipment (M-290th CLB): -

i. Tablet (Biotech) Section - New

The Board further decided that following already communicated comments of Prof. Brig (R) M.H Najmi in a similar case be conveyed to Drug Registration Board/ PE&R, Division DRAP for consideration and further necessary action at their end;

Semaglutide is a peptide and therefore vulnerable to inactivation by the gastric HC1 and proteolytic enzymes. The drug therefore, is formulated in combination with a permeation

	enhancer, Salcaprozate Sodium not only facilitates its absorption but also protects it from degradation in stomach. Any discrepancy in formulation of the table is likely to affect bioavailability of the active drug seriously. It is therefore strongly recommended that prior to registration, the firm may be asked to produce a test batch of the drug and get bio-equivalence studies performed from any accredited laboratory to ensure efficacy and safety of the drug in patients."			
2.	M/s Crystolite Pharmaceuticals, Plot No 1 &2, S-2, Industrial Zone Rawat. DML No.000778 (Formulation). **Sections (05):** 1. Lyophilized liquid vial for injection section (General) 2. Liquid Injectable (Vial) (General) Section 3. Liquid Injectable (ampoule)(General) Section 4. Eye Drop (General) Section 5. Eye Cream & Ointment (General) section Evaluator:- Zunaira Faryad (AD-Lic)	**14-12-2023**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director (QA/LT), DRAP, Islamabad. 2. Mrs. Tehreem Sara, FID-IV, DRAP, Islamabad. 3. Mr. Umer Lateef, Deputy Director (QA&LT), DRAP, Islamabad.
	Recommendations of the Panel: In view of the inspection conducted, reviewing the documents, interview of technical team, intent of the management and verification of manufacturing and testing facility such as FTIR, Atomic Absorption spectrometer, three (03) HPLC, Spectrometer, Dissolution Apparatus, LFC, TOC, Liquid Particle Counter, Air Sampler, polarimetry, ultrasonic bath, and other QC equipment along with 03 stability chambers (list already attached, the panel unanimously **recommends** the Grant of renewal of Drug manufacturing License by way of formulation (000778) to along with Quality Control, Microbiology as under: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment Section (General)			

	4. Topical Lotion Section (General) 5. Cream / Ointment Section (Steroidal) 6. Topical Lotion Section (Steroidal) 7. Oral Sachet Section (General) 8. Soft Gelatin Capsule (General) 9. Syrup Section (General) 10. Dry Vial Injection Section (Cephalosporin) 11. Capsule Section (Cephalosporin) 12. Oral Dry Suspension section (Cephalosporin) 13. Dry Vial Injection Section (Carbapenem) And also recommend the grant of following additional sections 14. Lyophilized liquid vial for injection section (General) 15. Liquid Injectable (Vial) (General) Section 16. Liquid Injectable (ampoule)(General) Section 17. Eye Drop (General) Section 18. Eye Cream & Ointment (General) section **Decision of the Central Licensing Board in 294th meeting:** On the recommendations of the panel of experts, the Board considered and approved the grant of following additional sections in the name of M/s Crystolite Pharmaceuticals, Rawat under DML No. 000778 (Formulation): - 1. Lyophilized liquid vial for injection section (General) 2. Liquid Injectable (Vial) (General) Section 3. Liquid Injectable (ampoule)(General) Section 4. Eye Drop (General) Section 5. Eye Cream & Ointment (General) section

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

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

<table>
<tr><th>S #</th><th>Name of the firm</th><th>Date of Inspection</th><th>Ranking/ Evaluation</th><th>Inspection Panel Members</th></tr>
<tr><td rowspan="4">1.</td><td>M/s Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi
DML No. 000025 (Formulation)
Period: Commencing on 22-06-2020 ending on 21-06-2025.
Evaluator:- Mubashir Iqbal (DD-Lic)</td><td>19-10-2023</td><td>Good</td><td>1. Syed Adnan Rizvi, Director, DTL, Government of Sindh, Karachi.
2. Shoaib Ahmed, Area FID-III, DRAP, Karachi.
3. Dr. Awais Ahmed, AD, CDL, Karachi.</td></tr>
<tr><td>Production Manager:</td><td colspan="3">Mr. Rashid M. Khan (MS. Pharm)</td></tr>
<tr><td>Quality Control Manager:</td><td colspan="3">Mr. Muhammad Farooq (M.Sc. Chemistry)</td></tr>
<tr><td colspan="4"><u>Recommendations of the panel:</u>
“M/s Pfizer Pakistan Limited situated at Plot No. B-2, S.I.T.E., Karachi was visited and inspected in detail on 19-10-2023 in compliance to the directions contained in DRAP, Islamabad letter No.F.2-2/89-Lic (Vol-VI) dated 9th December, 2021.
The panel inspected the firm in detail including all the manufacturing sections, stores amd QC Lab and found the facility as per approved lay out plan. The facility has been provided with necessary utilities, machineries and equipment as required under the guidelines. Necessary documents relating to QC, QA and installation qualification of machines, HVAC and other utilities were also seen in place.
However, the management has informed the panel that they are intended to surrender the latest approved layout plan vide DRAP Islamabad Letter No.2-2/89-lic (vol-VI) dated 28th march 2022 hence they will establish steroidal are instead of their psychotropic section as soon after the transfer of XANAX group to OBS Pakistan.
Based on built-in last approved design, the people met, documents reviewed, and observations made during the inspection, the panel unanimously recommends the grant of</td></tr>
</table>

renewal of Drug Manufacturing License No.000025 by way of formulation with effect from 22-6-2020 for following sections and regularization of their current layout plan as follows:

S.No.	***Sections***	***S.No.***	***Sections***
01.	*Tablet (General)*	*05.*	*Capsule (General)*
02.	*Liquid (General)*	*06.*	*Tablet (Psychotropic)*
03.	*Oral Powder for Suspension (General)*	*07.*	*Bulk Packaging Section*
04.	*Ointment/Gel & Lotion (General)*	*08.*	*Quality Control Laboratory*

Decision of the Central Licensing Board in 294th meeting:

The Board considered and approved the grant of renewal of DML No. 000025 by way of Formulation in the name of M/s Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi on the recommendations of the panel of experts subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for psychotropic section, for the period Commencing on 22-06-2020 ending on 21-06-2025 for the following sections subject to verification of testing equipment (M-290th CLB).

S.No.	***Sections***	***S.No.***	***Sections***
01.	*Tablet (General)*	*05.*	*Capsule (General)*
02.	*Liquid (General)*	*06.*	*Tablet (Psychotropic)*
03.	*Oral Powder for Suspension (General)*	*07.*	*Bulk Packaging Section*
04.	*Ointment/Gel & Lotion (General)*	*08.*	*Quality Control Laboratory*

2.	M/s SPL Pharmaceuticals (Pvt) Ltd, Plot No. 4, Phase-III, Hattar Industrial Estate, Hattar. DML No.000605 (Formulation). Period: Commencing on 19-02-2022 ending on 18-02-2027.	09-10-2023	Good	1. Prof. Dr. Fazal-e-Nasir, Pharmacy Department, University of Peshawar. 2. Mr. Faisal Shahzad, Area FID, DRAP, Peshawar. 3. Mr. Adnan Ali Shah, Assistant Director, DRAP, Islamabad.

	Evaluator:- Muhammad Yaqoob (AD-Lic)			
	Quality Control Incharge	Mr. Javed Khan S/o Ziarat Gul, (M.Sc Chemistry) CNIC No. 16101-3882600-9.		
	Production Incharge	Mr. Hassan Hammad Khalid S/o Muhammad Khalid Raja (Pharm-D) CNIC No. 37405-4778313-7.		
	Summary of inspection: 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, distilled water system and other allied facilities, the panel is of the view that the firm has provided sufficient facilities for below mentioned sections with good level of GMP compliance and unanimously **recommends** grant of renewal of below mentioned section as per DRAP Islamabad letter No.F.3-5/2005-Lic (Vol-I) dated 7th April, 2023:- 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment (General) 4. Capsule Section (Cephalosporin) 5. Dry Powder Suspension (Cephalosporin) 6. Dry Powder Injection (Cephalosporin) **Decision of the Central Licensing Board in 294th meeting:** The Board considered and approved the grant of renewal of DML No. 000605 by way of Formulation in the name of M/s SPL Pharmaceuticals (Pvt) Ltd, Plot No. 4, Phase-III, Hattar Industrial Estate, Hattar on the recommendations of the panel of experts for the period Commencing on 19-02-2022 ending on 18-02-2027 for the following sections subject to verification of testing equipment (M-290th CLB). 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment (General) 4. Capsule Section (Cephalosporin) 5. Dry Powder Suspension (Cephalosporin) 6. Dry Powder Injection (Cephalosporin)			
3.	M/s Crystolite Pharmaceuticals. DML No.000778 (Formulation).	14-12-2023	Good	4. Dr. Ghazanfar Ali Khan, Additional Director (QA/LT), DRAP, Islamabad. 5. Mrs. Tehreem Sara, FID-IV, DRAP, Islamabad.

	Period: Commencing on 30-8-2023 to 29-08-2028 Evaluator:- Zunaira Faryad (AD-Lic)			6. Mr. Umer Lateef, Deputy Director (QA&LT), DRAP, Islamabad.
	Quality Control Incharge	Abdul Basit B-Pharm		
	Production Incharge	Aamir Raza M.Sc Chemistry		

Summary of inspection:

In view of the inspection conducted, reviewing the documents, interview of technical team, intent of the management and verification of manufacturing and testing facility such as FTIR, Atomic Absorption spectrometer, three (03) HPLC, Spectrometer, Dissolution Apparatus, LFC, TOC, Liquid Particle Counter, Air Sampler, polarimetry, ultrasonic bath, and other QC equipment along with 03 stability chambers (list already attached, the panel unanimously recommends the Grant of renewal of Drug manufacturing License by way of formulation (000778) to along with Quality Control, Microbiology as under:

1. Tablet Section (General)
2. Capsule Section (General)
3. Cream/Ointment Section (General)
4. Topical Lotion Section (General)
5. Cream / Ointment Section (Steroidal)
6. Topical Lotion Section (Steroidal)
7. Oral Sachet Section (General)
8. Soft Gelatin Capsule (General)
9. Syrup Section (General)
10. Dry Vial Injection Section (Cephalosporin)
11. Capsule Section (Cephalosporin)
12. Oral Dry Suspension section (Cephalosporin)
13. Dry Vial Injection Section (Carbapenem)

And also recommend the grant of following additional sections

1. Lyophilized liquid vial for injection section (General)
2. Liquid Injectable (Vial) (General) Section
3. Liquid Injectable (ampoule)(General) Section
4. Eye Drop (General) Section
5. Eye Cream & Ointment (General) section

Decision of the Central Licensing Board in 294th meeting:

The Board considered and approved the grant of renewal of DML No. 000778 by way of Formulation in the name of M/s Crystolite Pharmaceuticals Rawat on the recommendations

	of the panel of experts for the period Commencing on 30-8-2023 to 29-08-2028 for the following sections. The Board observed that Dry Vial Injection Section (Carbapenem) section is not segregated and dedicated facility and did not renew the Dry Vial Injection Section (Carbapenem). 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment Section (General) 4. Topical Lotion Section (General) 5. Cream / Ointment Section (Steroidal) 6. Topical Lotion Section (Steroidal) 7. Oral Sachet Section (General) 8. Soft Gelatin Capsule (General) 9. Syrup Section (General) 10. Dry Vial Injection Section (Cephalosporin) 11. Capsule Section (Cephalosporin) 12. Oral Dry Suspension section (Cephalosporin)

Item-V: **Miscellaneous Cases**

Case No. 1 **CHANGE OF TITLE OF M/S SANOFI AVENTIS PAKISTAN LIMITED PLOT NO. 23 SECTOR 22 KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN UNDER DML NO. 000007 (FORMULATION)**

Evaluator: - Mubashir Iqbal (DD-Lic)

M/s Sanofi-Aventis Pakistan limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi, Pakistan has submitted application for change of title of the company under Drug Manufacturing License No. 000007 by way of (Formulation) 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:

Current Title of the firm	New Title of the firm
M/s. Sanofi-Aventis Pakistan limited	M/s. Hoechst Pakistan Limited

Decision of the Central Licensing Board in 294th meeting

On the basis of change if title in SECP, the Board considered and accepted for record the change of title of M/s Sanofi-Aventis Pakistan limited. DML No. 000007 (formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for psychotropic section as under;

Current Title of the firm	**New Title of the firm**
M/s. Sanofi-Aventis Pakistan limited	**M/s. Hoechst Pakistan Limited**

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

Case No. 2 **CHANGE OF TITLE OF M/S SANOFI AVENTIS PAKISTAN LIMITED PLOT NO. 23 SECTOR 22 KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN UNDER DML NO. 000368 (BASIC MANUFACTURER)**

Evaluator: - Mubashir Iqbal (DD-Lic)

M/s Sanofi-Aventis Pakistan limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi, Pakistan has submitted application for change of title of the company under Drug Manufacturing License No. 000368 by way of (Basic Manufacturing) with relevant fee of Rs.22,500/. 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:

Current Title of the firm	New Title of the firm
M/s. Sanofi-Aventis Pakistan limited	M/s. Hoechst Pakistan Limited

Decision of the Central Licensing Board in 294th meeting

The Board considered and accepted for record the change of title of M/s Sanofi-Aventis Pakistan limited. DML No. 000368 (formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for psychotropic section as under;

Current Title of the firm	**New Title of the firm**
M/s. Sanofi-Aventis Pakistan limited	**M/s. Hoechst Pakistan Limited**

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

Case No.3. **CHANGE OF MANAGEMENT OF M/S TRIGON PHARMACEUTICALS (PVT) LTD, 8-KM, THOKAR RAIWIND ROAD, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000342 BY WAY OF (FORMULATION).**

Evaluator: - Ume Laila (DD-Lic)

M/s Trigon Pharmaceuticals (Pvt) Ltd, 8-Km, Raiwind Road, Lahore, DML No.000342 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. Mrs. Shahida Safdar W/o Muhammad Safdar, CNIC No. 35202-2688806-4 2. Mr. Muhammad Safdar S/o Chaudhry Muhammad Shafi, CNIC No. 36501-3646813-9	1. Mr. Muhammad Safdar S/o Chaudhry Muhammad Shafi, CNIC No. 36501-3646813-9 2. Mr. Hadi Hassan S/o Muhammad Din Qureshi, CNIC No. 35202-5353860-7 3. Mr. Hashim Khan Tareen S/o Muhammad Asghar Khan Tareen, CNIC No 36302-5286384-7

Decision of the Central Licensing Board in 294th meeting

The Board observed that the form 29 was issued 31-10-2019 and deferred the request for submission of fresh form 29.

Case No.4. CORRECTION IN MINUTES OF 292ND MEETING OF CLB - REVISED/ADDITIONAL SECTIONS OF M/S GENIX PHARMA

Evaluator: - Mubashir Iqbal (DD-Lic)

The case for grant of revised/additional sections of M/s Genix Pharma (Pvt) Ltd., 44, 45B, Korangi Creek Road, Karachi under DML DML No.000351 (Formulation) was presented in 292nd meeting of CLB as under:

M/s Genix Pharma (Pvt) Ltd., 44, 45B, Korangi Creek Road, Karachi. DML No.000351 (Formulation). **Sections (13)** 1. Tablet Section-(General)-Revised 2. MDI (Meter Dose Inhaler) – New 3. Ointment/Cream/Gel - Revised 4. Suppository – New 5. Dry Powder for Suspension -Revised 6. Capsule Section (General) –Revised 7. Sachet (General) – Revised 8. Liquid Syrup (General) – Revised	22-09-2023 / *by way of Formulation*	Good	1. Mr. Ghulam Ali Lakho, Chief Drug Inspector, Karachi. 2. Mr. Abdul Rasool Sh. Additional Director, DRAP, Karachi. 3. Mr Shoaib Ahmed, Area FID, DRAP, Karachi.

9. Capsule Dry Powder inhaler (Steroid) – New 10. Tablet (Psychotropic) – New 11. Raw Material Store – Revised 12. Quality Control Laboratory - Revised 13. R&D – Revised Evaluator: Mubashir Iqbal (DD-Lic)			

M/s Genix Pharma (Pvt) Ltd., situated at Plot No.44, 45B, Korangi Creek Road, Karachi was inspected with reference to the directions contained in DRAP Islamabad Letter No.F.2-12/93-Lic, dated 03rd February, 2022 & 25th May,2023 in connection with the grant of new / Revised section: -

1. DPI Capsule (Steroid) – New
2. MDI (Meter Dose Inhaler)-New
3. Tablet (Psychotropic) – New
4. Suppository – New
5. Tablet Section (General) – Revised
6. Ointment/Cream/Gel (General) – Revised
7. Dry Powder Suspension (General) – Revised
8. Liquid Syrup (General) – Revised
9. Capsule (General) – Revised
10. Sachet (General) – Revised

Following are the observations:

The Revised/New sections are built as per layout plan approved by the DRAP authorities Islamabad vide letter No.F.2-12/93-Lic (Vol-VI) dated 03rd February, 2022 & 25th May, 2023. All production, quality control, research and development laboratory, warehouse and storage facilities were observed well maintained. Equipment were found commissioned and qualified, in general.

Adequate technical personnel were available and observed well conversant with the required knowledge of the GMP. Dedicated HVAC system operating through pharma grade AHUs (Air Handling Units system) for each sections of production facility with air process according to grades of area. Key staff has good qualifications, experience and skill according to the position and job description for employees.

Based on the stated observations the panel unanimously recommends the grant of New Sections of MDI, DPI (Steroid), Tablet Psychotropic & Suppositories and also recommends the regularization/revision of Tablet Section (General), Ointment/Cream/Gel (General), Dry

Powder Suspension (General), Liquid Syrup (General), Capsule (General), Sachet (General), QC Lab, Raw Material Store and R&D Lab made as per approved design for above mentioned sections under DML No.00351 by way of formulation.

Decision of the Central Licensing Board in 292nd meeting:

The Board considered and approved the grant of following additional sections in the name of M/s Genix Pharma (Pvt) Ltd., 44, 45B, Korangi Creek Road, Karachi under DML No. 000351 (Formulation) on the recommendations of the panel of experts subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for psychotropic section:

1. DPI Capsule (Steroid) – New
2. MDI (Meter Dose Inhaler)-New
3. Tablet (Psychotropic) – New
4. Suppository – New
5. Tablet Section (General) – Revised
6. Ointment/Cream/Gel (General) – Revised
7. Dry Powder Suspension (General) – Revised
8. Liquid Syrup (General) – Revised
9. Capsule (General) – Revised
10. Sachet (General) – Revised

While recording the minutes of 292nd meeting following facilities were inadvertently missed in the decision:

i. Raw Material Store – Revised
ii. Quality Control Laboratory – Revised
iii. R&D – Revised

Decision of the Central Licensing Board in 294th meeting

The Board considered the case and decided to approve the correction and approved the revision of following facilities.

i. Raw Material Store – Revised
ii. Quality Control Laboratory – Revised
iii. R&D – Revised

Case No. 5 CORRECTION IN MINUTES OF 292ND MEETING OF CLB - RENEWAL OF DML NO. 000486 (FORMULATION) OF M/s AKSON PHARMACEUTICALS (PVT.) LTD, MIRPUR, AZAD KASHMIR

Evaluator: - Muhammad Yaqoob (AD-Lic)

The Central Licensing Board in its 292nd meeting held on 4th October, 2023 considered and approved the grant of renewal of M/s Akson Pharmaceuticals (Pvt.) Ltd, Plot No. 9-B/1&2, Street No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir under DML No. 000486 (Formulation) and decided as under: -

> "The Board considered and approved the grant of renewal of DML No. 000486 by way of Formulation in the name of M/s Akson Pharmaceuticals (Pvt.) Ltd, Plot No. 9-B/1&2, Street No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir on the recommendations of the panel of experts for the period Commencing on 12-04-2021 ending on 11-04-2026 for the following sections.
>
> i. Tablet Section (General) Revised.
> ii. Tablet Section (Antibiotic).
> iii. Oral Liquid Section (General).
> iv. Capsule Section (General).
> v. Injectable Ampoule & Infusion (General).
> vi. Quality Control Laboratory.
> vii. Stores (RMS, FGS, PMS)

It is pertinent the mention that the panel recommends the renewal of Drug Manufacturing License to M/s Akson Pharmaceuticals located at No. 9-B/1&2m Street No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir having DML No. 000486 for following sections.

i. Tablet Section (General) Revised.
ii. Tablet Section (Antibiotic).
iii. Oral Liquid Section (General).
iv. Capsule Section (General).
v. Injectable Ampoule & Infusion.
vi. Lyophilized Powder for Injection (General) New.
vii. R&D Department (New).
viii. Quality Control Laboratory.
ix. Stores (RMS, PMS & FGS).

It is submitted that the following sections have been inadvertently missing while drafting of minutes: -

1. Lyophilized Powder for Injection (General) – New.
2. R&D Department (New).

Decision of the Central Licensing Board in 294th meeting

The Board considered the case and decided to approve the correction and approved the grant of following additional section / facility.

1. Lyophilized Powder for Injection (General) – New.
2. R&D Department (New)

Case No. 6 CHANGE OF MANAGEMENT M/S STAR LABORATORIES (PVT) LTD, 23-KM, MULATAN ROAD, LAHORE. UNDER DRUG

MANUFACTURING LICENSE NO. 000130 BY WAY OF (FORMULATION).

Evaluator: - Ume Laila (DD-Lic)

The firm, M/s Star Laboratories (Pvt) Ltd, 23-KM, Multan Road, Lahore, wherein the firm has submitted application for change of management with relevant fee of Rs. 75,000/. The detail of management is as under;

Previous Management as per Form-29	**Current Management as per Form-29**
1. Ch. Rehmat Ullah S/o Muhammad Bashir CNIC No. 35202-3035965-92. 2. Mr. Muhammad Asrar H. Malik S/o Iqbal Malik CNIC No.35202-2257887-3. 3. Mr. Muhammad Ashar H. Malik S/o Iqbal H Malik CNIC No. 35202-2766524-7.	1. Mr. Muhammad Asrar Hussain Malik S/o Iqbal Malik CNIC No.35202-2257887-3. 2. Mr. Muhammad Ashar Hussain Malik S/o Iqbal H Malik CNIC No. 35202-2766524-7. 3. Mr. Iqbal Hussain Malik S/o Jaml Din CNIC No. 35202- 8890175-3.

The case for change of management of M/s Star Laboratories (Pvt) Ltd, 23-Km, Multan Road, Lahore under DML No. 000130 by way of formulation was placed before the CLB in its 288th meeting and the board decided as under: -

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*"

The firm has replied and submitted relevant certified true copy of Form-29.

Decision of the Central Licensing Board in 294th meeting

The Board considered and accepted for record the change of management of M/s Star Laboratories (Pvt) Ltd, 23-KM, Multan Road, Lahore, DML No.000130 (formulation) from the date of change in SECP as under;

Previous Management as per Form-29	**Current Management as per Form-29**
1. Ch. Rehmat Ullah S/o Muhammad Bashir CNIC No. 35202-3035965-92.	1. Mr. Muhammad Asrar Hussain Malik S/o Iqbal Malik CNIC No.35202-2257887-3.

2. Mr. Muhammad Asrar H. Malik S/o Iqbal Malik CNIC No.35202-2257887-3. 3. Mr. Muhammad Ashar H. Malik S/o Iqbal H Malik CNIC No. 35202-2766524-7.	2. Mr. Muhammad Ashar Hussain Malik S/o Iqbal H Malik CNIC No. 35202-2766524-7. 3. Mr. Iqbal Hussain Malik S/o Jaml Din CNIC No. 35202- 8890175-3.

Case No. 7 **M/S SKYWIN PHARMACEUTICALS, PLOT NO. 01, AL-BADAR INDUSTRIAL ESTATE, PHASE II, 18-KM, SHEIKHUPURA ROAD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000971 BY WAY OF (FORMULATION).**

Evaluator: - Ume Laila (DD-Lic)

The case for grant of DML of M/S Skywin Pharmaceuticals, Lahore was placed before the CLB in its 290th meeting and the board decided as under: -

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.*

Liquid Vial Section (General) for confirmation whether SVP or LVP with supporting documents"

Assistant Director (I&E), DRAP, Lahore has submitted report which is as under:

> "*It is stated that the filling machine is equipped with plastic pump in Liquid Vial Section (SVP) (General) qualifies for filling of vials upto 100ml."*

The firm has replied and submitted relevant documents for grant of approval of deferred sections as under:

Sr. No.	Decision on Deferred Sections	Skywin's Response
1.	Tablet Section (Hormone) and Liquid Injection Ampoule (Hormone) for confirmation whether steroidal or non-steroidal	Steroidal Hormonal Section
2.	Liquid Vial Section (General) for confirmation whether SVP or LVP with supporting documents.	LVP

Decision of the Central Licensing Board in 294th meeting:

"The Board considered the facts and approved the grant of following sections 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.

Tablet Section (Hormone)Steriodal and Liquid Injection Ampoule (Hormone)Steriodal and Liquid Vial Section (General) SVP.

PERSONAL HEARING CASES

Case No. 8 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S CAYLEX PHARMACEUTICALS (PVT) LTD, LAHORE.

Evaluator: - Zunaira Faryad (AD-Lic)

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

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings/deficiencies was issued to the firm on 24-08-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
iii. Detail of management, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 duly attested by SECP (original).

v. Duly attested CNIC copies of all Directors.
vi. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vii. Duly attested resignation of earlier production Incharge.
viii. Duly attested resignation of proposed production Incharge from previous firm.

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

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

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

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

Decision of the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No. 000451 by way of formulation of M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

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

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

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

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

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

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

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

Decision of the Central Licensing Board in 294th meeting

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

Case No. 9 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S LAHORE PHARMA, LAHORE.

Evaluator: - Zunaira Faryad (AD-Lic)

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

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 01-07-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.

ii. Detail of premises including layout plan.

iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,

iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.

v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

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

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.

ii. Detail of premises including layout plan.

iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,

iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.

v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

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

Decision of the Central Licensing Board in 288th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5, Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No. 000084 by way of formulation of M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

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

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

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.

ii. Detail of premises including layout plan.

iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,

iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.

v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

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

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

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

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

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

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

Case No. 10 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000428 (FORMULATION) OF M/S FLOW PHARMACEUTICALS (PVT) LTD, 17-KM SHEIKHUPURA ROAD, LAHORE.

Evaluator: - Zunaira Faryad (AD-Lic)

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.

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

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

Mr. Saif-Ur-Rehman, Director of the firm appeared before the Board. He informed that the production/manufacturing operations of the firm are closed since 2019 due to renovation. The

Board after perusal of record and facts decided to suspend the Drug Manufacturing License No. 000428 (Formulation) of M/s Flow Pharmaceuticals (Pvt) Ltd, 17-Km Sheikhupura Road, Lahore for 6 months for fulfilment of codal formalities under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering & Advertising) rules, 1976 for not complying the provisions of Rule 5 (2A) of the Drugs (Licensing, Registering & Advertising) rules, 1976.

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

	Keeping in view the manufacturing facilities like building and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors was of the opinion to **recommend**: The renewal and regularization of Drug Manufacturing to M/s A&K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad for the following sections: 1. Oral Powder (General) (Veterinary) Section (Renewal & Regularization) 2. Oral Liquid (General) (Veterinary) Section (Renewal & Regularization) **3.** Bolus Section (Renewal) 4. Liquid Injectable (General) (Veterinary) Section (Revised) And grant of following additional section: 1. Oral Powder (Penicillin) (Veterinary) Section (New) **<u>Decision of the Central Licensing Board in 294th meeting:</u>** The Board observed that the dedication of the Penicillin section is not provided hence the Board deferred the decision on additional section and advised the firm to approach Licensing division for amendments. 1. Oral Powder (Penicillin) (Veterinary) Section (New)			
2.	M/s Medipak Ltd., 132-Industrial Estate Kot Lakhpat, Industrial Estate, Lahore. DML No.000257 (Formulation). **<u>Sections (01)</u>:** i. Plastic Ampoule (BFS) (General) Section. <u>Evaluator:- Ume Laila (DD-Lic)</u>	22-12-2023	**Good**	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr Abdul Rashid Sh FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	<u>Recommendations of the panel:</u> Keeping in view the manufacturing facility and availability of HVAC system, water system, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors recommends to grant additional section to M/s Medipak Limited 132/1, Industrial Estate Kot Lakhpat, Lahore for the following sections: 1. Plastic Ampoule (BFS) (General) Section.			

	Decision of the Central Licensing Board in 294th meeting: On the recommendations of the panel of experts, the Board considered and approved the grant of following section in the name of M/s Medipak Ltd., 132-Industrial Estate Kot Lakhpat, Industrial Estate, Lahore under DML No. 000257 (Formulation) subject to verification of testing equipment (M-290th CLB): - 1. Plastic Ampoule (BFS) (General) Section.			
3.	M/s Venus Pharma, 23-Km, Multan Road, Lahore. DML No.000300 (Formulation). **Sections (02):** i. Ampoule Section General (Human (New) ii. Ampoule Section Hormone (Human) New. Evaluator:- Ume Laila (DD-Lic)	**22-12-2023**	**Good**	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: Keeping in view the manufacturing facility like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors recommends the renewal of DML, grant additional sections (2) and regularization of following (04) sections too, to M/s Venus Pharma, 23-Km, Multan Road, Lahore for the following sections: 1. Tablet Section (Psychotropic) (Renewal) 2. Tablet Section (Steroid) Renewal) 3. Capsule Section (General) (Renewal) 4. Injectable Ampoule Section (Psychotropic) (Renewal) 5. Injectable Section (Steroid) (Renewal) 6. Liquid Injectable Section (General) (Veterinary) (Renewal) 7. Liquid Injectable Section (Steroid) (Veterinary) (Renewal) For Regularization of Sections: 1. Liquid Ampoule Section (General) (Revised) 2. Tablet Section (General) (Revised) 3. Cream/Ointment Section (Revised)			

	4. Infusion Section (General) (Revised) <u>For grant of additional Sections</u> 1. Ampoule Section General (Human (New) 2. Ampoule Section Hormone (Human) New. **<u>Decision of the Central Licensing Board in 294th meeting:</u>** On the recommendations of the panel of experts, the Board considered and approved the grant of following section in the name of M/s Venus Pharma, 23-Km, Multan Road, Lahore under DML No. 000300 (Formulation) subject to verification of testing equipment (M-290th CLB): i. Ampoule Section General (Human (New) ii. Ampoule Section Hormone (Human) New.			
4.	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. DML No.000887 (Formulation). **<u>Sections (04)</u>**: 1. Injectable (General) (Veterinary) Section (New) 2. Injectable (General Antibiotic) (Veterinary) Section (New) 3. Injectable (Penicillin) (Veterinary) Section (New) 4. Injectable (Steroid) (Veterinary) Section (New) <u>Evaluator:- Zunaira Faryad (AD-Lic)</u>	**13-12-2023**	**Good**	1. Dr. Farzana Ch., Expert Member. 2. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Mr Abdul Rasheed Sh. FID, DRAP, Lahore.
	<u>Recommendations of the panel:</u> Keeping in view the manufacturing facilities like building and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors recommends the Renewal of DML to M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad for the following sections: 1. Oral Liquid (General) (Veterinary) Section (Renewal)			

	2. Oral Liquid (General Antibiotic) (Veterinary) Section (Renewal) 3. Oral Powder General (Veterinary) Section (Renewal) 4. Oral Powder (General) Antibiotic) (Veterinary) Section (Renewal) 5. Oral Powder (Penicillin) Section (Renewal) Panel also recommends the following additional sections to M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad for the following sections: 1. Injectable (General) (Veterinary) Section (New) 2. Injectable (General Antibiotic) (Veterinary) Section (New) 3. Injectable (Penicillin) (Veterinary) Section (New) 4. Injectable (Steroid) (Veterinary) Section (New) **Decision of the Central Licensing Board in 294th meeting:** On the recommendations of the panel of experts, the Board considered and approved the grant of following section in the name of M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad under DML No. 000887 (Formulation) subject to verification of testing equipment (M-290th CLB): 1. Injectable (General) (Veterinary) Section (New) 2. Injectable (General Antibiotic) (Veterinary) Section (New) 3. Injectable (Penicillin) (Veterinary) Section (New) 4. Injectable (Steroid) (Veterinary) Section (New)

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

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s A&K Pharmaceuticals (Pvt) Ltd, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad. DML No.000534 (Formulation).	**14-12-2023**	**Good**	1. Mr. Muhammad Shamoon Ch., Expert Member. 2. FID, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Islamabad.

	Period: Commencing on 12-03-2019 ending on 11-03-2024. Evaluator:- Zunaira Faryad (AD-Lic)			
	Quality Control Incharge	Mr. Muhammad Ghulam Mustafa (Pharm-D)		
	Production Incharge	Mr. Shehbaz Ali (Pharm-D)		
	Recommendation of the Panel: Keeping in view the manufacturing facilities like building and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors was of the opinion to **recommend**: • The renewal and regularization of Drug Manufacturing to M/s A&K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad for the following sections: 1. Oral Powder (General) (Veterinary) Section (Renewal & Regularization) 2. Oral Liquid (General) (Veterinary) Section (Renewal & Regularization) 3. Bolus Section (Renewal) 4. Liquid Injectable (General) (Veterinary) Section (Revised) • And grant of following additional section: 1. Oral Powder (Penicillin) (Veterinary) Section (New) **Decision of the Central Licensing Board in 294th meeting:** The Board considered and approved the grant of renewal of DML No. 000534 by way of Formulation and regularization of layout plan in the name of M/s A&K Pharmaceuticals (Pvt) Ltd, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad on the recommendations of the panel of experts for the period Commencing on 12-03-2019 ending on 11-03-2024 for the following sections subject to verification of testing equipment (M-290th CLB). 1. Oral Powder (General) (Veterinary) Section (Renewal & Regularization) 2. Oral Liquid (General) (Veterinary) Section (Renewal & Regularization) 3. Bolus (Veterinary) Section (Renewal) 4. Liquid Injectable (General) (Veterinary) Section ((Renewal)			
2.	M/s Venus Pharma, 23-Km, Multan Road, Lahore.	**22-12-2023**	**Good**	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. FID, DRAP, Lahore.

	DML No. 000300 (Formulation). Period: Commencing on 25-12-2020 ending on 24-12-2025. <u>Evaluator:- Ume Laila (DD-Lic)</u>			3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.

<u>Recommendation of the Panel:</u>

Keeping in view the manufacturing facility like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors recommends the renewal of DML, grant additional sections (2) and regularization of following (04) sections too, to M/s Venus Pharma, 23-Km, Multan Road, Lahore for the following sections:

1. Tablet Section (Psychotropic) (Renewal)
2. Tablet Section (Steroid) Renewal)
3. Capsule Section (General) (Renewal)
4. Injectable Ampoule Section (Psychotropic) (Renewal)
5. Injectable Section (Steroid) (Renewal)
6. Liquid Injectable Section (General) (Veterinary) (Renewal)
7. Liquid Injectable Section (Steroid) (Veterinary) (Renewal)

<u>For Regularization of Sections</u>:

1. Liquid Ampoule Section (General) (Revised)
2. Tablet Section (General) (Revised)
3. Cream/Ointment Section (Revised)
4. Infusion Section (General) (Revised)

<u>For grant of additional Sections</u>

1. Ampoule Section General (Human (New)
2. Ampoule Section Hormone (Human) New.

<u>Decision of the Central Licensing Board in 294th meeting:</u>

The Board considered and approved the grant of renewal of DML No. 000300 by way of Formulation and regularization of layout plan in the name of M/s Venus Pharma, 23-Km, Multan Road, Lahore on the recommendations of the panel of experts for the period Commencing 25-12-2020 ending on 24-12-2025 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for psychotropic section, and verification of testing equipment (M-290th CLB).

<table>
<tr><td></td><td colspan="4">1. Tablet Section (Psychotropic) (Renewal)
2. Tablet Section (Steroid) Renewal)
3. Capsule Section (General) (Renewal)
4. Injectable Ampoule Section (Psychotropic) (Renewal)
5. Injectable Section (Steroid) (Renewal)
6. Liquid Injectable Section (General) (Veterinary) (Renewal)
7. Liquid Injectable Section (Steroid) (Veterinary) (Renewal)

<u>For Regularization of Sections</u>:

1. Liquid Ampoule Section (General) (Revised)
2. Tablet Section (General) (Revised)
3. Cream/Ointment Section (Revised)
4. Infusion Section (General) (Revised)</td></tr>
<tr><td>3.</td><td>M/s P.D.H., Pharmaceuticals (Pvt) Ltd., 19 Km, Ferozepur Road, Lahore.

DML No.000459 (Formulation).

Period: Commencing on 22-09-2020 and ending on 21-09-2025.

<u>Evaluator:- Ume Laila (DD-Lic)</u></td><td>04-12-2023</td><td>Good</td><td>1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore.
2. Mr Abdul Rashid Sh FID, DRAP, Lahore.
3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendation of the Panel:</u>

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

Keeping in view the observations made on the day of inspection and after going through the documentations and overall operations, the panel was of the opinion that the firm M/s PDH Pharmaceuticals (Pvt) Ltd., Lahore may be granted renewal of Drug Manufacturing License for the following sections:
1. Syrup (General) Section
2. Tablet (General) Section
3. Capsule Section (General)
4. Ophthalmic Section
5. Tablet (Antibiotic) Section
6. Dry Syrup (Antibiotic) Section</td></tr>
</table>

7. Sachet (General) Section

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

Decision of the Central Licensing Board in 294th meeting:

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

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

Quality Control Incharge	Ms. Abida Abbas (Pharm-D)
Production Incharge	Muhammad Yamin B-Pharm

4.	M/s Medpharm Research Lab, 28-Km, Ferozepur Road, Lahore. DML No.000878 (Formulation). Period: 25-02-2023 ending on 26-02-2028 Evaluator:- Ume Laila (DD-Lic)	25-10-2023	Good	1. Mr. Muhammad Shamoon Ch., Expert Member. 2. Abdul Rashid Sh FID, DRAP, Lahore. 3. Mr Ishtaiq Shafiq Assistant Director, DRAP, Lahore.

Recommendation of the Panel:

In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation e.t.c the panel of inspectors is of the opinion to **recommend** the renewal of Drug Manufacturing License and also grant of additional veterinary two following sections to M/s Medpharm Research Lab, 28-Km, Ferozepur Road, Lahore:

	1. Tablet (General) Section 2. Capsule Section (General) 3. Sachet (General) Section 4. Dry Powder Suspension (General) 5. Capsule (Cephalosporin) Section 6. Dry Powder Suspension (Cephalosporin) Section 7. Dry Powder Injection (Cephalosporin) Section. 8. Oral Powder (Veterinary) Section (New) 9. Oral Liquid (Veterinary) Section (New) **Decision of the Central Licensing Board in 294th meeting:** The Board considered and approved the grant of additional section and renewal of DML No. 000878 by way of Formulation in the name of M/s Medpharm Research Lab, 28-Km, Ferozepur Road, Lahore on the recommendations of the panel of experts for the period commencing on 25-02-2023 ending on 26-02-2028 for the following sections subject to verification of testing equipment (M-290th CLB). 1. Tablet (General) Section 2. Capsule Section (General) 3. Sachet (General) Section 4. Dry Powder Suspension (General) 5. Capsule (Cephalosporin) Section 6. Dry Powder Suspension (Cephalosporin) Section 7. Dry Powder Injection (Cephalosporin) Section. 8. Oral Powder (Veterinary) Section (New) 9. Oral Liquid (Veterinary) Section (New)			
5.	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. DML No.000887 (Formulation). Period: Commencing on 29-08-2023 ending on 28-08-2028 Evaluator:- Zunaira Faryad (AD-Lic)	**13-12-2023**	**Good**	1. Dr. Farzana Ch., Expert Member. 2. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 3. FID, DRAP, Lahore.
	Recommendations of the Panel: Keeping in view the manufacturing facilities like building and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors **recommends** the Renewal			

	of DML to M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad for the following sections: 1. Oral Liquid (General) (Veterinary) Section (Renewal) 2. Oral Liquid (General Antibiotic) (Veterinary) Section (Renewal) 3. Oral Powder General (Veterinary) Section (Renewal) 4. Oral Powder (General) Antibiotic) (Veterinary) Section (Renewal) 5. Oral Powder (Penicillin) Section (Renewal) Panel also **recommends** the following additional sections to M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad for the following sections: 1. Injectable (General) (Veterinary) Section (New) 2. Injectable (General Antibiotic) (Veterinary) Section (New) 3. Injectable (Penicillin) (Veterinary) Section (New) 4. Injectable (Steroid) (Veterinary) Section (New) **<u>Decision of the Central Licensing Board in 294th meeting:</u>** The Board considered and approved the grant of renewal of DML No. 000887 by way of Formulation in the name of M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad on the recommendations of the panel of experts for the period commencing on 29-08-2023 ending on 28-08-2028 for the following sections subject to verification of testing equipment (M-290th CLB). 1. Oral Liquid (General) (Veterinary) Section (Renewal) 2. Oral Liquid (General Antibiotic) (Veterinary) Section (Renewal) 3. Oral Powder General (Veterinary) Section (Renewal) 4. Oral Powder (General) Antibiotic) (Veterinary) Section (Renewal) 5. Oral Powder (Penicillin) Section (Renewal) **Quality Control Incharge** — Mr. Shoyab Ali (Pharm-D) **Production Incharge** — Ms. Sobia Yousaf (Pharm-D)			
6.	M/s Genesis Pharmaceuticals (Pvt) Ltd., 25-Sunder Industrial Estate, Lahore. DML No.000793 (Formulation). Period: Commencing on 01-04-2019 ending on to 31-03-2024. <u>Evaluator: - Zunaira Faryad (AD-Lic)</u>	**14-11-2023**	**Good**	1. Dr. Farzana Ch., Expert Member. 2. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Government of the Punjab, Lahore. 3. Mr Abdul Rasheed Sh FID, 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 to M/s Genesis Pharmaceuticals (Pvt) Ltd., 25-Sunder Industrial Estate, Lahore, by way of formulation for the following two sections only:

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

Decision of the Central Licensing Board in 294th meeting:

The Board considered and approved the grant of renewal of DML No. 000793 by way of Formulation in the name of M/s Genesis Pharmaceuticals (Pvt) Ltd., 25-Sunder Industrial Estate on the recommendations of the panel of experts for the period commencing on 01-04-2019 ending on to 31-03-2024 for the following sections subject to verification of testing equipment (M-290th CLB).

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

Quality Control Incharge	Mr. Muhammad Sohail (B. Pharm)
Production Incharge	Mr. Mohsin Raza (Pharm-D)

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	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). Decision of the Central Licensing Board in 293rd 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). **Decision of the Central Licensing Board in 294th meeting:** The Board observed that the firm have already Liquid injection section approved by Licensing Division and the Board considered and approved the grant of the following revised section in the name M/s Winbrains Research Laboratories, Hattar (Formulation) on the recommendations of the panel of experts: i. Liquid Injectable Section with Lyophilized Facility (Revised) The Board decided that the following comments/view of the panel be conveyed to Drug Registration Board/ PE&R, Division DRAP for further necessary action at their end; *"The 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."* The Board further decided that the final decision/recommendations by working group constituted for Semi-Automatic machine in aseptic area shall be implemented across the Board.

MINUTES OF MEETING OF 294th CENTRAL LICENSING BOARD

HELD ON 27th DECEMBER, 2023, QUALITY ASSURANCE CASES

(GMP NON-COMPLIANCE)

INDEX

	Name of firm	
Item No. I cGMP Non-Compliance Matters		
I.	M/s. Welwink Pharmaceuticals, G.T. Road, Industrial Estate, Gujranwala Cantt, Gujranwala	02-19

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 / 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.

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*.

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.

ACTION BY QA&LT

i. The firm was issued show cause notice dated 04.08.2023, wherein the firm was show cause in writing for reasons of violations mentioned above.

ii. The firm was also directed vide above mentioned letter to suspend the Production activities in the Liquid injectable and dry powder injectable sections with immediate effect.

iii. Nominations of two (02) aseptic manufacturing experts having at least 10 years' technical hands on experience in aseptic manufacturing operations for establishment of working group on aseptic manufacturing processes were demanded from Chairman Pharma Bureau, Pakistan and Chairman PPMA, Pakistan vide official correspondence dated 11.07.2023 and Reminder-I, dated 12.09.2023. However, despite a deadline extension up to 15.09.2023, no response was received at the QA&LT division.

RESPONSE BY THE FIRM

The firm has submitted response to show cause notice dated 04.08.2023 vide letter No. Nil dated 08.08.2023 received at QA&LT on 18.08.2023. Wherein the firm continues to deny the violation of conditions of DML stating that ***"The show cause notice alleges that our company has violated the Drug Manufacturing License by engaging in unauthorized manufacturing and storage of drugs"*** whereas, the referred letter mentions the violation of condition of license vide Section 23(1)(b) of Drugs Act 1976 explained vide Rule 20 Additional conditions of license to manufacture drugs by way of formulation, vide para (a) which mentions the requirement for compliance of Schedule B-II of the Drugs (LR&A) rules 1976. Which have been reported repeatedly by three different panels since 2019. Furthermore, this firm has wrongfully claimed that "no further assessments have been carried out that substantiate any instance of drug manufacturing within our injectable section" referring to the inspection conducted on 28.07.2022; however, the report from the same date as received in this office has information contrary the firm's claim. Since, the report vide page no. 11, 12, 13, 26, 27, 28, 29, 30, 31, 32 & 35 has critical observations pertaining to the sterile manufacturing facility which have not been addressed in the CAPA submitted by the firm; hence the section is rightful in maintaining this viewpoint that no further improvements have

taken place; the same is endorsed by the firm's own statement **"we would like to propose that either an inspection be scheduled subsequent to our submission of Corrective and Preventive Actions CAPA, allowing us the opportunity to address any identified concerns, or alternatively, we kindly request a comprehensive communication detailing the 12 points of contention along with relevant legal references"**; suggesting an obvious confusing paradox of what the firm actually intends.

In addition to the above the firm has wrongfully maligned the Director (QA&LT) of using inappropriate language regarding the firm's GMP; notwithstanding the factual position the acquisition is base less, since the undersigned was present during the proceedings and the Director QA&LT only reproduced the information already reported by the three different panels. However, this allegation attracts attention, regarding the confidentiality of information exchanged during the panel discussion.

RECOMMENDATION FROM QA&LT

The scientific rationale for emphasizing automation over semi-automatic systems in aseptic pharmaceutical manufacturing is grounded in risk reduction, precision, environmental control, data integrity, and process efficiency. These factors collectively contribute to the consistent production of sterile pharmaceutical products with a lower risk of contamination and higher quality, aligning closely with the principles outlined in the guidelines and regulatory expectations.

The guidelines specifically recommend the consideration of equipment such as RABS, isolators, and other systems to reduce the need for critical interventions into grade A environments and to minimize the risk of contamination. Additionally, they highlight the role of robotics and automation in eliminating direct human critical interventions, such as dry heat tunnel operations, automated lyophilizer loading, and sterilization in place. These recommendations underscore the significance of embracing automation in aseptic pharmaceutical manufacturing. By following these guidelines and embracing automation, pharmaceutical manufacturers can achieve a higher level of sterility assurance, precision, environmental control, and data integrity. Automation not only aligns with the principles outlined in the guidelines but also represents a proactive approach to reducing contamination risks, ensuring product quality, and safeguarding patient safety. In the pursuit of excellence in aseptic pharmaceutical manufacturing, the integration of automation technologies is not merely an option; it is a crucial imperative to meet the stringent demands of sterile product production in a scientifically rigorous and compliant manner.

Risk Reduction and Contamination Control:

Automation minimizes the potential for human errors, which are a significant source of contamination risk in aseptic pharmaceutical manufacturing. Human interventions, even with strict aseptic techniques, can introduce microbial contaminants, particles, or endotoxins into the critical processing areas. Automated systems, such as isolators and robotic solutions, reduce the presence of human operators in these areas, significantly

lowering the risk of contamination. This aligns with the guidelines' emphasis on controlling microbial, endotoxin/pyrogenic, and particle contamination.

Precision and Environmental Control:

Aseptic manufacturing requires strict control over environmental conditions, including temperature, humidity, and air quality. Manual or semi-automatic systems may struggle to maintain these conditions consistently. Automation, on the other hand, excels in precise control and monitoring of environmental parameters. It ensures that cleanroom and isolator conditions (e.g., grade A with grade B background) are consistently met during critical operations like filling and sealing.

Minimizing Human Interventions:

The guidelines highlight the importance of minimizing aseptic manipulations and critical interventions that could disrupt the sterile environment. Automation achieves this goal by reducing the need for manual interventions. Automated systems are designed to handle tasks like compounding, filling, and capping with precision and without direct human contact, thereby minimizing the risk of contamination.

Consistency and Reproducibility:

Automated systems provide a high level of consistency and reproducibility in aseptic processes. They perform tasks with the same level of precision every time, reducing batch-to-batch variability. This aligns with the goal of maintaining product quality and sterility, as emphasized in the guidelines.

Data Integrity and Documentation:

Automation facilitates robust data collection, monitoring, and documentation throughout the manufacturing process. This aligns with regulatory expectations for data integrity. Automated systems generate comprehensive and accurate records of critical manufacturing steps, which are essential for regulatory compliance and batch release.

Preparation and Filling:

For the preparation and filling of sterile products, the guidelines recommend performing these processes in grade A environments with a grade B background. Automation can effectively achieve and maintain these environmental conditions, ensuring product sterility.

Aseptic Connections:

The guidelines suggest that aseptic connections should be performed in grade A with a grade B background. Automation and intrinsic sterile connection devices are effective in reducing the risk of contamination during connections.

Interventions:

Automation is encouraged as a means to minimize human interventions in aseptic processes. Automated systems and robotics can perform critical tasks with precision, reducing the need for manual interventions.

Enhanced Process Efficiency:

Automated systems often result in more efficient and faster manufacturing processes. They can operate continuously, reducing production cycle times. This efficiency not only benefits pharmaceutical manufacturers by increasing productivity but also reduces the exposure of products to potential contaminants during extended processing times.

The QA&LT Division is privileged to present this agenda item to the esteemed Central Licensing Board (CLB) with an unwavering commitment to advancing pharmaceutical manufacturing standards in Pakistan. Our recommendations, rooted in international guidelines such as the "WHO Good Manufacturing Practices for Sterile Pharmaceutical Products," "The revised Annex 1 to the PIC/S GMP Guide on the Manufacture of Sterile Products," and "Good Manufacturing Practices, QALT/GL/MP/004," emphasize the pivotal role of automation in aseptic pharmaceutical manufacturing. These guidelines underscore the importance of automation for risk reduction, contamination control, precision, environmental management, data integrity, and process efficiency. This is not a matter of preference but a fundamental necessity to ensure the utmost quality, safety, and efficacy of pharmaceutical products produced within our nation's borders. We strongly urge the Central Licensing Board (CLB) to give careful consideration to these recommendations. By doing so, we can strengthen our regulatory framework and oversight, especially concerning semi-automatic filling machines, and align ourselves more closely with international best practices. Through the adoption of automation and adherence to these guidelines, we can enhance sterility assurance, elevate environmental control, fortify data integrity, and optimize manufacturing processes. In taking these steps, we not only demonstrate our commitment to international standards but also underscore our dedication to protecting public health and patient safety. The QA&LT Division is fully prepared to collaborate closely with the CLB and all relevant stakeholders to ensure the effective implementation of these recommendations. Together, we can advance the pharmaceutical manufacturing industry in Pakistan while upholding the highest standards of quality and safety. Your careful consideration of this critical matter is greatly appreciated.

PROCEEDINGS OF 292nd MEETING OF CLB: -

Representative of QA&LT presented the case before the CLB and the instant matter was deliberated in detail by all the members of the board.

DECISION OF 292nd MEETING OF CLB: -

The Board after thorough deliberation on the facts of the matter; the Board decided as under:

i. *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.*
ii. *Following panel has been constituted for verification of rectification status and assessment of the GMP compliance of the firm: -*
    a. *Mr. Ahzar Jamal Saleemi, Chief Drug Controller, Punjab or his Nominee.*

b. *Mr. Younas Khattak, Chief Drug Inspector, Khyberpakhtunkhwa.*
c. *Nominee number 1, DRAP Islamabad.*
d. *Nominee number 2, DRAP Lahore.*

iii. *The Board displayed consternation vis-à-vis the lack of response from PPMA and Pharma Bureau regarding the constitution of a working group comprising of representatives of Divisions of QA&LT, Licensing of DRAP and from PPMA and Pharma Bureau (observer), which was assigned the task 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 the 292nd meeting of CLB.*

iv. *The Board directed the Division of QA&LT to issue final reminder, with a specified timeline not exceeding 05 days, the Board nominated Mr. Ghulam Ali Lakho to join the above mentioned working group on behalf of the Board along with one nominee from the Division of PE&R. The Board further decided that incase nominations from PPMA and Pharma Bureau are not received the meeting of the working group shall convene and submit the recommendations before the upcoming meeting of CLB.*

MEETING OF WORKING GROUP ON ASEPTIC MANUFACTURING: -

The meeting convened as per schedule on December 22, 2023, at 10:00 AM in the Committee Room-II, 4th Floor, T.F Complex, G-9/4 Islamabad. The Expert Working Group, constituted by the Central Licensing Board during its 292nd Meeting, gathered to address critical considerations related to the Aseptic manufacturing process in the pharmaceutical industry. Following members were present:

i. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Government of Sindh, Karachi.
ii. Mr. Babar Khan, Nominee of the Director, Licensing, DRAP, Islamabad.
iii. Mr. Muneeb Ahmed Cheema, Nominee of the Director, PE&R, DRAP, Islamabad.
iv. Dr. Hasan Afzaal, Nominee of the Director, QA&LT, DRAP, Islamabad.
v. Dr. Shaikh Kaiser Waheed, Nominee of PPMA.
vi. Mr. Hamid Raza, Nominee of PPMA.
vii. Mr. Nadeem Alamgir, Nominee of Pharma Bureau, Pakistan.

The meeting was called to order, and the agenda primarily focused on formulating recommendations concerning the use of manual/semi-automatic filling and sealing machines in the aseptic filling area of dry powder injectable sections, as assigned during the 290th & 292nd CLB meetings. During the deliberations, participants engaged in comprehensive discussions, leveraging their expertise to explore various aspects of aseptic manufacturing processes. The group explored potential recommendations that align with industry best practices and regulatory standards. To facilitate efficient communication, an online link was provided to all participants prior to the meeting, ensuring seamless engagement in the discussions.

Preamble:

The working group assembled to address pivotal concerns surrounding sterile manufacturing practices, with a specific focus on the Dry Powder Injection Section of pharmaceutical manufacturing. This strategic initiative was born out of the 290th & 292nd CLB Meeting, emphasizing the importance of collaboration among representatives from the Divisions of QA&LT, Licensing, and PE&R of DRAP, alongside the representatives of PPMA and Pharma Bureau.

Mandate:

i. Filling Machines Evaluation: Evaluate manual/semi-automatic powder filling machines for efficiency and compliance.
ii. Compliance Examination: Examine adherence to recent DRAP and PIC/S guidelines, specifically referring to "Guide to Good Manufacturing Practice for Medicinal Products Annexes, PE 009-17."
iii. Recommendations: Formulate guidance for industry-wide decisions in aseptic manufacturing.
iv. Harmonization: Foster unified practices in critical manufacturing operations.
v. Informed Decision-Making: Ensure stakeholders access accurate information for decisions aligned with the latest regulatory standards.
vi. Alignment with Standards: Align manufacturing practices with evolving regulatory standards, referring to "Guideline on Good Manufacturing Practices 2023.

Legal framework:

Discussion revolved around the legal framework governing pharmaceutical manufacturing, highlighting key sections of the DRAP Act 2012, which empower the authority to enforce Good Manufacturing Practices (GMP) and promote the manufacture and export of pharmaceutical products meeting international standards, following sections of DRAP Act 2012 were discussed:

i. Section 4(1)(c)); Empowers DRAP for GMP enforcement.
ii. Section 4(1)(e); Facilitates sector upgradation to meet international standards (
iii. Section 7(c)(ix); Authorizes implementation of internationally recognized standards.
iv. In-depth exploration of minimum requirements outlined in Drugs (Licensing, Registering & Advertising) Rules 1976, Schedule B-I&II.

Minimum requirements/standards:

The meeting extensively delved into the minimum requirements and standards outlined in the Drugs (Licensing, Registering & Advertising) Rules 1976, particularly in Schedule B-I&II. Specific attention was given to room conditions, personnel requirements, and processing activities essential for aseptic manufacturing.

I. Filling and Sealing Room Standards (Schedule B-I):

The deliberation centered on the vital stipulations set forth in Schedule B-I of the Drugs (Licensing, Registering & Advertising) Rules 1976, with a pronounced emphasis on the imperative of aseptic

conditions in the filling and sealing room. Particular attention was directed towards specific criteria governing the filling and sealing unit, underscoring its significance in upholding stringent manufacturing practices. The discourse resolutely advocated for adherence to these standards, firmly discouraging manual filling and sealing of aseptic products

II. Barrier Technology (Schedule B-II):

The meeting extensively covered the requirements mentioned in Schedule B-II, Part-II, Section 2, Section 4.1, emphasizing the utilization of absolute-barrier technology and automated systems to minimize human interventions in processing areas. The discussion highlighted the advantages of such techniques in ensuring the sterility of manufactured products.

III. Aseptic Processing Conditions (Schedule B-II):

Part-II, Section-I outlined the conditions for products manufactured under aseptic conditions. The handling of starting materials and all further processing was emphasized to be conducted in a Grade A or B area. Continuous environmental monitoring standards were stressed for both viable and non-viable particles.

IV. Personnel Requirements (Schedule B-II):

Part-II, Section-I, 3.1 underscored the importance of having only the minimum number of personnel required in clean areas, especially during aseptic processes. The need for inspections and control conducted from outside the areas was emphasized to minimize potential contamination risks.

V. Simulation of Aseptic Operations (Schedule B-II):

Part-II, Section-I, 7.3 highlighted the valuable role of simulating aseptic operations through trials using nutrient media supporting microbial growth. Such simulations, including sterile media fills and broth fills, contribute to the overall validation of an aseptic process.

VI. Control of Activities in Clean Areas (Schedule B-II):

Part-II, Section-I, 7.5 emphasized the importance of keeping activities in clean areas to a minimum, especially during aseptic operations. Controlled and methodical movement of personnel was stressed to avoid excessive shedding of particles and organisms.

VII. Key Points from Guideline on Good Manufacturing Practices 2023:

The working group carefully considered several crucial points from the "Guideline on Good Manufacturing Practices 2023," referencing Annex-1: Manufacture of sterile medicinal products published by PIC/S.

VIII. Barrier Technology Implementation:

Under section 4. Premises (4.18-4.22), the discussion highlighted the implementation of barrier technology for manual aseptic processing activities, with permissible integrity verification criteria. The use of Isolator with specified conditions was recommended, and alternative approaches to the use of Restricted Access Barrier Systems (RABS) or isolators were discussed.

IX. Cleanroom Grades for Sterile Products:

Under section 4. Premises (4.3), the meeting emphasized the importance of maintaining four grades of cleanroom/zone for the manufacture of sterile products. Grade A, designated for high-risk operations, was particularly emphasized. The maintenance of unidirectional airflow and minimizing direct intervention into the grade A area was underscored.

X. Closed System Implementation:

Under section 8.127, the meeting stressed the use of closed systems to reduce the risk of microbial, particle, and chemical contamination from the adjacent environment. The design of closed systems should always aim to reduce the need for manual manipulations and associated risks.

XI. Single Use Systems (SUS):

Under section 8.132, the discussion highlighted the use of Single Use Systems (SUS) as an alternative to reusable equipment in the manufacture of sterile products. The design of SUS should focus on reducing the need for manipulations and the complexity of manual interventions.

XII. Validation of Manual Operations:

Under section 9.39, it was emphasized that where manual operation occurs, such as aseptic compounding or filling, each type of container, container closure, and equipment train should be initially validated with each operator participating in at least 3 consecutive successful aseptic processes. Periodic revalidation with one aseptic process approximately every 6 months for each operator was recommended to ensure ongoing compliance.

PPMA'S VIEW POINT

Expansion of Information:

It is important to note that the PPMA (Pakistan Pharmaceutical Manufacturers Association) representative has expressed a specific requirement. They have requested the submission of a comprehensive working paper that details the proposed plan or transition. This working paper is expected to provide an in-depth analysis and breakdown of the various aspects involved in the proposed changes.

Review Process:

This working paper, once submitted, will undergo a thorough examination and discussion within the Central Executive Council. The Central Executive Council is a key decision-making body within the PPMA, responsible for addressing important industry matters.

Follow-up Meeting:

Following the initial review within the Central Executive Council, there will be a subsequent meeting arranged to further discuss and advance the matter. This follow-up meeting is crucial for gaining additional insights, addressing any concerns, and collectively deciding on the way forward.

Concerns Raised by PPMA Representatives:

It's worth noting that the PPMA representatives have raised a specific concern. They have articulated that the proposed transition could potentially result in a shortage of Dry Powder for injection. This concern adds a layer of complexity to the deliberations and emphasizes the need for a detailed and careful examination of the proposed changes.

Importance of Further Deliberation:

Given the potential impact on the supply of Dry Powder for injection, it becomes imperative to thoroughly deliberate on the matter. The follow-up meeting, mentioned earlier, will serve as a platform for stakeholders to discuss, analyze, and collectively make decisions that ensure the smooth transition without compromising the availability of critical medical supplies.

In summary, the PPMA representative has emphasized the importance of a detailed working paper, subsequent deliberation within the Central Executive Council, and a follow-up meeting to address concerns and facilitate the proposed transition effectively, taking into consideration the potential impact on the supply of Dry Powder for injection.

RECOMMENDATION OF THE WORKING GROUP:

After comprehensive deliberations, the nominees from the Divisions of QA&LT, Licensing, and PE&R of DRAP, along with the representative of Pharma Bureau, unanimously agreed to the gradual implementation of Schedule B-I&II alongside international guidelines. This decision reflects a commitment to continuous improvement in aseptic manufacturing practices.

*In conclusion, the working group (**excluding the PPMA representation**), following in-depth evaluation and collaborative discussions, has collectively decided to recommend the CLB to revoke the exemption under Schedule B-I of the Drugs (Licensing, Registering & Advertising) Rules 1976, allowing modifications at the discretion of the Central Licensing Board. The group strongly recommends that manufacturers transition to at least a Semi-Automatic Filling and Sealing Unit in accordance with the stipulations of Schedule B-I and recent regulatory standards, as articulated in the "Guide to Good Manufacturing Practice for Medicinal Products Annexes, PE 009-17" and the "Guideline on Good Manufacturing Practices 2023." This decision underscores our unwavering commitment to upholding the highest standards in pharmaceutical manufacturing, promoting harmonization, and ensuring the production of safe and effective medicinal products in accordance with the established regulatory framework. We express our gratitude for the invaluable contributions of all members to these deliberations.*

It is to further add that; the PPMA representative requested the provision of a detailed working paper, which would undergo deliberation with the Central Executive Council and a follow up meeting shall be conducted for the furtherance of the matter, since the PPMA representatives presented the stance that this transition may lead to creation of a shortage of Dry Powder for injection.

The matter was placed before the board for information and perusal of the request made by the PPMA representative regarding, deliberation with the Central Executive Council and a follow up meeting; furthermore, since the instant matter i.e. of M/s Welwink Pharmaceuticals and M/s Winbrains Research Laboratories was linked with the outcomes of the Aseptic Working Group's recommendations, henceforth the same is placed before the board for consideration.

DECISION OF 294th MEETING OF CLB: -

i. *In light of the decision of the CLB from its 292nd meeting, the 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, following panel has been constituted for verification of rectification status and assessment of the GMP compliance of the firm: -*
    a) *Mr. Ahzar Jamal Saleemi, Chief Drug Controller, Punjab or his Nominee.*
    b) *Mr. Younas Khattak, Chief Drug Inspector, Khyberpakhtunkhwa.*
    c) *Nominee number 1, DRAP Islamabad.*
    d) *Nominee number 2, DRAP Lahore.*

ii. *The panel shall verify the rectification status regarding the GMP related issues other than the use of Manual/Semi-Automatic Filling & Sealing Machine; whereas the later shall be linked with the final recommendations of the Working Group on Aseptic Manufacturing and its subsequent decision in the upcoming CLB meeting.*