MINUTES OF 292nd MEETING OF CENTRAL LICENSING BOARD HELD ON 4th October, 2023

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292nd meeting of the Central Licensing Board (CLB) was held on 4th October, 2023 in the Committee Room, Drug Regulatory Authority of Pakistan, Ground Floor, NCLB, 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. Naveed Anwer, Drug Controller Rawalpindi (Nominee of Chief Drugs Controller), Government of the Punjab, Lahore	Member
3.	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Baluchistan, Quetta	Member
4.	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Government of Khyber Pakhtunkhwa.	Member
5.	Mr. Ghulam Ali Lakho, Chief Inspector of Drugs , Government of Sindh, Karachi	Member
6.	Mr. Ajmal Sohail, Director, Division of Quality Assurance and Lab Testing, Drug Regulatory Authority of Pakistan, Islamabad	Member
7.	Mr. Abid Ali, Deputy Draftsman, Ministry of Law & Justice Division, Islamabad	Member

Mr. Babar Khan Additional Director / Secretary Licensing Board presented the agenda before the Board. Mrs. Ume Liala Deputy Director (Lic), Mr. Yaqoob Kakar, Assistant Director (Lic), Abdullah Assistant Director (Lic), Mr. Hasan Afzaal and QA, Mr. Sannaullah DD (QC) and assisted the Secretary Central Licensing Board in presenting the agenda. The Board deliberated and decided the following case on priority as per orders from the Honorable Islamabad High Court.

Item-I **CONFIRMATION OF THE MINUTES OF 291stMEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 291st meeting of Central Licensing Board which was held on 30th May, 2023.

A. DRUG LICENSING DIVISION

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

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s Orbis Pharmaceuticals, Plot No. K/138, Phase-II, S.I.T.E., Karachi. Evaluator: Mubashir Iqbal (DD-Lic)	07-08-2023 / By way of formulation	Good	1. Mr. Abdul Rasool Sh. Area FID, DRAP, Karachi / Additional Director, DRAP, Karachi. 2. Mr. Ghulam Ali Lakho, Member Central Licensing Board. 3. Abdul Waheed Abbasi AD DRAP, Karachi.
	Production Manger			Ms. Anum Shakeel D/o Muhammad Shakil Ahmed (Pharm-D)
	Quality Control Manager.			Mr. Faizan Baig S/o Muzaffar Baig (M.Sc Chemistry)
	Recommendations of the panel:			
	As per instructions contained in DRAP Islamabad Letter No.F.2-11/2017-Lic, dated: 20th July, 2023, a detailed inspection of Ms. Orbis Pharmaceuticals situated at Plot No. K-138 phase II, SITE-Superhighway, carried out by the constituted panel on 07th August 2023. During opening meeting their Organogram JDs, SMF, approved design, HVAC provision and design, lists of machines, equipment, technical persons & products intended to be manufactured were discussed and reviewed in details as per the mandate given and found an adequate level of compliance. Training records since their appointment and several working SOPs were discussed at length and found an adequate retrieval and an appropriate maintenance of key documents. The firm is found built as per approved design. Total 34 AHUs are provided in production, QC Lab and in stores provided with 140 ton of chilling capacity and 52 tons of separate AHUs. Water Treatment Plant, Compressed air, dust-collection system centralized & steam generator are other utilities provided for better compliance. Some high-tech machines liker sheer mixer, NJV encapsulation, Auto-coater, a conventional cota and other production machines are well installed & Commissioned. Similarly, QC Lab also has been provided with some latest equipment like a HPLC, IR, UV, Dissolution & DT apparatus etc. The firm has hired a team of qualified, experienced and well-trained team in QC, QA, Stores and in Production. A separate R&D Lab with required equipment is also developed as per approved design. Necessary working SOP &documents are prepared for better working. IPQC & WIP are given at each floor. Keeping in view the above stated facts and based on the attitude of the management towards continuous improvements, the panel unanimously recommends the grant of DML (By way of formulation) to firm for following sections.			

<table>
<tr><td></td><td colspan="4">Tablet (G), Capsule (G), Dry Powder Suspension (G), Sachet (G), Lotion (Steroids/Non-steroids), Liquid Syrup/Suspension/Solution (G) & Cream/Ointment (Steroid/Non Steroid) based on the provision of separate sampling booth as per approved design.
<u>Decision of the Central Licensing Board in 292nd 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 Orbis Pharmaceuticals, Plot No. K/138, Phase-II, S.I.T.E., Karachi on the recommendations of the panel of experts for the following sections.
1. Tablet (General)
2. Capsule (General)
3. Dry Powder Suspension (General)
4. Sachet (General)
5. Lotion Section (General),
6. Liquid Syrup/Suspension/Solution (General)
7. Cream/Ointment (General)</td></tr>
<tr><td>2</td><td>M/s Gelcaps (Pakistan) Limited, Plot No. B-43, Hub Industrial Trading Estate, District Lasbela, Balochistan.

Evaluator: Mubashir Iqbal (DD-Lic)</td><td>15-07-2023</td><td>Good</td><td>1. Mr. Muhammad Salik Zahid, Chief Drug Inspector, Quetta.
2. Mr. Sajjad Ahmed Abbasi, Deputy Director, CDL, Karachi.
3. Mr Kirshan Area FID, DRAP, Quetta.</td></tr>
<tr><td></td><td colspan="3">Production Manager</td><td>Mr. Altaf Hussain S/o Koural Khan (B-Pharm)</td></tr>
<tr><td></td><td colspan="3">Quality Control Manager.</td><td>Mr. Ahmed Saeed S/o Moshin Ali Ansari (M.Sc Chemistry)</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>

M/s Gelcaps (Pakistan) Limited situated at Plot No. B-43, Hub Industrial Trading Estate, District Lasbela, Baluchistan was visited and inspected in detail on 15th July, 2023 in compliance to the directions contained in DRAP, Islamabad Letter No.F.4-3/2023-Lic dated 5th June, 2023 in connection with grant of DML by way of formulation.
Based on the people met, documents reviewed, and observations made during the inspection, the panel recommends the grant of Drug Manufacturing License by way of formulation for following one section only: -

<table><tr><td>S. No.</td><td>Name of Section</td></tr><tr><td>01</td><td>Capsule (General)</td></tr></table>
It is pertinent to mention that the panel was given mandate for inspection for the purpose of grant of DML for following two (02) sections: -

<table><tr><td>S. No.</td><td>Name of Section</td></tr><tr><td>1.</td><td>Capsule (General)</td></tr><tr><td>2.</td><td>Soft Gelatin Capsule (General) - New</td></tr></table>
However, the panel has recommended grant of only one (01) section i.e. Capsule (General).

<u>Decision of the Central Licensing Board in 292nd meeting:</u></td></tr>
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	The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Gelcaps (Pakistan) Limited, Plot No. B-43, Hub Industrial Trading Estate, District Lasbela, Baluchistan on the recommendations of the panel of experts for the following sections. 1. Capsule (General)			
3	M/s Pharmnova (Pvt) Ltd., Plot No.54 & 193 Deh Kanto Tappo, Landhi, Bin Qasim, Karachi Evaluator: Mubashir Iqbal (DD-Lic)	22-08-2023 / DML by way of Semi-Basic	Good	1. Mr. Abdul Rasool Sh. Additional Director, DRAP, Karachi. 2. Syed Hakim Masood, Area FID, DRAP, Karachi. 3. Mr Abdul Waheed Abbasi, Assistant Director (I&E), DRAP, Karachi.
	Production Manger			Mr. Ghulam shabbir S/o Mitho Khan (B-Pharm)
	Quality Control Manager.			Mr. Mohsin Sabih Jafri S/o Muhammad Taqi Jafri (M.Sc Chemistry)
	Recommendations of the panel: As per the given scope a detailed inspection of Ms. Pharmnova (Private) Limited situated at Plot No.193/54 Deh Kanto Tappo Landhi bin Qasim Karachi was carried out, wherein the panel thoroughly inspected their newly & purposefully constructed building for the production of Empty Hard Gel Capsules production. The panel reviewed in detailed the respective documents like Qualification records and SOPs made for smooth functioning of the unit. The firm has initially four fully automatic compact lines of UAE made capsule manufacturing machines. The sections and entire facility is provided with 39 AHUs terminally located HEPA filters in production section, cutting & joining, sorting and one AHU is given in microbiology lab. 900 tons' capacity chillers installed along with boiler, purified water and RO System. Other utilities are also suitably provided like Compressed Air, UPS System & Self-power generation with sufficient capacity. Well-Defined & Spacious stores are given. QC Lab was found well-equipped. The firm has also hired well-experienced technical persons. Based on the stated facts, documents reviewed, people met and attitude of the management towards continuous improvements, the panel unanimously recommends the grant of DML by way of Semi-Basic to the firm for Empty Hard Gel Capsules for the sizes including (00, 0, 1, 2, 3 & 4). **<u>Decision of the Central Licensing Board in 292nd 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 Pharmnova (Pvt) Ltd., Plot No.54 & 193 Deh Kanto Tappo, Landhi, Bin Qasim, Karachi on the recommendations of the panel of experts for the following section; 1. Empty Hard Gel Capsules for the sizes including (00, 0, 1, 2, 3 & 4). The Board further decided and approved manufacturing of above mentioned Empty Hard Gel Capsules sizes subject to submission of prescribed fee per size.			
4	M/s Q. Track Pharma, Plot No. D-90-91, Sector-D, H.I.T.E. Lasbella, Hub, Balochistan.	**19-09-2023 /**	**Good**	1. Mr. Muhammad Salik Zahid, Chief Drug Inspector, Baluchistan. 2. Mr Kirshan Area FID, DRAP, Quetta.

	Evaluator: Mubashir Iqbal (DD-Lic)	DML by way of Formulation		3. Mr. Abdul Waheed, Assistant Director (I&E), DRAP, Quetta.
	Production Manger			Mr. Mahtab Ahmed S/o Ahmed Khan Panhwar (Pharm-D)
	Quality Control Manager.			Mr. Muhammad Kalam S/o Muhammad Usman (M.Sc Chemistry)

Recommendations of the panel:

M/s Q. Track Pharma, situated at Plot No. D-90-91, Sector-D, H.I.T.E. Lasbella, Hub, Balochistan was visited and inspected in detail on 19th of September, 2023 in compliance to the directions contained in DRAP, Islamabad Letter No.F.2-6/2019 dated 14th September, 2023, in connection with grant of Drug Manufacturing License by way of Formulation.

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

Based on the people met, documents reviewed, and observations made during the inspection, the panel recommends the grant of Drug Manufacturing License by way Formulation for following sections only: -

S. No.	Name of Section
01	Tablet (General)
02	Capsule (General)
03	Dry Powder Suspension (General)
04	Sachet (General)
05	Warehouse (General)
06	Quality Control Lab

Decision of the Central Licensing Board in 292nd meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Q. Track Pharma, Plot No. D-90-91, Sector-D, H.I.T.E. Lasbella, Hub, Balochistan on the recommendations of the panel of experts for the following sections/facilities;

1. Tablet (General)
2. Capsule (General)
3. Dry Powder Suspension (General)
4. Sachet (General)
5. Stores (RMS, FGS, PMS)
6. Quality Control Laboratory

5	M/s Misaq Pharmaceutical (Pvt) Ltd, Plot No. 7-B, Woven Garments Zoom, Value Addition City, 1.5 Km, Khurrianwala-Sahianwala Road Faisalabad.	09-06-2023	Good	1. Prof. Dr. Mehmood Ahmed. (Member PQCB, Lahore) 2. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Muzammil Waheed.

	Sections (07): - 1. General Tablet Section. 2. General Capsule Section. 3. Cream/Ointment/Lotion (General) 4. Cream/Ointment/Lotion (Steroid). 5. General Liquid Injectable (Ampoule) / (Vials) 6. Dry Powder (General). 7. External Liquids Section. (Evaluator: Mrs. Ume Laila DD)			(Director, DTL, Faisalabad.
	Production Manager:			Mr. Luqman Ali S/o Rasheed Ahmed (B-Pharm)
	QC In-charge:			Mr. Abid Hussain S/o Muhammad Ramzan (M.Sc. Chemistry)
	It is pertinent to mention that the panel was given mandate for above mentioned sections. However, panel has submitted following recommendations; <u>Recommendations of the panel:</u> "Keeping in view the manufacturing facility like, building, HVAC system, installed Production machinery, equipment in Quality Control, Technical & experienced personnel having adequate documentation regarding production, QA, quality control, microbiology lab, purified water production and testing facilities. Panel thoroughly observed their revised layout plan approved by DRAP, Islamabad. The Panel of inspectors recommend the grant of new Drug Manufacturing License by way of formulation to M/s Misaq Pharmaceutical (Pvt) Ltd, 7-B, Woven Garments Zoom, Value Addition City, 1.5 Km, Khurrianwala-Sahianwala Road Faisalabad, in respect of following sections only" 1. General Tablet Section. 2. General Capsule Section. 3. Steroid Semisolid. 4. General Semisolid. 5. General Liquid Injectable (Ampoule) / (Vials) 6. Dry Powder Suspension.			

<table>
<tr><td></td><td colspan="4">7. External Liquids Section (Except Povidone)
Decision of the Central Licensing Board in 292nd meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Misaq Pharmaceutical (Pvt) Ltd, Plot No. 7-B, Value Addition City, Khurrianwala, Sahianwala (FIEDMC), Faisalabad on the recommendations of the panel of experts for the following section;

1. General Tablet Section.
2. General Capsule Section.
3. Cream/Ointment (General)
4. Cream/Ointment (Steroid).
5. General Liquid Injectable Ampoule / Vials
6. Dry Powder (General).
7. External Liquids Section (Except povidone iodine)
8. Quality Control Lab alongwith Microbiology Lab
9. R&D Facility</td></tr>
<tr><td>6</td><td>M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-Km, Adyalia Road, Post Office Dahgal, Rawalpindi.

(Evaluator: Mrs. Ume Laila DD)</td><td>06-06-2023 / by way of Semi-Basic</td><td>Good</td><td>1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.

2. Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Islamabad.

3. Mr. Mubashir Iqbal, Deputy Director (Licensing), DRAP, Islamabad</td></tr>
<tr><td></td><td colspan="2">Production Manger</td><td colspan="2">Mr. Muhammad Atif Islam S/o Muhammad Islam (Pharm-D).</td></tr>
<tr><td></td><td colspan="2">Quality Control Manager</td><td colspan="2">Mr. Zia Ur Rehman Zia S/o Khan Sherin (M.Sc Chemistry).</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>

“Panel inspected the unit and has evaluated the various documents in connection with production, Quality Control and Quality Assurance. Various technical aspects were also discussed with firm management at length. Based on the physical inspection of the unit, evaluation of the documents and discussion with the technical staff, undertaking given by the CEO of the firm, Panel has recommended the facility for grant of Drug Manufacturing License for Palletization (by way of Semi-Basic process) to M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-Km, Adaya Road, Post Office Dahgal, Rawalpindi. The evaluation of equipment and their capacity for the approval of individual APIs through process of palletization (by</td></tr>
</table>

	way of Semi-Basic process) required to be conducted time to time by the panel of DRAP as and when applied by the firm and desired by Central Licensing Board." **Decision of the Central Licensing Board in 292nd meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Semi-Basic Manufacture in the name of M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-Km, Adaya Road, Post Office Dahgal, Rawalpindi on the recommendations of the panel of experts for following facility i. Pelletization			
7	M/s Pharmaqio, 10-Km, BasaliChowk, ChakBeli Road, Rawalpindi. (Evaluator: Mrs. Ume Laila DD)	26-06-2023 / *by way of Formulation*	Good	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad. 2. Mr. Atiq Ul Bari, Federal Inspector of Drugs, DRAP, Peshawar. 3. Mr. Adnan Shahid ullah, Deputy Director (QA/LT), DRAP, Islamabad
	Production In-charge:			Mr. Syed Salauddin S/o Syed Mobeen (B-Pharm)
	QC In-charge:			Mr. Shahab Ali S/o M. Anwar (B-Pharm)
	Recommendations of the panel: *"M/s Pharmaqio was inspected in compliance to letter No. F.1-33/2016 dated 02-06-2023 by the panel for grant of Drug Manufacturing License. The manufacturing facility is located at 10-Km, Basali Chowk, Chakbeli road, Rawalpindi. During the inspection it was observed that the building has been constructed as per approved layout plan, all the required machinery and equipment in production and Quality Control were available, HVAC was functional, water system qualification was under process. Generator as per power backup was available, Firefighting system was in place. As per inspection conducted, people met and record / Documentation reviewed the panel unanimously recommends the grant of drug manufacturing license.*"			

	GROUND FLOOR (Dedicated Facility)	FIRST FLOOR
	1. Capsule Section (Cephalosporin) 2. Dry powder Suspension Section (Cephalosporin) 3. Dry Powder Injectable Section (Cephalosporin)	1. Capsule Section (General) 2. Table Section (General) 3. Cream / Ointment Section (General) 4. Sachet Section (General) 5. Dry Suspension Section (General) 6. Liquid Injection Section (General)

Decision of the Central Licensing Board in 292nd meeting:

	The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Pharmaqio, 10-Km, BasaliChowk, ChakBeli Road, Rawalpindi on the recommendations of the panel of experts for the following sections; GROUND FLOOR (Dedicated Facility) 1. Capsule Section (Cephalosporin) 2. Dry powder Suspension Section (Cephalosporin) 3. Dry Powder Injectable Section (Cephalosporin) FIRST FLOOR 1. Capsule Section (General) 2. Table Section (General) 3. Cream / Ointment Section (General) 4. Sachet Section (General) 5. Dry Suspension Section (General) 6. Liquid Injection Section (General)			
8	M/s Levon Pharmaceuticals, 13.5-Km Sheikhupura Road, Sheikhupura. **Sections (02)** 1. Dry Powder Suspension (Cephalosporin) Section. 2. Capsule (Cephalosporin) Section. (Evaluator: Mrs. Ume Laila DD)	23-08-2023 / *by way of Formulation*	Good	1. Dr. Farzana Chaudhry, Expert Member Policy Board. 2. Abdul Rashid Shaikh, Area Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.
	Production In-charge:			Mr. Awais Shaukat S/o Shaukat Ali (Pharm-D)
	QC In-charge:			Mr. Muhammad Zeeshan Naeem S/o Naeem Akhtar (M.Sc Chemistry)
	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 grant of DML to M/s Levon Pharmaceuticals, 13.5-Km, Sheikhupura Road, Sheikhupura for following sections: 1. Dry Powder Suspension (Cephalosporin) Section. 2. Capsule (Cephalosporin) Section. **Decision of the Central Licensing Board in 292nd meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Levon Pharmaceuticals, 13.5-Km Sheikhupura Road, Sheikhupura on the recommendations of the panel of experts for the following sections;			

<table>
<tr><td></td><td colspan="4">1. Dry Powder Suspension (Cephalosporin) Section.
2. Capsule (Cephalosporin) Section.</td></tr>
<tr><td rowspan="4">9</td><td>M/s Nutrion (Pvt.) Ltd, Plot No. 186, 192, 193/S, New Industrial Estate, Mirpur, AJ&K.

(Evaluator: Muhammad Yaqoob, AD)</td><td>24-06-2023</td><td>Good</td><td>1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.
2. Mr. Abdullah, Deputy Director (Controlled Drugs), DRAP, Islamabad.
3. Mr. Muhammad Umar Latif, Deputy Director (QA/LT), DRAP, Islamabad</td></tr>
<tr><td colspan="2">Production Manager</td><td colspan="2">Mr. Badar Rizwan S/o Muzaffar Ahmed (B-Pharmacy).</td></tr>
<tr><td colspan="2">Quality Control Manager</td><td colspan="2">Mr. Abdul Haleem Khan S/o Muhammad Ibrahim (M.Sc Chemistry).</td></tr>
<tr><td colspan="4">Recommendations of the panel:
“The establishment has been inspected by the panel for grant of DML. During the inspection various observations were made which were reported above in detail. In the follow-up inspection, the establishment has made marked improvement in their requirements with reference to QC/QA, documentation and SOPs. In view of the follow up inspection, reviewing the documents, intent of the management, the panel recommends the Establishment for grant of Drug Manufacturing License for following sections:

1. Liquid Syrup (General-Vet) Section.

Decision of the Central Licensing Board in 292nd meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Nutrion (Pvt) Ltd, Plot No. 186, 192, 193/S, New Industrial Estate, Mirpur, AJ&K on the recommendations of the panel of experts for the following section subject to confirmation of necessary equipment specially FTIR, TOC analyzer, HPLC Stability Chamber etc;
1. Liquid Syrup (General-Vet) Section.</td></tr>
<tr><td rowspan="3">10</td><td>M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd, Plot No.95-A, Industrial Estate, K.L.P. Road, Rahim Yar Khan.

(Evaluator: Mrs. Ume Laila DD)</td><td>26-09-2023</td><td>Good</td><td>1. Mr. Shamoon Ch, Expert Member.
2. Mrs Ume Laila, Deputy Director, Licensing DRAP, Islamabad.
3. Mr. Abdul Rashid Sheikh, FID, DRAP, Lahore.</td></tr>
<tr><td colspan="2">Production Manager</td><td colspan="2">Mr. Muhammad Ishfaq (Pharm-D)</td></tr>
<tr><td colspan="2">Quality Control Manager</td><td colspan="2">Mr. Waseem Haider (M.Sc Chemistry)</td></tr>
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	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 grant of DML to M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd, Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan for the following sections: Ground Floor: i. Tablet (General) Section ii. Liquid Injection Vials (General) Section iii. Liquid Injection Ampoule (General) Section First Floor**:** i. Capsule (Cephalosporin) Section ii. Dry Powder for Injection (Cephalosporin) Section iii. Dry Powder for suspension (Cephalosporin) Section iv. Cream / Ointment (General) Section v. Eye Drops (General) Section **Decision of the Central Licensing Board in 292nd meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd, Plot No.95-A, Industrial Estate, K.L.P. Road, Rahim Yar Khan on the recommendations of the panel of experts for the following sections; Ground Floor: i. Tablet (General) Section ii. Liquid Injection Vials (General) Section iii. Liquid Injection Ampoule (General) Section First Floor: i. Capsule (Cephalosporin) Section ii. Dry Powder for Injection (Cephalosporin) Section iii. Dry Powder for suspension (Cephalosporin) Section iv. Cream / Ointment (General) Section v. Eye Drops (General) Section

Item- II: **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 Oncogen Pharma (Pvt) Ltd., Plot No. W11-26 & 27/A3, Korangi	20-06-2023 /	Good	1. Mr. Abdul Rasool Sh. Additional Director, DRAP, Karachi.

	Creek Industrial Park, Karachi. DML No. 000960 (Formulation) **Section (01):** 1. Liquid Injectable (Oncology)-New. Evaluator: Mubashir Iqbal (DD-Lic)	*by way of Formulation*		2. Mr Ghulam Ali lakho, Chief Drug Inspector, Sindh. 3. Mr Shoaib Ahmed, Area FID, DRAP, Karachi.

M/s Oncogen Pharma (Pvt) Ltd., situated at Plot No.WH-26 & 27-A3, Korangi Creek Industrial Park (KCIP) Karachi was inspected with reference to the directions contained in DRAP Islamabad Letter No.F.2-11/2019-Lic, dated 14th JUNE 2023 in connection with the grant of New Sections Sterile Liquid Injection (Oncology) and Sterile Injection (Lyophilized) (Oncology)

Following are the observations:

The firm is built as per the layout plan approved by the DRAP authorities Islamabad vide letter No.F.2-11/2019-Lic dated 13th June 2021. All production, quality control, warehouse and storage facilities were observed well maintained, and continuous monitoring systems were seen in place. The equipment was found commissioned and qualified, in general. Adequate technical personnel were available and observed well conversant with the required knowledge of the GMP. An efficient HVAC system operating through pharma-grade dedicated AHUs (Air Handling Units system) for each section of the production facility with air process according to grades of area. The facility is segregated, dedicated and fully contained for Sterile Liquid Injection (Oncology) and Sterile Injection (Lyophilized) (Oncology) with access control for staff, who has assigned responsibilities only for the Injectable facility. Key staff has required qualification, experience and skill according to the position and job description for employees.

Based on the people met, documents reviewed, and considering the findings of the inspection, the dedicated Sterile Liquid Injection (Oncology) and Sterile Injection (Lyophilized) (Oncology) manufacturing facility of M/s Oncogen Pharma (Pvt) Limited situated at Plot No.WH-26 & 27-A3, Korangi Creek Industrial Park (KCIP) Karachi is considered to be designed and established at an excellent level of compliance with GMP requirements. Therefore, the panel recommends the approval for the grant of new Sections Sterile Liquid Injection (Oncology) and Sterile Injection (Lyophilized) (Oncology).

It is pertinent to mention that the panel was given mandate for inspection for the purpose of grant of additional section i.e. **Liquid Injectable (Oncology).**

However, the panel has recommended grant of following two (02) sections: -

S. No.	Name of Section
1.	Sterile Liquid Injection (Oncology)
2.	Sterile Injection (Lyophilized) (Oncology)

	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 Oncogen Pharma (Pvt) Ltd., Plot No.W11-26 & 27/A3, Korangi Creek Industrial Park, Karachi under DML No. 000960 (Formulation) on the recommendations of the panel of experts: 1. Liquid Injectable (with Lyophilizer facility) (Oncology)-New.			
2	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 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)	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.
	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's 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			
3	M/s Sami Pharmaceuticals (Pvt) Ltd., Plot No.F-95, S.I.T.E., Karachi.	**22-09-2023** /	**Good**	1. Mr. Ghulam Ali Lakho, Chief Drug Inspector, Karachi.

	DML No.000907 (Semi-Basic Manufacture). **<u>APIs (03</u>** 1. Duloxetine HCI 20% w/w Pellets 2. Linezolid Taste Mask Granule 3. Misoprostol DC Grande Granules. Evaluator: Mr Abdullah AD Lic	*by way of Semi-Basic Manufactur e*		2. Mr. Abdul Rasool Sh. Additional Director, DRAP, Karachi. 3. Mr Shoaib Ahmed Area FID, DRAP, Karachi.
	The firm holds valid Manufacturing License No.000907 for processing various APIs through Semi Basic Manufacturing. The firm has already license for producing the following APIs, which require almost similar processes to those required for producing the APIs now applied for 1. Deloxetine HCL 20% w/w Pellets, 2. Linezolid Taste Mask Granules, 3. Misoprostol DC Grad Granules. The firm has a well-equipped Product Development Unit for developing formulation and analytical procedures by experienced qualified staff; list of equipment installed for developing formulation. During the course of inspection detailed visit was conducted in production area which was found neat and clean. Complete areas visited was found neat and clean. GMP practices were being followed. The firm has given separate change rooms Men and material. Relevant Stops were found in place and followed in proper way. The firm has equipment which have proper CIP system. They have provided automatic loop vacuum transfer system of material to fluid bed processor in order to avoid the mixing of dust particles. List of machineries used in production is hereby annexed. The firm has all Equipment CRF 21 Part 11 compliant and fully controlled through PLC / HMI. During the inspection the panel observed that maintain the stability of their pharmaceutical products. Supply and Return Air Ducts were found clean and properly labelled. The firm has installed water treatment system as per their requirement for formulation and cleaning. Cleaning and operation Log Books and SOPs were checked and found in order and satisfactory. The firm has posses all required testing equipment and instruments for their In-process lab was found in good working condition. Qualified staff was interviewed and found having sufficient knowledge regarding pharmacopeias testing methods. Stability Studies Data of the APIs applied for approval, was thoroughly checked and found satisfactory. CONCLUSION: Keeping in the view the management commitment for continues improvement, existing technical staff, facilities, the panel unanimously recommends the grant of following additional molecules to be further processed under the DML No. 000907 (Semi-Basic) 1. Duloxetine HCI 20% w/w Pellets 2. Linezolid Taste Mask Granule 3. Misoprostol DC Grade Granules **<u>Decision of the Central Licensing Board in 292nd meeting:</u>**			

	The Board considered and approved the grant of following additional APIs in the name of M/s Sami Pharmaceuticals (Pvt) Ltd., Plot No. F-95, S.I.T.E., Karachi under DML No. 000907 (Semi-Basic Manufacture) on the recommendations of the panel of experts: 1. Duloxetine HCI 20% w/w Pellets 2. Linezolid Taste Mask Granule 3. Misoprostol DC Grade Granules			
4	M/s Horizon Healthcare (Pvt.) Ltd, Plot No 35-A, Small Industrial Estate, Taxila DML No.000856 (Formulation). <u>Sections (07)</u> 1. Dry Powder for Inhalation Section (New) in place of Capsule (General) Section. 2. Solution for Inhalation Section (New). 3. Ear/Eye Drops-II (General) Section (New). 4. Research & Development Section. 5. Cream/Ointment/Gel (General) Section (Revised). 6. Dry Powder Injection (Vial) (General) Section (Revised). 7. Dry Powder Injection (Vial) (Steroid) Section (Revised). Evaluator: Muhammad Yaqoob AD Lic	**07-06-2023** / *by way of Formulation*	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad. 2. Mrs. Tehreem Sara, Area FID, DRAP, Islamabad. 3. Mr. Muhammad Umar Latif, Deputy Director (QA&LT), DRAP, Islamabad.
	<u>Recommendations of the panel: -</u> In the light of above inspection and the improvement made by the firm the panel unanimously agreed to recommend the renewal of the license by way of Formulation in the following sections: <u>Approved Sections (Existing)</u> 1. Tablet (General) Section. 2. Liquid Injectable Section (Ampoule) (General). 3. Dry Powder Injection Vial (General) Revised 4. Dry Powder Injection Vial (Steroid) Revised. 5. Cream/Ointment/Gel Section Revised.			

	6. Ear/Eye Drops Section (I). The panel further inspected the following additional section applied by the firm & after verification of the manufacturing and testing facility recommends the grant of following additional sections: <u>Newly Applied Section</u> 1. Dry Powder for Inhalation Section (DPI) (the firm withdraw Capsule (General) section and applied above section in place of that). 2. Solution/Suspension for Inhalation Section. 3. Ear/Eye Drop Section (II)(General) (Single Dose). 4. Research & Development Section. It is pertinent to mention here that as per available record of Licensing Division, mandate for inspection of Research & Development Section has not been given to panel members. **<u>Decision of the Central Licensing Board in 292nd meeting:</u>** The Board considered and approved the grant of following additional sections in the name of M/s Horizon Healthcare (Pvt.) Ltd, Plot No 35-A, Small Industrial Estate, Taxila under DML No. 000856 (Formulation) on the recommendations of the panel of experts: 1. Dry Powder for Inhalation Section (New) in place of Capsule (General) Section. 2. Solution for Inhalation Section (New). 3. Ear/Eye Drops-II (General) Section (New). 4. Cream/Ointment/Gel (General) Section (Revised). 5. Dry Powder Injection (Vial) (General) Section (Revised). 6. Dry Powder Injection (Vial) (Steroid) Section (Revised). 7. Research & Development Section. The Board further decided to accept the recommendation of the panel about R& D Laboratory for regularization. The capsule section (General) is withdrawn by the firm and hence canelled.			
5	M/s Leads Pharma (Pvt) Ltd, Plot No. 81, Street No. 6, I-10/3, Industrial Area, Islamabad. DML No. 000392 (Formulation). Sections/Facility: (05) 1. Aerosol (Steroid / Antibiotic) Vet. 2. Liquid Injection – Vial – SVP (Steroid) Vet. 3. Finished Goods Stores – Veterinary. 4. Raw Material Store – Veterinary. 5. Packing Material Store – Veterinary.	14-02-2023 & 20-06-2023 / *by way of Formulation*	Good	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Dr. Muhammad Athar, Senior Scientific Officer, NARC, Islamabad. 3. Mrs. Tehreem Sara, Area FID, DRAP. Islamabad.

	(Evaluator: Muhammad Yaqoob, AD)			
	Recommendations of Inspector (s): Keeping in view the area visited and people met and the compliance of the management with the suggestion given in the previous inspection. The panel unanimously agreed to recommend the approval of the following additional section for the production of Veterinary products referred by Licensing Division vide letter No. F. 34/2013-Lic(Vol-III) dated 27-12-2022: 1. Aerosol (Steroid / Antibiotic) Vet. 2. Liquid Injection – Vial – SVP (Steroid) Vet. 3. Finished Goods Stores – Veterinary. 4. Raw Material Store –Veterinary. 5. Packing Material Store – Veterinary. **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 Leads Pharma (Pvt) Ltd, Plot No. 81, Street No. 6, I-10/3, Industrial Area, Islamabad under DML No. 000392 (Formulation) on the recommendations of the panel of experts: 1. Aerosol (Steroid / Antibiotic) Vet. 2. Liquid Injection – Vial – SVP (Steroid) Vet. 3. Finished Goods Stores – Veterinary. 4. Raw Material Store –Veterinary. 5. Packing Material Store – Veterinary.			
6	M/s Lawari International, Valley Road, GulkadaSaidu Sharif, Swat. DML No. 000658 (Formulation). **Sections:** 1. Oral Dry Powder for Suspension (Ceph). 2. Capsule (Cephalosporin). 3. Dry Powder for Injection Vial (Cephalosporin). 4. Liquid Injection Ampoule (General). (Evaluator: Muhammad Yaqoob, AD Lic)	**26-07-2023** / *by way of Formulation*	**Good**	1. Mr. Abbas Khan, DG, Drug Control and Pharmacy Services, Peshawar 2. Mr. Faisal Shahzad, Additional Director / Area Federal Inspector of Drugs, DRAP, Peshawar. 3. Mr. Abdullah, Assistant Director, (Lic), DRAP, Islamabad.
	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 WFI water system and other allied facilities, the panel is of the view that the firm has provided sufficient facilities for below mention sections with good			

	level of GMP compliance and unanimously recommends grant of below mentioned new sections as per DRAP Islamabad letter No.F.3-8/20078-Lic (Vol-I) dated 15th June, 2023: 1. Oral Dry Powder for Suspension (Cephalosporin). 2. Capsule (Cephalosporin). 3. Dry Powder for Injection Vial (Cephalosporin). 4. Liquid Injection Ampoule (General). **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 Lawari International, Valley Road, GulkadaSaidu Sharif, Swat under DML No. 000658 (Formulation) on the recommendations of the panel of experts: 1. Oral Dry Powder for Suspension (Cephalosporin). 2. Capsule (Cephalosporin). 3. Dry Powder for Injection Vial (Cephalosporin). 4. Liquid Injection Ampoule (General).			
7	M/S Shrooq Pharmaceuticals (Pvt) Ltd, 18-Km, Ferozepur Road, Lahore. DML No. 000586 (Formulation) **Section (01):** Dry Powder Suspension (General) Section.	07-06-2023 / *by way of Formulation*	Good -	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Sheikh, FID, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director (I&E), DRAP, Lahore.
	Recommendations of the panel: "Considering the firms profile, building, already approved production areas in-process quality control system, QC testing, machinery / equipment, material management, HVAC system, water treatment etc., the panel recommends the grant of following additional section to M/s Shrooq Pharmaceuticals (Pvt) Ltd, 18-Km, Ferozepur Road, Lahore.: - i. Dry Powder Suspension (General) Section **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of following section revised in the name of M/S Shrooq Pharmaceuticals (Pvt.) Ltd, 18-Km, Ferozepur Road, Lahore under DML No. 000586 (Formulation) on the recommendations of the panel of experts. i. Dry Powder Suspension (General) Section (Additional/New)			
8	M/s World Biz Pharmaceuticals Company (Pvt) Ltd, Plot No. 340, Multan Industrial Estate, Multan. DML No. 000942 (Formulation) **Section (01):** 1. Tablet Section (General) 2. Capsule Section (General) (Evaluator: Mrs. Ume Laila DD)	18-07-2023 / *by way of Formulation*	Good -	1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab 2. Mr. Abdul Rashid Sheikh, FID, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.

	Recommendations of the panel: "Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control, Testing Facilities, Technical Personnel met and documentation, the panel of inspectors recommends the grant of following additional sections to M/s World Biz Pharmaceuticals Company (Pvt.) Ltd, Plot No. 340, Multan Industrial Estate, Multan: - 1. Tablet Section (General) 2. Capsule Section (General) **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 World Biz Pharmaceuticals Company (Pvt.) Ltd, Plot No. 340, Multan Industrial Estate, Multan under DML No. 000942 (Formulation) on the recommendations of the panel of experts: i. Tablet Section (General) ii. Capsule Section (General)			
9	M/s Novamed Pharmaceutical (Pvt) Ltd, 28-Km, Ferozepur road, Lahore. DML No. 000590 (Formulation) **Section (01):** 1. Dry Powder Injectable General Section (Evaluator: Mrs. Ume Laila DD)	18-07-2023 / *by way of Formulation*	Good -	1. Dr. Zaka-ur-Rehman, Ex-COO, PDTRC, Lahore (Expert Member) 2. Mr. Abdul Rashid Sheikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "In view of inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation etc. the panel **recommends** the grant of the following additional section to M/s Novamed Pharmaceuticals, Lahore: - 1. Dry Powder Injectable (General) Section **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 Novamed Pharmaceutical (Pvt) Ltd, 28-Km, Ferozepur road, Lahore under DML No. 000590 (Formulation) on the recommendations of the panel of experts: i. Dry Powder Injectable General Section			
10	M/s Weather Folds Pharmaceuticals, 69/2, Phase-II, Industrial Area, Hattar. DML No. 000644 (Formulation).	26-04-2023 & 16-08-2023	Good	i. Prof. Dr. Muzammil Hasan Najmi, Member Policy Board, Expert. ii. Mr Faisal Shahzad, Federal Inspector of Drugs, DRAP, Peshawar. iii. Mr. Saadat Ali Khan, Assistant Director

Section**:** Tablet Section Biological Evaluator: Mr Muhammad Yaqoob AD Lic			(Biological), DRAP, Islamabad.

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 WFI water system and other allied facilities, the panel is of the view that the firm has provided sufficient facilities for below mention sections with good level of GMP compliance and unanimously recommends grant of below mentioned new section as per DRAP Islamabad letter No.F.3-6/2007-Lic (Vol-II) dated 13th January, 2023:

1. Tablet Section Biological.

It is pertinent to mentioned that the panel of Inspectors / Experts was constituted on 13th January, 2023 and give mandate for following sections: -

1. Biological rDNA Section in place of licensed section Dry Powder Injection.
2. Biological Non-rDNA Section in place of licensed Section Sachet (General).
3. Biological Viral Liquid in place of licensed Section Liquid Syrup (General).
4. Tablet (Biological).

One of the panel member Brig. (Retd) Professor M H Najmi, SI (M) has given their comments / views which is mentioned below: -

"In view of the peculiar nature of the product (Semaglutide Tablet) intended to be manufactured in the section inspected vide DRAP letter No.F.3-6/2007-Lic (Vol-II) dated 13-01-2023, the following recommendations are made for consideration of the Registration Board.

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 tablet 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."

Decision of the Central Licensing Board in 292nd meeting:

The Board considered and approved the grant of following additional section in the name of M/s Weather Folds Pharmaceuticals, 69/2, Phase-II, Industrial Area, Hattar, DML No. 000644 (Formulation) on the recommendations of the panel of experts:

1. Tablet (Biological).

The Board further decided that following comments/view be conveyed to Drug Registration Board/ PE&R, Division DRAP for further necessary action at their end;

	"In view of the peculiar nature of the product (Semaglutide Tablet) intended to be manufactured in the section inspected vide DRAP letter No.F.3-6/2007-Lic (Vol-II) dated 13-01-2023, the following recommendations are made for consideration of the Registration Board. *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."*			
11	M/s Genetics Pharmaceuticals (Pvt) Ltd, Plot No.539-A, Sunder Industrial Estate, Lahore DML No. 000845 (Formulation) (Evaluator: Mrs. Ume Laila DD)	13-09-2023	Good	1. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Ishtaiq Shafiq, Assitant Director, 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 grant of additional section; Syrup Section (General) to M/s Genetics Pharmaceuticals (Pvt) Ltd, Plot No.539-A, Sunder Industrial Estate, Lahore. **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of following additional section in the name of M/s Genetics Pharmaceuticals (Pvt) Ltd, Plot No.539-A, Sunder Industrial Estate, Lahore under DML No. 000845 (Formulation) on the recommendations of the panel of experts: 1. Syrup Section (General)			
12	M/s Unison Chemical Works, Post office Araian 15-Km Raiwind Road, Lahore. DML No. 000174 (Formulation) (Evaluator: Mrs. Ume Laila DD)	26-07-2023 & 28-09-2023	Good	1. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Ishtaiq Shafiq, Assitant Director, 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 grant of additional section to M/s Unison Chemical Works, Post office Araian 15-Km Raiwind Road, Lahore for the following section: 1. Liquid Ampoule (Steroid) Section 2. Research and Development Laboratory-New **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 Unison Chemical Works, Post office Araian 15-Km Raiwind Road, Lahore under DML No. 000175 (Formulation) on the recommendations of the panel of experts: 1. Liquid Ampoule (Steroid) Section 2. Research and Development Laboratory-New			
13	M/s Searle Pakistan Ltd., C-14 Mangopir Road SITE Karachi. DML No. 000012 (Formulation) Section (01): 1. Research & Development Laboratory. Evaluator: Mr Mubashar Iqbal DD Lic	30-08-2023 / *by way of Formulation*	Good	1. Additional Director (E&M), DRAP, Karachi. 2. Area FID, DRAP, Karachi. 3. Mr. Krishan, AD, DRAP, Karachi.
	Recommendations of the panel: During Inspection the panel inspected in detail their new Research and development laboratory section and reviewed several relevant documents and SOPs. The firm has satisfactorily installed necessary machineries required for R&D lab. Necessary documents in this regards were reviewed in detail and found an optimal level of compliance. The people met were found well versed about the relevant laws and Sops. Here the panel is of opinion to recommend the grant of Amendments in their research and development laboratory in connection with the letter No.F.2-1/2004-Lic (Vol-II) dated 20th January, 2023. **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of following additional section in the name of M/s Searle Pakistan Ltd., C-14 Mangopir Road SITE Karachi under DML No. 000012 (Formulation) on the recommendations of the panel of experts: 1. Research & Development Laboratory.			

Item-III: **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 / Type of License</th><th>Ranking/ Evaluation</th><th>Inspection Panel Members</th></tr>
<tr><td rowspan="4">1</td><td>M/s Horizon Healthcare (Pvt.) Ltd Plot No 35-A, Small Industrial Estate, Taxila

DML No.000856 (Formulation)

Period: Commencing on 24.04.2022 & ending on 23.04.2027.

Evaluator: Muhammad Yaqoob AD Lic</td><td>07-06-2023

/

by way of Formulation</td><td>Good</td><td>1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad.
2. Mrs. Tehreem Sara, Area FID, DRAP, Islamabad.
3. Mr. Muhammad Umar Latif, Deputy Director (QA&LT), DRAP, Islamabad.</td></tr>
<tr><td colspan="2">Production In-charge</td><td colspan="2">Mr. Rehmat Hadi S/o Hakim Jan (Pharm-D)</td></tr>
<tr><td colspan="2">QC In-charge</td><td colspan="2">Mr. Waqar Ahmed S/o Amir Khusro Khan (M.Sc. Chemistry)</td></tr>
<tr><td colspan="4">Recommendations of the panel: -
In the light of above inspection and the improvement made by the firm the panel unanimously agreed to recommend the renewal of the license by way of Formulation in the following sections:

Approved Sections (Existing)

i. Tablet (General) Section.
ii. Liquid Injectable (Ampoule) (General) Section.
iii. Dry Powder Injection (Vial) (General) Revised.
iv. Dry Powder Injection (Vial) (Steroid) Revised.
v. Cream/Ointment/Gel (General) Section Revised.
vi. Ear/Eye Drops (General) Section.
The panel further inspected the following additional section applies by the firm & after verification of the manufacturing and testing facility recommends the grant of following additional sections:
Newly Applied Section</td></tr>
</table>

	vii. Dry Powder for Inhalation Section (DPI) (the firm withdraw capsule (General) Section and applied above section in place of that). viii. Solution/Suspension for Inhalation Section. ix. Ear/Eye Drop Section (II)(General) (Single Dose). x. Research & Development Section. **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000856 by way of Formulation in the name of M/s Horizon Healthcare (Pvt.) Ltd Plot No 35-A, Small Industrial Estate, Taxila on the recommendations of the panel of experts for the period Commencing on 24.04.2022 & ending on 23.04.2027 for the following sections. **Approved Sections (Existing)** i. Tablet (General) Section. ii. Liquid Injectable (Ampoule) (General) Section. iii. Dry Powder Injection (Vial) (General) Revised. iv. Dry Powder Injection (Vial) (Steroid) Revised. v. Cream/Ointment/Gel (General) Section Revised. vi. Ear/Eye Drops (General) Section. Newly Applied Section i. Dry Powder for Inhalation Section (DPI) (the firm withdraw capsule (General) Section and applied above section in place of that). ii. Solution/Suspension for Inhalation Section. iii. Ear/Eye Drop Section (II)(General) (Single Dose). iv. Research & Development Section.			
2.	M/s DeMont Research Laboratories (Pvt) Ltd, 20-Km, Lahore Sharakpur Road, Sheikhupura. DML No. 000844 (Formulation). **Period:** Commencing on 25.08.2021 ending on 24.08.2026. Evaluator: Mrs Zunaira Faryad AD Lic	23-05-2023 / *by way of Formulation*	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore
	Production In-charge		Mr. Muhammad Shahid Iqbal Khan S/o Muhammad Atlas Khan (B-Pharm)	
	QC In-charge		Mr. Muhammad Basit Majeed S/o Muhammad Ibrahim (M.Sc. Chemistry)	
	Recommendations of the panel: - In view of above inspection proceedings and facilities verified such as company profile, building, material management, production, in-process controls, quality control testing, machinery/equipment, air handling, water treatment system, personnel and documentation e.t.c. the panel **recommends** the renewal of Drug Manufacturing License (by way of formulation) to			

	M/s DeMont Research Laboratories (Pvt) Ltd, 20-Km Sharkpur Road, Sheikhupura by way of formulation for following sections only: i. Tablet (General) Section. ii. Capsule (General) Section. iii. Dry Powder Suspension (General) Section. iv. Sachet (General) Section. **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000844 by way of Formulation in the name of M/s DeMont Research Laboratories (Pvt) Ltd, 20-Km, Lahore Sharikpur Road, Sheikhupura on the recommendations of the panel of experts for the period Commencing on 25.08.2021 ending on 24.08.2026 for the following sections. i. Tablet (General) Section. ii. Capsule (General) Section. iii. Dry Powder Suspension (General) Section. iv. Sachet (General) Section.			
3	M/s Akson Pharmaceuticals (Pvt) Ltd, Plot No. 9-B/1&2, Sreet No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir. DML No.000486 (Formulation). Period: Commencing on 12-04-2021 ending on 11-04-2026. (Evaluator: Muhammad Yaqoob, AD Lic)	05-05-2023 / *by way of Formulation*	Good	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad. 2. Mr. Zaheer Iqbal, Deputy / Drugs Controller, Mirpur. 3. Muhammad Yaqoob, Assistant Director, DRAP, Islamabad.
	Production In-charge	Mr. Rashid Ahmad S/o Sher Ahmad (B-Pharm)		
	Quality Control In-charge	Mr. Muhammad Azeem S/o Ch. Mangu Khan (M.Sc Chemistry).		

	Recommendations of the panel: - The establishment has all the basic requirements required for manufacturing of pharmaceuticals with reference to personnel, machinery / equipment, documentation, quality control / quality assurance, allied supporting facilities (HVAC, Water Treatment Plan). Further the establishment has equipment such as FTIR, HPLC, UV-visible spectrophotometer etc for testing of registered products. TherefoFre, based on the inspection conducted and the commitment shown by the management of M/s Akson Pharmaceuticals for further improvement, the panel unanimously 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. Warehouse **Decision of the Central Licensing Board in 292nd meeting:** 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 SVP ampoule/infusion (General). vi. Quality Control Laboratory. vii. Stores (RMS, FGS, PMS)			
4	M/s Star Laboratories (Pvt) Ltd. 23-Km, Multan Road, Lahore DML No.000130 (Formulation). Period: Commencing on 14-12-2019 ending on 15-12-2024.	30-05-2023 / *by way of Formulation*	Good	1. Mrs. Majida Mujahid, Add: Dir, DRAP, Lahore 2. Mr. Abdul Rashid Sheikh (FID), DRAP, Lahore 3. Mr. Farooq Arslan, AD, DRAP, Lahore

Production In-charge:	Mr. Ubaid Mahmood Khan S/o Mahmood Rashid Khan(B-Pharm)
QC In-charge:	Mr. Abdul Jalik Khawaja S/o Muhammad Akram Khawaja (B-Pharm)

Recommendations of the panel:

"The panel of inspectors recommends the renewal of DML bearing No. 000130 (F) and regularization of M/s Star Laboratories (Pvt) Ltd. 23-Km, Multan Road, Lahore, as per approved layout plan by the authorities of DRAP, Islamabad for the following Sections" :-

GROUND FLOOR	BASEMENT	FIRST FLOOR
A. Veterinary Sections: 1. Liquid Injectable (General Section) (Vial) 2. Liquid Injectable (Hormone Section) (Vial) B. Human Sections: 1. Oral Liquid (General) Section. 2. Liquid Injectable Ampoule (General) Section. 3. Liquid Injectable Ampoule (Psychotropic) Section. 4. Liquid Injection Vial (General) Section. C. Penicillin Section-Veterinary: 1. Dry Powder for Injection (Veterinary Penicillin) 2. Liquid Injectable Vial (Vet Penicillin)	A. Veterinary: 1. Oral Powder Section (General) 2. Sachet (General) 3. Oral Bolus Section (General) B. Human: 1. Tablet (General) Section 2. Powder for Oral Suspension (General) Section. 3. Capsule (General) Section. 4. Tablet (Psychotropic) Section	A. Veterinary: 1. Oral Liquid / Drench Section (Vet-General). 2. Aerosol / Spray (Vet-Steroidal Section). 3. Aerosol / Spray (Vet-General Section). B. Cephalosporin Block-Human: 1. Dry Powder for Injection (Human-Cephalosporin) 2. Oral Dry Powder Suspension (Human-Cephalosporin) 3. Capsule (Human-Cephalosporin) C. Quality Control Laboratory.

However, Capsule (Human-Cephalosporin) section was not mentioned in panel inspection letter No. F.1-27/5-Lic(Vol-II) dated 19th August, 2022. However, the section is approved which is evident from renewal letter No. F.1-27/85-Lic(Vol-III) dated 16th October, 2016.

Decision of the Central Licensing Board in 292nd meeting:

The Board considered and approved the grant of renewal of DML No. 000130 by way of Formulation in the name of M/s Star Laboratories (Pvt.) Ltd. 23-Km, Multan Road, Lahore on the recommendations of the panel of experts for the period Commencing on 14-12-2019 ending on 15-12-2024 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 sections. **GROUND FLOOR** **A. <u>Veterinary Sections:</u>** 1. Liquid Injectable (General Section) (Vial) 2. Liquid Injectable (Hormone Section) (Vial) **B. <u>Human Sections:</u>** 3. Oral Liquid (General) Section. 4. Liquid Injectable Ampoule (General) Section. 5. Liquid Injectable Ampoule (Psychotropic) Section. 6. Liquid Injection Vial (General) Section. **C. <u>Penicillin Section-Veterinary:</u>** 7. Dry Powder for Injection (Veterinary Penicillin) 8. Liquid Injectable Vial (Vet Penicillin) **BASEMENT** **C. <u>Veterinary:</u>** 1. Oral Powder Section (General) 2. Sachet (General) 3. Oral Bolus Section (General) **D. <u>Human:</u>** 4. Tablet (General) Section 5. Powder for Oral Suspension (General) Section. 6. Capsule (General) Section. 7. Tablet (Psychotropic) Section **FIRST FLOOR** **D. <u>Veterinary:</u>** 1. Oral Liquid / Drench Section (Vet-General). 2. Aerosol / Spray (Vet-Steroidal Section). 3. Aerosol / Spray (Vet-General Section). **E. <u>Cephalosporin Block-Human:</u>** 4. Dry Powder for Injection (Human-Cephalosporin) 5. Oral Dry Powder Suspension (Human-Cephalosporin) **F. <u>Quality Control Laboratory.</u>**			
5	M/s Raazee Therapeutics (Pvt) Ltd, 48-Km, Lahore Kasur Road, Kasur. DML No. 000437 (Formulation) Period: Commencing on 18-12-202 ending on 17-12-2027.	**07-03-2023** *by way of Formulation*	**Good**	1. Mrs. Majida0020 Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Farooq Aslam, AD, DRAP, Lahore.
	<u>Production In-charge:</u>		Mr. Muhammad Imran Khalil S/o Ch. Khalil Ahmed (B-Pharm)	
	<u>QC In-charge:</u>		Mr. Riasat Ali S/o Nawazish Hussain (M.Sc. Chemistry)	

	Recommendations of the panel: *"Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control, Technical personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation and regularization of layout plan to M/s Raazee Therapeutics (Pvt) Ltd, situated at 48-Km, Lahore-Kasur Road, Kasur, in respect of following sections only: -* 1. Oral Liquid Section (General) 2. Tablet section (General) 3. Capsule Section (General) 4. Dry Powder Suspension (General Antibiotic Section) 5. Capsule Section (Cephalosporin) 6. Dry Powder Suspension Section (Cephalosporin) 7. Dry Powder Injectable Section (Cephalosporin) 8. Liquid Vial Injectable (General Antibiotic) 9. Liquid Ampoule Injectable (General Antibiotic) **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000437 by way of Formulation in the name of M/s Raazee Therapeutics (Pvt) Ltd, 48-Km, Lahore Kasur Road, Kasur on the recommendations of the panel of experts for the period Commencing on 18-12-202 ending on 17-12-2027 for the following sections. 1. Oral Liquid Section (General) 2. Tablet section (General) 3. Capsule Section (General) 4. Dry Powder Suspension (General Antibiotic Section) 5. Capsule Section (Cephalosporin) 6. Dry Powder Suspension Section (Cephalosporin) 7. Dry Powder Injectable Section (Cephalosporin) 8. Liquid Vial Injectable (General Antibiotic) 9. Liquid Ampoule Injectable (General Antibiotic).			
6	M/s Novins Internantional (Pvt) Ltd., Plot No. E-37&38, Port Qasim Authority, Karachi. DML No. 000541 (Formulation) Period: Commencing on 15-02-23 ending on 14-02-2028.	**17-08-2023** / *by way of Formulation*	**Good**	1. Additional Director, DRAP, Karachi. 2. Area FID, DRAP, Karachi. 3. Assistant Director, DRAP, Karachi.
	Production Incharge:		Mr. Qaiser Aziz (B-Pharm)	
	QC Incharge:		Ms. Sumaira Shaheen D/o Asghar Ali Khan (M.Sc Chemistry)	

<table>
<tr><td></td><td colspan="4">Recommendations of the panel:
“Based on people met, areas visited and commitment of the management for continuous improvement, expansion and export potential, the panel unanimously was of the view to recommend Renewal of Drug Manufacturing License No.000541 as per DRAP, Islamabad letter of even no. dated 26th June’ 2023 to the firm M/s Novins International (Pvt) Ltd., situated at A-29, N.W.I.Z., Karachi for following sections:
<table>
<tr><td>i. Tablet (General)</td><td>ii. Capsule (General)</td><td>iii. Ointment (General)</td></tr>
</table>

<u>Decision of the Central Licensing Board in 292nd meeting:</u>

The Board considered and approved the grant of renewal of DML No. 000541 by way of Formulation in the name of M/s Novins International (Pvt) Ltd., Plot No. E-37&38, Port Qasim Authority, Karachi on the recommendations of the panel of experts for the period Commencing on 15-02-23 ending on 14-02-2028 for the following sections.
1. Oral Liquid Section (General)
2. Tablet section (General)
3. Capsule Section (General)
4. Dry Powder Suspension (General Antibiotic Section)
5. Capsule Section (Cephalosporin)
6. Dry Powder Suspension Section (Cephalosporin)
7. Dry Powder Injectable Section (Cephalosporin)
8. Liquid Vial Injectable (General Antibiotic)
9. Liquid Ampoule Injectable (General Antibiotic).</td></tr>
<tr><td>7</td><td>M/s Medisave Pharmaceuticals, Plot No. 578-579, Sunder Industrial Estate, Lahore.
DML No. 000681 (Formulation)
Period: Commencing on 26-01-20 ending on 25-01-2025</td><td>21-08-2023
/
by way of Formulation</td><td>Good</td><td>1. Dr. Zaka-ur-Rehman, COO (PDTRC)
2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.
3. Mr. Ishtiaq Shafiq, AD, DRAP, Lahore.</td></tr>
<tr><td></td><td colspan="2">Production In-charge:</td><td colspan="2">Mr. Abdul Rasheed Bhatti (B-Pharm)</td></tr>
<tr><td></td><td colspan="2">QC In-charge:</td><td colspan="2">Mr. Tariq Mahmood S/o Shah Din (M.Sc. Chemistry)</td></tr>
</table>

	Recommendations of the panel: *"Keeping in view the facilities like, building, HVAC system, machinery, equipment, instrument, personnel, documentation, the panel of inspectors* ***recommends*** *the renewal of Drug Manufacturing License and Regularization of the following ten (10) section only to M/s* ***Medisave Pharmaceuticals, Plot No. 578-579, sunder Industrial Estate, Lahore*** *by way of formulation: -* 1. Injectable (Ampoule) (General) 2. Syrup (General) 3. Infusion (SVP) (General) 4. Tablet (Antibiotic) 5. Dry Powder Suspension (Antibiotic) 6. Tablet (General) 7. Dry Powder Suspension (Cephalosporin) 8. Capsule Section (General) 9. Injectable (Vial) (Cephalopsorin) 10. Capsule (Cephalosporin) 11. QC Lab 12. Warehouse **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000681 by way of Formulation in the name of M/s Medisave Pharmaceuticals, Plot No. 578-579, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period commencing on 25-01-2020 ending on 24-01-2025 for the following sections. 1. Injectable (Ampoule) (General) 2. Syrup (General) 3. Infusion (SVP) (General) 4. Tablet (Antibiotic) 5. Dry Powder Suspension (Antibiotic) 6. Tablet (General) 7. Dry Powder Suspension (Cephalosporin) 8. Capsule Section (General) 9. Injectable (Vial) (Cephalosporin) 10. Capsule (Cephalosporin) 11. Quality control Lab 12. Stores (RMS, FGS, PMS)			
8	M/s Moringa Pharmaceutical (Pvt) Ltd, 35-A, Sunder Industrial Estate, Lahore. DML No. 000769 (Formulation) Period: Commencing on 07-03-2023 Ending on 06-03-2028 (Evaluator: Mrs. Ume Laila DD)	25-08-2023	Good	1. Prof. Dr. Mahmood Ahmad Expert Member 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Assistant Director, DRAP, Lahore

	Production In-charge:		Mr. Faiz Ahmed Chishti S/o Faiq Ahmed Chishtri (B-Pharm)	
	QC In-charge:		Mr. Imran Siddiqui S/o Muhammad Siddiqui (M.Sc. Chemistry)	
	Recommendations of the panel: *"Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control, testing facility, Technical personnel met and documentation, the panel of inspectors recommends the grant of renewal of DML for following sections to M/s Moringa Pharmaceuticals (Pvt) Ltd*35-A, Sunder Industrial Estate, Lahore.*:* 1. *Tablet Section (General)* 2. *Capsule Section (General)* 3. *Oral Dry Powder Suspension Section (General)* 4. *Liquid Syrup Section (General)* **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000769 by way of Formulation in the name of M/s Moringa Pharmaceutical (Pvt) Ltd, 35-A, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period Commencing on 07-03-2023 Ending on 06-03-2028 for the following sections. 1. Tablet Section (General) 2. Capsule Section (General) 3. Oral Dry Powder Suspension Section (General) 4. Liquid Syrup Section (General)			
9	M/s Novartana Pharmaceuticals, 87-B, Sunder Industrial Estate, Lahore. DML No. 000738 (Formulation) Period: Commencing on 16-08-22 ending on 15-08-2027 (Evaluator: Mrs. Ume Laila DD)	24-08-2023 *by way of Formulation*		1. Muhammad Shamoon Ch. Expert Member 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, AD, DRAP, Lahore 4. Ms. Uzma Barkat, AD, DRAP, Lahore
	Production In-charge:		Mr. Muhammad Tufail Naveed Ahmed S/o Din Muhammad Jatoi (B-Pharm)	
	QC In-charge:		Ms. Sana Gul Gillani D/o Gul Hassan Shah (Pharm-D)	

	Recommendations of the panel: *"The Inspection of M/s Novartana Pharmaceuticals (Pvt) Ltd, Lahore was conducted on 24-08-2023 with reference to DRAP Islamabad letter No. F.1-29/2010-Lic(Vol-I) dated 18-08-2023 for grant of renewal of drug manufacturing license and verify the rectification status of the observations regarding General Liquid Injection (Ampoule & Vial) Sections of the inspection dated 08-09th June, 2023. There was not any manufacturing activity going on at the time of inspection therefore active operations were not witnessed during this course of inspection.* *In the light of inspection conducted by the panel and based on the findings given above, it was noted that the firm had rectified most of the shortcomings reported in the previous inspection. The firm was advised improvements as detailed above in the report. The firm was advised to perform HVAC requalification as per standard requirements before start of production in the General Liquid Injection (Ampoule & Vial) Section. The firm's management showed positive intent and submitted plan to replace the HVAC, AHUs within 6 months.* *In view of the above, the panel of inspectors recommends that:* *1) The firm M/s Novartana Pharmaceuticals (Pvt) Ltd, Lahore may be considered for the grant of renewal of drug manufacturing license by way of formulation for the following sections:* *i. Tablet Section (General)* *ii. Capsule Section (General)* *iii. Oral Liquid Section (General)* *iv. Liquid Injectable Section (General Ampoule)* *v. Liquid Injectable Section (General Vial) (SVP)* 2) The panel also recommends resumption of production in the General Liquid Injectable Sections (Ampoule / Vial). 3) The Panel also recommends that a thorough GMP inspection of the firm may be conducted by a panel of inspectors during active production in the unit. **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000738 by way of Formulation in the name of M/s Novartana Pharmaceuticals, 87-B, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period commencing on 15-08-2022 ending on 14-08-2027 for the following sections. 1. Tablet Section (General) 2. Capsule Section (General) 3. Liquid Syrup Section (General) 4. Liquid Ampoule / Vial General Section 5. Liquid Vial SVP General Section			
10	M/s Biorific Pharma, Plot No. 43, Industrial Triangle, Kahuta Road, Islamabad. DML No.000848 (Formulation). Period: Commencing on 25-11-2021 ending on 24-11-2026.	15-06-2023 / *by way of Formulation*	Good	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad. 2. Ms. Saima Hussain, Assistant Director (Reg), DRAP, Islamabad. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Islamabad.

	(Evaluator: Muhammad Yaqoob, AD Lic)			
	Production In-charge	Syed Mohsin Ali Shah S/o Syed Mubarak Ali Shah (Pharm-D),		
	Quality Control In-charge	Mr. Abdur Rahim S/o Fazle Rahim (B-Pharm)		
	Summary & Conclusion. The establishment has been inspected by the panel for renewal of DML. During the inspection various observations were made which were reported above in detail. In the follow-up inspection, the establishment has made marked improvement in their requirements with reference to QC/QA, documentation and SOPs. In view of the follow up inspection, reviewing the documents, intent of the management, the panel recommends the Establishment for renewal of Drug Manufacturing License for following sections: - 1. Dry Powder (General-Vet) Section. 2. Liquid Syrup (General-Vet) Section. **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000848 by way of Formulation in the name of M/s Biorific Pharma, Plot No. 43, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the period Commencing on 25-11-2021 ending on 24-11-2026 for the following sections subject to confirmation of necessary equipments specially FTIR, TOC, HPLC Stability Chamber etc. 1. Dry Powder (General-Vet) Section. 2. Liquid Syrup (General-Vet) Section.			
11	M/s Rite Bio Sciences (Formerly M/s AAA Health Pharmaceutical Laboratories), (Pvt.) Ltd. Plot No.9-A, Street N-5, RCCI, Rawat. DML No.000871 (Formulation). **Period:** Commencing on 13.09.2022 ending on 12.09.2027. (Evaluator: Mst. Zunaira Faryad, AD (Lic))	22-08-2023	Good	1. Mr. Muhammad Arif Chaudhary, Additional Director, CD, DRAP, Islamabad. 2. Mr. Nouman Yousaf, Deputy Director, DRAP Islamabad. 3. Hafiz Muhammad Umair, AD, DRAP, Islamabad (Nominated by Additional Director QA&LT, Islamabad).
	Production In-charge		Mr. Jehangir Abbas S/o Faiz Ur Rehman (B-Pharm)	
	QC In-charge		Mr. Ameer Hussain S/o Muhammad Yousaf (M.Sc. Chemistry)	
	Recommendations of the panel: - The panel considering that the establishment has the necessary equipment / machinery for manufacturing and testing/analysis of their registered products i.e., FTIR, HPLC, stability			

chambers, hot/cold incubators, UV-spectrophotometer with the personnel of required qualification and experience, unanimously recommends the establishment of renewal of Drug Manufacturing License for the period 13-09-2022 to 12-09-2027 for the following sections:

1. Tablet Section (General)
2. Capsule Section (General)
3. Dry Powder Suspension Section (General)
4. Capsule Section (Cephalosporin)
5. Dry Suspension Section (Cephalosporin)

Decision of the Central Licensing Board in 292nd meeting:

The Board considered and approved the grant of renewal of DML No. 000871 by way of Formulation in the name of M/s Rite Bio Sciences, (Pvt.) Ltd. Plot No.9-A, Street N-5, RCCI, Rawat on the recommendations of the panel of experts for the period Commencing on 13.09.2022 ending on 12.09.2027 for the following sections.

1. Tablet Section (General)
2. Capsule Section (General)
3. Dry Powder Suspension Section (General)
4. Capsule Section (Cephalosporin)
5. Dry Suspension Section (Cephalosporin).

12	M/s Curexa Health (Private) Ltd, Plot No.517, Sunder Industrial Estate, Lahore. DML No.000864 (Formulation). **Period:** Commencing on 14.06.2022 ending on 13.06.2027. (Evaluator: Mst. Zunaira Faryad, AD (Lic))	25-08-2023	Good	1. Azhar Jamal Saleemi, Deputy Drug Controller, Punjab, Lahore. 2. Abdul Rashid Shaikh, Area FID, DRAP Lahore. 3. Farooq Aslam, Assistant Director, DRAP Lahore.
	Production In-charge		Mr. Naeem Sarwar S/o Chaudhary Muhammad Sarwar (B-Pharm)	
	QC In-charge		Mr. Kamal Subhani S/o Chaudhary Fazal Muhammad (M.Sc. Chemistry).	

Recommendations of the panel: -

Keeping in view the manufacturing facility like building, HVAC system, sanitation, production machinery, equipment in quality control, testing facilities, technical personnel and documentation, the panel of inspectors recommends the grant of renewal of Drug Manufacturing License to M/s Curexa Health (Private) Limited, Plot No.517, Sunder Industrial Estate, Lahore for the following sections:

i. Dry Powder Injections (Cephalosporins) Section
ii. Dry Powder Suspension (Cephalosporins) Section
iii. Capsules (Cephalosporins) Section

Decision of the Central Licensing Board in 292nd meeting:

	The Board considered and approved the grant of renewal of DML No. 000864 by way of Formulation in the name of M/s Curexa Health (Private) Ltd, Plot No.517, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period Commencing on 14.06.2022 ending on 13.06.2027 for the following sections. 1. Dry Powder Injections (Cephalosporin) Section 2. Dry Powder Suspension (Cephalosporin) Section 3. Capsules (Cephalosporin) Section.			
13	M/s Karsons Pharmaceuticals, Plot#01, Street No.SS-3, National Industrial Zone, Rawat DML No.000854 (Formulation). **Period:** Commencing on 11.04.2022 ending on 10.04.2027. (Evaluator: Mst. Zunaira Faryad, AD (Lic))	19-05-2023	Good	1. Dr. Ghazanfar Ali Khan, Additional Director QA&LT, DRAP, Islamabad. 2. Fahad Nadeem Deputy Drugs Controller (NCLB), DRAP, Islamabad. 3. Mst. Zunaira Faryad, Assistant Director (Lic), DRAP, Islamabad.
	Production In-charge			Mr. Masud Anwar Chaudhary (B-Pharmacy)
	QC In-charge			Mr. Arshad Iqbal S/o Rahim Gul Khattak (Pharm-D)
	Recommendations of the panel: - The firm has developed SOPs/ Plans for internal audit and to handle the market complaints. The firm is conversant with training of the employees, procedures for waste management as defined and is performing the internal trainings as per SOPs also. The firm also perform mock recall to validate / effectiveness of procedures. Keeping in view the facts observed during inspection, the panel (constituted vide letter No.F.1-9/2011-Lic (PIRIMS) dated 29-05-2023 recommends the renewal of DML#000854 (by way of formulation) w.e.f.11-04-2022 to 10-04-27 to M/s Karsons Pharmaceuticals, Plot#01, Street No.SS-3, National Industrial Zone, Rawat with the following sections Namely, i. Tablet (General) ii. Capsule (General) iii. Dry Suspension (General) iv. Ointment /Cream/ Gel (General) **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000854 by way of Formulation in the name of M/s Karsons Pharmaceuticals, Plot#01, Street No.SS-3, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period Commencing on 11.04.2022 ending on 10.04.2027 for the following sections. 1. Tablet (General) 2. Capsule (General) 3. Dry Suspension (General)			

<table>
<tr><td></td><td colspan="4">4. Ointment /Cream/ Gel (General).</td></tr>
<tr><td>14</td><td>M/s Ahad International Pharmaceutical, 31-Km, Gomal University Multan Road, Qayum Nagar Dera Ismail Khan

DML No.000433 (Formulation).

Period: Commencing on 24-07-2019 ending on 23-07-2024.

(Evaluator: Muhammad Yaqoob, AD)</td><td>25-02-2023 & 15-09-2023</td><td>Good</td><td>1. Prof. Dr. Jamshed Ali Khan, Department of Pharmacy, Peshawar University, Peshawar.
2. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.
3. Mr. Atiq Ul Bari, Area FID, DRAP, Peshawar.</td></tr>
<tr><td></td><td>Production In-charge</td><td colspan="3">Mr. Asghar Ali Asghar S/o Ghulam Abbas (Pharm-D).</td></tr>
<tr><td></td><td>Quality Control In-charge</td><td colspan="3">Mrs. Noreen W/o Aman Ullah Khan (B-Pharm).</td></tr>
<tr><td></td><td colspan="4">As per available record panel was given mandate for renewal of DML & regularization of following section: -
1. Liquid Injectable Vial SVP (General) – Regularization.
2. Liquid Injectable Ampoule (General) – Regularization.
3. Warehouse- Regularization.
4. Quality Control Laboratory – Regularization.
<u>Recommendations of the panel: -</u>
Based on the areas inspected, the people met, documents reviewed, the intension towards further improvements and the corrective and preventive action taken, the firm is considered to be operating at good level of compliance with cGMP guide lines as per drug act, 1976 and rules framed there under. The panel unanimously recommended the grant of renewal of DML No.000433 by way of formulation and regularization of sections with reference to DRAP's letter No.F.3-8/92-Lic (Vol-I) dated 19th December, 2022 to M/s Ahad International Pharmaceutical, 31-Km, Gomal University Multan Road, Qayum Nagar Dera Ismail Khan.

<u>Decision of the Central Licensing Board in 292nd meeting:</u>

The Board considered and approved the grant of renewal of DML No. 000433 by way of Formulation in the name of M/s Ahad International Pharmaceutical, 31-Km, Gomal University Multan Road, Qayum Nagar Dera Ismail Khan on the recommendations of the panel of experts for the period Commencing on 24-07-2019 ending on 23-07-2024 for the following sections subject to confirmation of necessary equipment specially FTIR, TOC analyer, HPLC Stability Chamber etc;
.
1. Liquid Injectable Vial SVP (General) – Regularization.
2. Liquid Injectable Ampoule (General) – Regularization.
3. Store (RMS, FGS, PMS)- Regularization.
4. Quality Control Laboratory – Regularization.</td></tr>
</table>

15	M/s Heal Pharmaceuticals (Pvt) Ltd, W-33, Hayatabad Industrial Estate, Peshawar, KP DML No. 000612 (Formulation) Period: Commencing on 21-03-2022 Ending on 20-03-2027. (Evaluator: Muhammad Yaqoob, AD)	16-03-2023	Good	1. Prof. Dr. Jamshed Ali Khan, Expert Member 2. Mr. Faisal Shahzad, Additional Director, DRAP, Peshawar. 3. Mr. Atiq Ul Bari, FID, DRAP, Peshawar
	Production In-charge	Mr. Imran Khan S/o Khan Khail (B-Pharm).		
	Quality Control In-charge	Mr. Farukh Sier S/o Maqbool Ahmad (M.Sc Chemistry).		

As per available record panel was given mandate for renewal of DML for following section: -

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

Recommendations of the panel:

"Based on the areas inspected, the people met, documents reviewed, the intension towards further improvements and the corrective and preventive action taken, the firm is considered to be operating at good level of compliance with cGMP guide lines as per drug act, 1976 and rules framed thereunder, the panel unanimously recommended the grant of renewal of DML No. 000612 by way of formulation to M/s Heal Pharmaceuticals (Pvt) Ltd, W-33, Hayatabad Industrial Estate, Peshawar, Khyber Pakhtunkhwa.

Decision of the Central Licensing Board in 292nd meeting:

The Board considered and approved the grant of renewal of DML No. 000612 by way of Formulation in the name of M/s Heal Pharmaceuticals (Pvt) Ltd, W-33, Hayatabad Industrial Estate, Peshawar, KP on the recommendations of the panel of experts for the period Commencing on 21-03-2022 Ending on 20-03-2027 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 confirmation of necessary equipment specially FTIR, TOC analyzer, HPLC Stability Chamber etc;.

1. Tablet (Psychotropic).
2. Cream / Ointment (General).

	3. Sachet Section (General). 4. Liquid / Syrup Section (General). 5. Capsule Section (General). 6. Tablet Section (General). 7. Tablet Section (Antibiotic). 8. Capsule (Cephalosporin). 9. Dry Powder Suspension (Cephalosporin)**.**			
16	M/s Zeta Pharmaceuticals, 87-B, Sunder Industrial Estate, Lahore. DML No. 000738 (Formulation) Period: Commencing on 23-06-2020 Ending on 22-06-2025 Evaluator: Mrs Ume Laila DD Lic	24-08-2023	**Good**	1. Muhammad Shamoon Ch. Expert Member 2. Majida Mujahid (Additional Director / Area FID, DRAP, Lahore. 3. Mehwish Jamil Butt, Assistant Director, DRAP, Lahore.
	Production In-charge			Mr. Muhammad Shafiq
	QC In-charge			Hafiz Muhammad Abid Rasool
	Recommendations of the panel: Keeping in view the facilities like building, HVAC system, Equipment, instrument, Machinery, Personnel the panel of inspectors is of the opinion to recommend the renewal of Drugs Manufacturing License to M/s Zeta Pharmaceuticals Plot #494, Sunder Industrial Estate, Raiwind Road Lahore Bearing Lic No.000818 and regularization of the following approved sections: i. Tablet Section (General) ii. Capsule Section (General) iii. Sachet Section (General) **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000738 by way of Formulation in the name of M/s Zeta Pharmaceuticals, 87-B, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period Commencing on 23-06-2020 Ending on 22-06-2025 for the following sections. 1. Tablet Section (General) 2. Capsule Section (General) 3. Sachet Section (General)			
17	M/s Schazoo Zaka (Pvt) Ltd, 35-Km, Lahore Jaranwala Road, Sheikhupura.	25-08-2023	Good	1. Dr. Zaka ur Rehman, Expert Member 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.

	DML No. 000636 (Formulation) Period: Commencing on 18-06-2023 Ending on 17-06-2028 (Evaluator: Mrs. Ume Laila DD)			3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore
	Production In-charge			Hafiz Muhammad Tayyab Shahid S/o Muhammad Hussain Farooqi (B-Pharm)
	QC In-charge			Mr. Muhammad Awais S/o Muhammad Idrees (MSc-Chemistry)
	<u>Recommendations of the panel:</u> *"Keeping in view the facilities like, building, HVAC system, machinery, equipment, instruments, personnel, documentation, the panel of inspectors recommends the renewal of DML and Regularization of the following seven (07) sections only to M/s Schazoo Zaka (Pvt) Ltd, 35-Km, Lahore Jaranwala Road, Sheikhupura:* 1. Tablet (Anti TB) 2. Dry Powder Suspension (Anti TB) 3. Sachet Section (Anti TB) 4. Tablet (General) 5. Dry Powder Suspension (General) 6. Capsule (General) *7.* Sachet (General) **<u>Decision of the Central Licensing Board in 292nd meeting:</u>** The Board considered and approved the grant of renewal of DML No. 000636 by way of Formulation in the name of M/s Schazoo Zaka (Pvt) Ltd, 35-Km, Lahore Jaranwala Road, Sheikhupura on the recommendations of the panel of experts for the period Commencing on 19-06-2023 Ending on 18-06-2028 for the following sections. 1. Tablet (Anti TB) 2. Dry Powder Suspension (Anti TB) 3. Sachet Section (Anti TB) 4. Tablet (General) 5. Dry Powder Suspension (General) 6. Capsule (General) 7. Sachet (General)			
18	M/s Ameer Pharma (Pvt) Ltd, 23-Km, Sheikhupura Road DML No.000604 (Formulation).	24-08-2023	Good	1. Dr. Zaka Ur Rehman, Expert Member. 2. Abdul Rashid Shaikh, Area FID, DRAP Lahore. 3. Ishtaiq Shafiq, Assistant Director, DRAP Lahore.

	Period: Commencing on 30-12-2021 ending on 29-12-2026 . (Evaluator: Mst. Zunaira Faryad, AD (Lic))			
	Production In-charge			Mr. Abdul Rouf
	Quality Control In-charge			Mr. Abdul Qayyum
	Recommendations of the panel: - Keeping in view the manufacturing facility like building, HVAC system, sanitation, production machinery, equipment in quality control, testing facilities, technical personnel and documentation, the panel of inspectors recommends the grant of renewal of Drug Manufacturing License to M/s Ameer Pharma (Pvt.) Ltd, 23-Km, Sheikhupura Road, Lahore for the following sections: i. Liquid Vial Injectable (General-Human) ii. Oral Liquid Section (Human) iii. Liquid Vial Injectable (Narcotics/Psychotropic-Human) iv. Tablet Section (General) (Human) v. Dry Powder Vial Injection for Cephalosporin (Human) vi. Liquid Vial Injectable (Steroid-Human) vii. Liquid Injectable (General Antibiotic-Human) **Decision of the Central Licensing Board in 292nd meeting:** The Board considered and approved the grant of renewal of DML No. 000604 by way of Formulation in the name of M/s Ameer Pharma (Pvt.) Ltd, 23-Km, Sheikhupura Road on the recommendations of the panel of experts for the period Commencing on 30-12-2021 ending on 29-12-2026 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. 1. Liquid Vial Injectable (General-Human) 2. Oral Liquid Section (Human) 3. Liquid Vial Injectable (Narcotics/Psychotropic-Human) 4. Tablet Section (General) (Human) 5. Dry Powder Vial Injection for Cephalosporin (Human) 6. Liquid Vial Injectable (Steroid-Human) 7. Liquid Injectable (General Antibiotic-Human)			
19	M/s Pharma Zone Chemicals (Pvt) Ltd, Plot#37, Sunder Industrial Estate, Lahore	**21-09-2023**	**Good**	1. Muhammad Shamoon Ch, Ex-Expert Member. 2. Majida Mujahid, Additional, DRAP Lahore. 3. Farooq Aslam, Assistant Director, DRAP Lahore.

	DML No.000861 (Semi-Basic). **Period:** Commencing on 12-06-2022 ending on 11-06-2027. (Evaluator: Abdullah AD)			
	Production In-charge			Mr. Ali Junaid (Pharm-D)
	Quality Control In-charge			Mr. Muhammad Asif (M.Sc Chemistry

Conclusion:

Based on the areas inspected, the people met and documents reviewed and considering the findings of inspection the panel verifies that the firm possesses facility for manufacturing of APIs including listed below API:

Name of API through Semi Basic Manufacture		
1	General	Taste Masked Granules (APIs): 1) Ciprofloxacin 2) Levofloxacin 3) Moxifloxacin 4) Clarithromycin 5) Linzolid 6) Loratadine 7) Voriconazole Enteric Coated (EC) Sustained Release (SR) /Delayed Dual Release (DDR) and Immediate Release Pellets: 1) Omeprazole (Enteric Coated Pellets) 2) Esomeprazole (Enteric Coated Pellets) 3) Lansoprazole (Enteric Coated Pellets) 4) Diclofenac Sodium (Enteric coated and Sustained released Pellets) 5) Dexlansoprazole (Delayed Dual Release Pellets) 6) Pantoprazole Sodium (Delayed Release Pellets) 7) Diclofenac Potassium (Delayed Release Pellets) 8) Itraconazole (Immediate Release Pellets) 9) Duloxetine HCI (Delayed Release Pellets) 10) Fluoxetine (Sustained / Immediate/ Delayed Release Pellets) 11) Doxycycline Hyclate (Delayed/Immediate Release Pellets) 12) Orlistate (Sustained / Immediate/ Delayed Release Pellets) 13) Rabeprazole Sodium (Delayed Release Pellets) 14) Venlafaxine HCI (Sustained Release Pellets)

		15) Tamsulosin HCI (Sustained Release Pellets) 16) Mebeverine HCI (Sustained Release Pellets) 17) Itopride HCI (Sustained Release Pellets) 18) Domperidone (Sustained Release Pellets) 19) Fexofenadine HCI (Sustained / Immediate Release Pellets)
02	Cephalosporin	Oral Semi Synthetic Cephalosporin (APIs) Active Pharmaceutical Ingredients: 1) Cefixime 2) Cephradine 3) Cefadroxil 4) Cefaclor **5)** Cephalexin Hydrate

Recommendations of the panel: -

The panel of inspectors recommends for the renewal of drug manufacturing License under DML No.000861 in favor of M/s Pharma Zone Chemicals (Pvt) Ltd, Plot#37, Sunder Industrial Estate, Lahore to manufacture Active Pharmaceutical Products by way of Semi-Basic manufacturing as per above mentioned list.

Decision of the Central Licensing Board in 292nd meeting:

The Board considered and approved the grant of renewal of DML No. 000861 by way of Semi Basic Manufacture in the name of M/s Pharma Zone Chemicals (Pvt.) Ltd, Plot#37, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period Commencing on 12-06-2022 ending on 11-06-2027 for the following APIs. The Board advised the firm to submit flow charts of the all APIs/intermediates and processing fee.

Name of API through Semi Basic Manufacture		
1	General	Taste Masked Granules (APIs): 1) Ciprofloxacin 2) Levofloxacin 3) Moxifloxacin 4) Clarithromycin 5) Linzolid 6) Loratadine 7) Voriconazole Enteric Coated (EC) Sustained Release (SR) /Delayed Dual Release (DDR) and Immediate Release Pellets: 1) Omeprazole (Enteric Coated Pellets) 2) Esomeprazole (Enteric Coated Pellets) 3) Lansoprazole (Enteric Coated Pellets) 4) Diclofenac Sodium (Enteric coated and Sustained released Pellets) 5) Dexlansoprazole (Delayed Dual Release Pellets)

		6) Pantoprazole Sodium (Delayed Release Pellets) 7) Diclofenac Potassium (Delayed Release Pellets) 8) Itraconazole (Immediate Release Pellets) 9) Duloxetine HCI (Delayed Release Pellets) 10) Fluoxetine (Sustained / Immediate/ Delayed Release Pellets) 11) Doxycycline Hyclate (Delayed/Immediate Release Pellets) 12) Orlistate (Sustained / Immediate/ Delayed Release Pellets) 13) Rabeprazole Sodium (Delayed Release Pellets) 14) Venlafaxine HCI (Sustained Release Pellets) 15) Tamsulosin HCI (Sustained Release Pellets) 16) Mebeverine HCI (Sustained Release Pellets) 17) Itopride HCI (Sustained Release Pellets) 18) Domperidone (Sustained Release Pellets) 19) Fexofenadine HCI (Sustained / Immediate Release Pellets)
02	Cephalosporins	Oral Semi Synthetic Cephalosporins (APIs) Active Pharmaceutical Ingredients: 1) Cefixime 2) Cephradine 3) Cefadroxil 4) Cefaclor 5) Cephalexin Hydrate

20.	M/s Vetcon Pharmaceuticals (Pvt)Ltd, Plot No. 7-10 B, Industrial Estate, Bhimber, AJK. DML No.000307 (Formulation). Period: Commencing on 29-06-2019 ending on 28-06-2025. (Evaluator: Muhammad Yaqoob, AD)	**26-01-2023**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad. 2. Mr. Fahad Nadeem, Deputy Director, DRAP, Islamabad. 3. Mr. Muhammad Umar, Deputy Director (QA/LT), DRAP, Islamabad.
	Production In-charge	Mr. Muhammad Anwar Bajwa (B-Pharm).		
	Quality Control In-charge	Mr. Muhammad Ali Bajwa S/o Muhammad Anwar Bajwa (Pharm-D).		
	As per available record of Licensing Division panel was mandate for renewal of Drug Manufacturing License for following sections"- 1. Liquid Vials Injectable (General) – Veterinary. 2. Dry Powder Vials Injectable (General) – Veterinary.			

3. Oral Liquid / Drench (General) – Veterinary.
4. Quality Control Laboratory.
5. Warehouse.

Summary & Conclusion.

The firm has maintained SOPs for internal audit and to handle the market complaints. They are concerned with the training of the employees; procedures for waste management are defined. It is advised to strengthen the QA to meet the requirements and to devise a mechanism for approval of SOPs through MR. Keeping in view the facts observed during inspection, the panel (constituted vide letter No.F.5-1/90-Lic (Vol-II) dated 23-12-2022 unanimously recommends renewal of DML by way of formulation to M/s Vetcon Pharmaceuticals (Pvt.) Ltd, Plot No.7-10 B, Industrial Estate Bhimber, AJK DML No.000307 with following sections subject to verification of equipments required vide 290th meeting of CLB: -

2. Liquid Vials Injectable (General) – Veterinary.
3. Dry Powder Vials Injectable (General) – Veterinary.
4. Oral Liquid / Drench (General) – Veterinary.
5. Quality Control Laboratory.
6. Warehouse.

Decision of the Central Licensing Board in 292nd meeting:

The Board considered and approved the grant of renewal of DML No. 000307 by way of Formulation in the name of M/s Vetcon Pharmaceuticals (Pvt)Ltd, Plot No. 7-10 B, Industrial Estate, Bhimber, AJK on the recommendations of the panel of experts for the period Commencing on 29-06-2019 ending on 28-06-2025 for the following sections subject to confirmation of necessary equipment specially FTIR, TOC analyzer, HPLC Stability Chamber etc;

1. Liquid Vials Injectable (General) – Veterinary.
2. Dry Powder Vials Injectable (General) – Veterinary.
3. Oral Liquid / Drench (General) – Veterinary.
4. Quality Control Laboratory.
5. Store (RMS, PMS, FGS).

Item-IV: **MISCELLANEOUS**

Case No-01 **SITE VERIFICATION OF M/S BIO PANACEA LABORATORIES, SHEIKHUPURA.** (Evaluator: - Zunaira Faryad (AD-Lic.)

M/s Bio Panacea Laboratories, 13-Km, Sheikhupura-Lahore Road, Lahore applied for site verification of proposed plot. After application was completed by the firm, FID was requested to conduct site inspection of proposed site and submit report regarding suitability of plot for establishment of pharmaceutical unit.

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

2.	Location	:	The proposed site was located in agricultural area at 13-Km, Sheikhupura-Lahore Road, Lahore Sheikhupura.
3.	Surrounding	:	The dimensions of the plot are as follows: On the front side of the plot, there was 20 feet wide un-paved rasta. On the back side of the proposed site, there were agricultural land. On the right side of proposed side there was there was agricultural land. On the left side the site there was Bashir Polymers with in the same boundary wall, however the management allocate about 04 Kanals land for the proposed unit.
4.	Size	:	The plot size (234*86=20124) sq. feet. Documents of the proposed site are attached as provided by the management. The site plan /dimension of the plot is also annexed with report.
5.	Recommendations	:	At the distance of 300-400 meters there was a very active border / paper mill which was producing huge quantity of smoke and the approach was also not appropriate. The above observation led to the conclusion that the site is not as per requirement, laid down under paragraph 1 of section 1 of schedule "B" (SRO 470 (1)/98, dated 15-05-1998) under Rule 16(a) of the of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Hence the proposed site is not suitable for establishment a pharmaceutical unit as of today as the same was also discussed in detail with the owners.

Decision of the Central Licensing Board in 292nd meeting

The Board considering the facts on the record and after thread bare deliberations decided to give personal hearing to the firm M/s Bio Panacea Laboratories, 13-Km, Sheikhupura-Lahore Road, Lahore in the upcoming meeting of the Board

The Board further decided to authorize Chairman CLB to constitute 2-member panel (other than the officer already inspected the site) for re-inspection of the same site if desired by the applicant. Moreover, Chairman CLB is authorized to issue notice to the applicant for personal hearing before the CLB.

Case No 02. **SITE VERIFICATION REPORT OF M/S PREMIER LIFE PHARMACEUTICAL ((PVT) LTD, PLOT NO. 181/1, ROAD L.9, INDUSTRIAL ESTATE GADOON AMAZAI, SWABI.**

Site verification report of M/s Premier Life Pharmaceutical ((Pvt) Ltd, Plot No. 181/1, Road L.9, Industrial Estate Gadoon Amazai, Swabi. The inspection was conducted by Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad and Atiq Ul Bari, Federal Inspector of Drugs, Peshawar in response to this office letter No. 3-6/2022-Lic dated 29th May, 2023. The recommendations of the inspection report are as under:-

The undersigned inspected the Plot No. 181/1, Road L-9, Industrial Estate, Gadoon Amazai, Swabi, Khyber Pakhtunkhwa on 22-06-2023. The said plot is proposed site for M/s Premier Life Pharmaceutical (Pvt) Ltd. The plot is situated in the Industrial Estate of Gadoon Amazai, Swabi, KPK having the necessary amenities such as road infrastructure, water and electrical supply. No environmental pollution was found at the time of inspection and a unit of chip board is situated 100 meters away from the back corner of the plot.

The premises has already built halls with partitions / rooms and a double story built block for security guards / admin. The pictures are attached with the report.

Further the Establishment has already submitted an undertaking that they would build a technical floor as per DRAP's requirement. Therefore, the proposed premises is suitable for the construction of the pharmaceutical unit.

Decision of the Central Licensing Board in 292nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm M/s Premier Life Pharmaceutical ((Pvt) Ltd, Plot No. 181/1, Road L.9, Industrial Estate Gadoon Amazai, Swabi before the forth-coming meeting of CLB.

Case No 3. **WITHDRAWAL OF DRUG MANUFACTURING LICENSE NO. 000937 BY WAY OF BASIC MANUFACTURE OF M/S HERBION PAKISTAN (PVT) LTD, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad, wherein firm has submitted an application for withdrawal of their Drug Manufacturing License No. 000937 by way of Basic Manufacture. Firm has also returned original DML (Form-2) and inspection book.

Decision of the Central Licensing Board in 292nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad DML No. No. 000937 by way of Basic Manufacture in the upcoming meeting of the Board.

Case No. 4. **M/S CONVELL LABORATORIES, SAIDU SHARIF, SWAT UNDER DRUG MANUFACTURING LICENSE NO. 000509 BY WAY OF FORMULATION.**

M/s Convell Laboratories, is licensed firm under Drug Manufacturing License No. 000509 by way of Formulation situated at Saidu Sharif, Swat. The Central Licensing Board in its

270th meeting held on 23rd May, 2019 has considered and approved the renewal of Drug Manufacturing License w.e.f. 26-02-2018.

2. An unfortunate incident was occurred in the premises. The Federal Inspector of Drug-I, Peshawar, DRAP vide letter No. 11-58/2005-Convell-DRAP(P) dated 18/05/2022 wherein the FID submitted inspection report and recommendation regarding said incident of M/s Convell Laboratories, Saidu Sharif, Swat which is reproduced as under;

> *"Please refer to the subject cited above and to say that it was learnt from media and reliable sources that building of M/s. Convell Laboratories, Saidu Sharif Swat, having Drug Manufacturing License (DML) No. 000509, granted under the Drugs (Licensing, Registering and Advertising Rules, 1976, has collapsed on 14.05.2022 afternoon. Under the said rules, it is the responsibility of the manufacturer to maintain/ensure/comply with all the conditions required for DML.*
>
> *In order to assess the factual position, the firm was visited on 17.05.2022. The firm's production manager Mr. Fazal Mabood was available at the firm's premises who informed about the collapse of the building. During the site visit, it was observed that;*
>
> i. *Major building part of the firm including tablet general, capsule general, liquid syrup general, dry suspension general, tablet psychotropic, ware house, finished goods and section of H&OTC vide E.No.00121 (Tablet, Capsule, Oral Liquid syrup, Sachet) have been totally collapsed.*
> ii. *Some remaining tilted walls/ major slabs are also being demolished by the firm.*
> iii. *Small portion of the building having Ceph section and QC is intact, however, due to major collapse, dirt/ dust, building scrap, this area is also totally nonoperational.*
> iv. *The approved management of the firm was involved in legal matters as informed by technical person and not available at the site. Inspection book was also not available at the time of visit.*

3. In the light of above mentioned position, it is submitted that the conditions under which DML No. 000509 was granted in accordance with the Drugs (L.R.&A), Rules 1976 of the Drugs Act 1976/ DRAP Act, 2012 no more exist. Hence, the DML No. 000509 of M/s. Convell Laboratories, Saidu Sharif, Swat may be cancelled as per laid down procedure under the DRAP, Act, 2012."

> <u>Proceedings and Decision by the Central Licensing Board in 287th meeting:</u>
>
> Mr. Abid Hameed Puri Advocate and Ikram ul Haq Managing Director appeared before the Board and contended that Unit was consist of two blocks. One block consists of Ceph section and QC and other block consist of tablet general, capsule general, liquid syrup general, dry suspension general, tablet psychotropic, ware house, finished goods. Block consist of Ceph section and QC is intact while other block is demolished due to blast. They further contended that minimum requirements for holding a license exists therefore, licence may not be cancelled. The further contended that there is no production activity carried out and they may be allowed to carry production activity in Ceph block. The Board after hearing the arguments decided to get the unit inspected by the panel of following officers before taking any conclusive decision.
>
> 1. Mr. Muhammad Younas Khattak, CDI, Peshawar.

2. Federal Inspector of Drugs, DRAP, Peshawar.
3. Assistant Director, DRAP, Peshawar

In response to this Division's letter dated 4th July, 2022 inspection report is submitted by Mr. Atiq Ul Bari, FID / Additional Director, DRAP, Peshawar of M/s Convell Laboratories, Saidu Sharif, Swat in the light of decision of Central Licensing Board in its 287th meeting held on 24th June, 2022. The inspection was carried out on 29-07-2022. The recommendations of the panel are as under:-

> *"Based on the unit inspected (Cephalosporin section and Quality Control Lab) and considering the findings of inspection, the panel verified the claim of the firm that heir above part of unit is intact and may carry production activities as per GMP guidelines described in Drugs Act, 1976 and rules framed thereunder."*

Decision of the Central Licensing Board in 288th meeting

The Board observed that the case requires complete investigation on the matter before further proceeding. The board further decided to refer the case to area FID Peshawar for complete investigation in the light of the case filed by the local Government, police inquiry, building fitness certificate by the concerned government department and nature of incidence, etc.

In the light of board decision, a letter was issued to the firm on 17th November, 2022.

In response to the above letter, Mr. Faisal Shahzad, FID-I, DRAP, Peshawar wherein he had submitted a complete investigation report of M/s Convell, Swat.

Case Investigation officer Mr. Jehan Alam, Thana Saidu Sharif was requested to provide complete case details. In response, the investigation officer submitted his report along with following documents;

a) Report of Bomb Disposal Squad dated 26.12.2022 where in incident dated 14. 05. 2022 was referred causing death of two persons along twelve injured. It was also added that after removal of scrap of collapsed building, area was examined in detail with devices. No ditch connected to any explosive was found. Further, the explosion occurred due to unknown reason.

b) Certificate No. NIL dated NIL issued by Nee/um Air Conditioning Engineers that they installed HVAC in the building on 05. 05.2010 at the firm and certified that there is no any type of explosive occur due to installed HVAC system except electric short circuit.

c) Letter of Sui Northern Gas Pipelines Limited (SNGPL) RefSWT0:24 dated 25.10.2022 wherein it is certified that M/s. Convell Laboratories is not SNG PL consumer and gas connection does not exist in the firm.

d) Letter No. BS-11970112-W dated 28.11.2022 issued by office of the Sub Divisional Officer, Building Sub Division-I, Saidu Sharif wherein it is mentioned that no data is available about the structural design and type of structure and the collapse of building structures due to blast loading is a specialized field. Hence, the reasons of building collapse could not be ascertained.

e) Letter No. 346/PDls-S (l'lT&TA) (Convel Lab Faizabad) dated 16.06.2022 issued by the Provincial Drug Inspectors, Swat wherein it is submitted that their role is related with the quality of drugs/ medicines in the market. As far as incident occurred in the premises of M/s. Convel Laboratories, Swat, the matter comes under the domain of Drug Regulatory Authority at Islamabad.

f) Letter No. 2229-19 dated 25.11.2022 issued by the Peshawar Electric Supply Company wherein it is recorded that as per site visit and investigations of this office, it was observed that there were no defect/fault in PESCO installations i.e. Transformer and energy meter at the course of time during the sad incident occurred on dated 14.05.2022.

g) Letter No. 460AIADICPC/05/SWT dated 16.05.2022 issued by Consumer Protection Council, Industries and Commerce, District Swat wherein it is reported that the factory was established in 1974 and only registered with Drug Regulatory Authority of Pakistan and license is valid till 26.02.2023. The department also referred statement of factory Manager that there was no boiler or pressure vessel in the factory and DRAP officials visit the factory. Total cost of loss is round about l 20Million. Furthermore, there is no record of said factory in their office of nor they intimated this office about their factory till date.

h) Letter No. DDL/Swat/G.Misc:l0531 dated 28.06.2022 issued by the office of the Deputy Director Labour, Swat where in it submitted that action under the prevailing Law, present case is fixed for 30. 06.2022 regarding compensation under Workmen Compensation Act, 2013. The case is sub-judiced before the Court of Commissioner Compensation Malakand Division, Swat please.

i) Copy of FIR No. 367 dated 16.05.2022 lodged against the firm by the police department.

Investigating officer in his report has replied to DRAP, Peshawar letter indicating that on 14.05.2022 a mysterious explosion occurred in the Convell Laboratories, Swat resulting in collapse of ceiling of manufacturing area and walls resulting in two deaths and twelve injured. ASI Mr. Wazir Zada started inquiry. During inquiry, reports from above mentioned departments were sought in which electric short circuit/ building materials reasons were not indicated. Further, report of Bomb Disposal Squad is also negative for any explosives involved in the incident. In addition, no proof of any insurance matter has surfaced. Workers of the company have also submitted affidavits in favor of the owner of the company. Till date investigations, there is no evidence of any negligence by the owner of the company. As soon as investigations are complete, case shall be submitted before the court.

2. The firm M/s. Conveil Laboratories, Swat was also required to submit status of remaining portion of the building along with building fitness certificate from concerned department, local government permission to carryout/ continue production activities after collapse and any other necessary information related to the case without concealment of any facts related to case. The firm submitted their reply along with five files wherein the firm has provided following information/ documents;

File 1: A blast occurred in their premises of unknown reason. Scrap of collapsed building was not lifted until the local police needed it during the process of investigation and further permission of local police scrap was removed. The reconstruction of collapsed building foundation is now in

progress. Copy of approved layout plan and certificate of structural soundness of building and construction specification are also attached. The remaining Ceph. Portion of the building having Ceph. Capsules and Ceph. Dry suspension and QC lab area is fully intact. However, this part of the building is also renovated with firefighting system, electric wiring in the building with all precautionary measures to avoid short circuit and all staff is being trained for rescue activities and self-help in case of any emergency. The firm has also submitted an undertaking on stamp paper for submitting genuine and correct information to the best of their knowledge and belief an nothing has been concealed.

File 2: The firm informed that officers of TMA inspected the premises is not attached with any other building. TMA granted permission for reconstruction of collapsed building. Copy of letter No. 84/BCAITMA dated 02.12. 2022 issued by Tehsil Municipal Administration, Babuzai (Mingora) is provided. Also provide Building Strength Certificate issued by office of C& W. Swat.

File 3: The firm has provided documents related to police case including FIR, letters of all the concerned departments who were approached by the police department which are already mentioned under Annexure-II above.

File 4: The firm provided recent documents/ personal hearing and inspection reports related to DRAP including panel report dated 29.07.2022 for submitting recommendation to resume production activities.

File 5: The firm has informed that a number of technical and non-technical staff members are employed in the factory who have lost their bread and butter due to this incident. A number of allied person's employment is also affected and also causing shortage of drugs provided to patients. Besides this, Swat has been the victim of terrorism and Talibanization for many years. Floods of 2010 and 2022 has also destroyed infrastructure of the area leading to poverty and unemployment. The firm has been a source of employment to number of poor people in the area. Finally, the .firm has requested to allow the resumption of production in Ceph. Area.

3. In the light of current position of the case i.e,

a) Report provided by the Investigating Officer that, until date no evidence has surfaced against the management of the firm for their negligence in the unfortunate incident of building collapse along with letters from concerned departments.

b) TMA has granted NOC for re-construction of the collapsed building as per documents provided by the firm.

c) Building strength certificate No.681 /2-M dated 16. 12.22 issued by the office of the Chief Engineer C&W Division No-I, Swat Saidu Sharif wherein it is mentioned that the building namely Convell Laboratories Pharmaceutical Manufacturers, Faizabad Saidu Sharif Swat was inspected, visually inspected the building portion-II, & found no damage done due to burst/ blast in portion-I production unit, hence the subject building portion-II is fit for intended purpose subject to the condition that no such machinery plants or other equipment likely to burst during operations shall not be placed in the same for safety purpose **(File** 2).

d) Report of the DRAP panel dated 29.07.2022 **(File 4)** for allowing production in Cephalosporin section as per GMP guidelines mentioned under The Drugs (L.R.A. Rules) 1976 of the Drug Act 1976/ DRAP Act, 2012,

Case may be placed before the CLB, along with record obtained from the 1/0 and the firm, for consideration for resumption of production in the Ceph. Sections as per DRAP panel inspection report dated 29.07.2022, if in accordance with all relevant rules. It is further added that DRAP officers conduct GMP inspection, which only ascertains the GMP compliance; manufacturing / testing procedures, protocol adopted by the firm as per the Drugs Act, 1976/ DRAP Act, 2012 and verify the facility of the firm for GMP compliance. It is not the mandate of DRAP to ascertain strength of building and safety of installed electric panels or equipment. The verification of strength of building, safety of installed electric panels/ equipment, firefighting system etc., is a technical job that pertains to civil/ electrical engineers and is responsibility of the manufacturer to comply with all such requirements as laid down by relevant/ concerned departments.

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

1. The Board decided to serve the Show cause notice to the firm for following sections:
    a. Tablet General Section
    b. Capsule General Section
    c. Liquid Syrup General Section
    d. Dry Suspension General
    e. Tablet Psychotropic Section
    f. Warehouse
2. Board observed that the firm has provided a scanned copy of the C&W letter and Board decided to verify the authenticity/ genuineness and validity of the letter issued by Executive Engineer.
3. Board further decided that the firm shall complete the application of renewal of DML for further period within 15 days as the renewal of DML of the firm will expired on 26-02-2023.
4. The Board shall submit an undertaking on stamp paper for taking responsibility regarding civil and electrical work and to stop production immediately in case of any mis-happening.
5. The production of cephalosporin area shall be allowed after submission of undertaking and reply from C&W department Swat.

A Show Cause Notice was issued on 20th March, 2023 in the light of decision of 289th meeting of Central Licensing Board held on 23rd January, 2023 and firm has not rectified shortcomings till to date.

A letter of personal hearing was served on 20th October, 2023 to the said firm for 292nd meeting of Central Licensing Board schedule to be held on 04-10- 2023.

Decision of the Central Licensing Board in 292nd meeting

Mr. Dawood Kamal, the Council of the firm, and Mr. Matiullah (Operational Director), as representative of the firm, appeared before the Board. They also contended that they have submitted an improved revised layout plan for approval. The Board after hearing representative(s) of the firm and perusal of the facts, decided to suspend the following sections for two years, effective from 4-10-2023 to 03-10-2025, or until compliance with the requirements of the DML.

a. Tablet General Section
b. Capsule General Section

c. Liquid Syrup General Section
d. Dry Suspension General
e. Tablet Psychotropic Section
f. Warehouse

Case No. 5. **CHANGE OF MANAGEMENT OF M/S NOVARTIS PHARMA PAKISTAN LIMITED, PLOT NO.C-21, S.I.T.E., KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000003 BY WAY OF (FORMULATION).**

M/s Novartis Pharma Pakistan Limited, Plot No.C-21, S.I.T.E., Karachi, Drug Manufacturing License No.000003 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-29.	**New Management as per Form-29.**
1. Mr. Zaid Bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhery CNIC No.42000-0519991-5. 2. Mr. Badaruddin Fateh Ali Vellani S/o Fatehali Wali Muhammad Vellani CNIC No. 42301-0918221-7. 3. Ms. Wajeeha Khan D/o Muhammad Moinuddin Khan CNIC No.61101-1895277-6. 4. Mr. Christopher Snook S/o David Patrick Snook Passport No.507622357. 5. Mr. Muhammad Arif Tahir S/o Tahir Moeen CNIC No.42000-0472657-7.	1. Mr. Zaid Bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhery CNIC No.42000-0519991-5. 2. Mr. Badaruddin Fateh Ali Vellani S/o Fatehali Wali Muham mad Vellani CNIC No. 42301-0918221-7. 3. Mr. Christopher Snook S/o David Patrick Snook Passport No.507622357. 4. Mr. Muhammad Arif Tahir S/o Tahir Moeen CNIC No.42000-0472657-7.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Novartis Pharma Pakistan Limited, Plot No.C-21, S.I.T.E., Karachi, Drug Manufacturing License No.000003 by way of formulation as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020**;**

Previous Management as per Form-29	**New Management as per Form-29**
1. Mr. Zaid Bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhery CNIC No.42000-0519991-5. 2. Mr. Badaruddin Fateh Ali Vellani S/o Fatehali Wali Muhammad Vellani CNIC No. 42301-0918221-7. 3. Ms. Wajeeha Khan D/o Muhammad Moinuddin Khan CNIC No.61101-1895277-6. 4. Mr. Christopher Snook S/o David Patrick Snook Passport No.507622357. 5. Mr. Muhammad Arif Tahir S/o Tahir Moeen CNIC No.42000-0472657-7.	1. Mr. Zaid Bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhery CNIC No.42000-0519991-5. 2. Mr. Badaruddin Fateh Ali Vellani S/o Fatehali Wali Muham mad Vellani CNIC No. 42301-0918221-7. 3. Mr. Christopher Snook S/o David Patrick Snook Passport No.507622357. 4. Mr. Muhammad Arif Tahir S/o Tahir Moeen CNIC No.42000-0472657-7.

Case No. 6. **CHANGE OF MANAGEMENT OF M/S NOVARTIS PHARMA PAKISTAN LIMITED, 15-WEST WHARF DOCKYARD ROAD, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000193 BY WAY OF (FORMULATION).**

M/s Novartis Pharma Pakistan Limited, 15-West Wharf Dockyard Road, Karachi, Drug Manufacturing License No.000193 by way of formulation have submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-29	New Management as per Form-29
1. Mr. Zaid Bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhery CNIC No.42000-0519991-5. 2. Mr. Badaruddin Fateh Ali Vellani S/o Fatehali Wali Muhammad Vellani CNIC No. 42301-0918221-7. 3. Ms. Wajeeha Khan D/o Muhammad Moinuddin Khan CNIC No.61101-1895277-6. 4. Mr. Christopher Snook S/o David Patrick Snook Passport No.507622357. 5. Mr. Muhammad Arif Tahir S/o Tahir Moeen CNIC No.42000-0472657-7.	1. Mr. Zaid Bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhery CNIC No.42000-0519991-5. 2. Mr. Badaruddin Fateh Ali Vellani S/o Fatehali Wali Muham mad Vellani CNIC No. 42301-0918221-7. 3. Mr. Christopher Snook S/o David Patrick Snook Passport No.507622357. 4. Mr. Muhammad Arif Tahir S/o Tahir Moeen CNIC No.42000-0472657-7.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Novartis Pharma Pakistan Limited, 15-West Wharf Dockyard Road, Karachi, Drug Manufacturing License No.000193 by way of formulation as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:

Previous Management as per Form-29	New Management as per Form-29
1. Mr. Zaid Bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhery CNIC No.42000-0519991-5. 2. Mr. Badaruddin Fateh Ali Vellani S/o Fatehali Wali Muhammad Vellani CNIC No. 42301-0918221-7. 3. Ms. Wajeeha Khan D/o Muhammad Moinuddin Khan CNIC No.61101-1895277-6. 4. Mr. Christopher Snook S/o David Patrick Snook Passport No.507622357. 5. Mr. Muhammad Arif Tahir S/o Tahir Moeen CNIC No.42000-0472657-7.	1. Mr. Zaid Bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhery CNIC No.42000-0519991-5. 2. Mr. Badaruddin Fateh Ali Vellani S/o Fatehali Wali Muham mad Vellani CNIC No. 42301-0918221-7. 3. Mr. Christopher Snook S/o David Patrick Snook Passport No.507622357. 4. Mr. Muhammad Arif Tahir S/o Tahir Moeen CNIC No.42000-0472657-7.

Case No. 7 **CHANGE OF MANAGEMENT OF M/S LUCKY CORE (Frmerly M/s. ICI) INDUSTRIES LIMITED, S-33, HAWKES BAY ROAD, KARACHI UNDER DML NO 000006 (BY WAY OF FORMULATION)**

M/s Lucky Core (Frmerly M/s. ICI) Industries Limited, S-33, Hawkes Bay Road, Karachi submitted the documents for change in management. The firm has deposited fee of Rs. 75,000/- for change of management detail is as under:

Previous Management	Retiring Management	New Management as per Form-29
1. Asif Jooma S/o Omar Valli Jooma CNIC# 42301-3175078-7. 2. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tahawur Zaidi CNIC#42301-1740521-7. 3. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC#42201-5355492-7. 4. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC#42000-0568372-5. 5. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC#42201-6464247-3. 6. Jawed Yunus Tabba S/o Muhammad Yunus CNIC#42201-2111104-7. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz Bawany CNIC#42000-3004991-0. 8. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC#42301-8986425-7.	1. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC#42301-8986425-7.	1. Asif Jooma S/o Omar Valli Jooma CNIC# 42301-3175078-7. 2. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tahawur Zaidi CNIC#42301-1740521-7. 3. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC#42201-5355492-7. 4. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC#42000-0568372-5. 5. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC#42201-6464247-3. 6. Jawed Yunus Tabba S/o Muhammad Yunus CNIC#42201-2111104-7. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz Bawany CNIC#42000-3004991-0. 8. Adnan Afridi S/o Iqbal Afridi CNIC#42301-3039230-3.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Lucky Core (Frmerly M/s. ICI) Industries Limited, S-33, Hawkes Bay Road, Karachi as under;

Previous Management	Retiring Management	New Management as per Form-29

1. Asif Jooma S/o Omar Valli Jooma CNIC# 42301-3175078-7. 2. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tahawur Zaidi CNIC#42301-1740521-7. 3. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC#42201-5355492-7. 4. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC#42000-0568372-5. 5. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC#42201-6464247-3. 6. Jawed Yunus Tabba S/o Muhammad Yunus CNIC#42201-2111104-7. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz Bawany CNIC#42000-3004991-0. 8. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC#42301-8986425-7.	i. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC#42301-8986425-7.	i. Asif Jooma S/o Omar Valli Jooma CNIC# 42301-3175078-7. ii. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tahawur Zaidi CNIC#42301-1740521-7. ii. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC#42201-5355492-7. v. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC#42000-0568372-5. v. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC#42201-6464247-3. vi. Jawed Yunus Tabba S/o Muhammad Yunus CNIC#42201-2111104-7. ii. Amina Abdul Aziz Bawany w/o Abdul Aziz Bawany CNIC#42000-3004991-0. ii. Adnan Afridi S/o Iqbal Afridi CNIC#42301-3039230-3.

Case No. 8. **CHANGE OF MANAGEMENT OF M/S PAKISTAN PHARMACEUTICAL PRODUCTS (PVT) LTD., D-122 SITE KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000091 BY WAY OF (FORMULATION).**

M/s Pakistan Pharmaceutical Products (Pvt) Ltd., D-122 SITE Karachi, Drug Manufacturing License No.000091 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under:-

Previous Management as per Form-29	New Management as per Form-29.
1. Mr. Owais Ahmed Allahwala S/o. Nasir Ahmed Allahwala CNIC No. 42201-9237873-7. 2. Mr. Nasir Ahmed Allahwala S/o Noor Ahmed Allahwala CNIC No. 42201-6814153-3.	1. Mr. Muhammad Qaiser Musani S/o Yusuf Musani CNIC No.42101-7627309-3. 2. Mr. Masood Kabir S/o Kabir Uddin CNIC No.42401-1908483-9.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Pakistan Pharmaceutical Products (Pvt) Ltd., D-122 SITE Karachi, Drug Manufacturing License No.000091 by way of formulation as under:-

Previous Management as per Form-29	New Management as per Form-29.
1. Mr. Owais Ahmed Allahwala S/o. Nasir Ahmed Allahwala CNIC No. 42201-9237873-7. 2. Mr. Nasir Ahmed Allahwala S/o Noor Ahmed Allahwala CNIC No. 42201-6814153-3.	1. Mr. Muhammad Qaiser Musani S/o Yusuf Musani CNIC No.42101-7627309-3. 2. Mr. Masood Kabir S/o Kabir Uddin CNIC No.42401-1908483-9.

Case No. 9. <u>CHANGE OF MANAGEMENT OF M/S ASIAN CONTINENTAL (PVT) LTD., D/32 SITE SUPER HIGHWAY KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000643 BY WAY OF (FORMULATION).</u>

M/s Asian Continental (Pvt) Ltd., D/32, S.I.T.E., Super Highway, Karachi, Drug Manufacturing License No.000643 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under:-

Previous Management as per Form-29.	New Management as per Form-29.
1. Syed Nophil Rizvi S/o Syed Ilias Rizvi, CNIC No.61101-2485512-9. 2. Syed Ilias Rizvi S/o Syed Tufail Ahmed Rizvi, CNIC No.61101-0224893-5. 3. Mrs. Talat Rizvi W/o Syed Ilias Rizvi, CNIC No. 61101-1274091-4. 4. Mrs. Umama Rizvi Walana W/o Muhammad Faisal Amir Walana CNIC No.61101-1824396-2. 5. Mrs. Maliha Rizvi W/o Ozair Faisal Anis NIC No.611018-704201-8.	1. Syed Nophil Rizvi S/o Syed Ilias Rizvi, CNIC No.61101-2485512-9. 2. Mrs. Ayesha Rizvi W/o Syed Nophil Rizvi, CNIC No.42000-7844632-2. 3. Mrs. Talat Rizvi W/o Syed Ilias Rizvi, CNIC No. 61101-1274091-4. 4. Mrs. Umama Rizvi Walana W/o Muhammad Faisal Amir Walana CNIC No.61101-1824396-2. 5. Mrs. Maliha Rizvi W/o Ozair Faisal Anis NIC No.611018-704201-8.

<u>Decision of the Central Licensing Board in 292nd meeting</u>

The Board considered and accepted for record the change of management of M/s Asian Continental (Pvt) Ltd., D/32, S.I.T.E., Super Highway, Karachi, Drug Manufacturing License No.000643 by way of formulation as under:

Previous Management as per Form-29.	New Management as per Form-29.
1. Syed Nophil Rizvi S/o Syed Ilias Rizvi, CNIC No.61101-2485512-9. 2. Syed Ilias Rizvi S/o Syed Tufail Ahmed Rizvi, CNIC No.61101-0224893-5. 3. Mrs. Talat Rizvi W/o Syed Ilias Rizvi, CNIC No. 61101-1274091-4.	1. Syed Nophil Rizvi S/o Syed Ilias Rizvi, CNIC No.61101-2485512-9. 2. Mrs. Ayesha Rizvi W/o Syed Nophil Rizvi, CNIC No.42000-7844632-2. 3. Mrs. Talat Rizvi W/o Syed Ilias Rizvi, CNIC No. 61101-1274091-4.

4. Mrs. Umama Rizvi Walana W/o Muhammad Faisal Amir Walana CNIC No.61101-1824396-2. 5. Mrs. Maliha Rizvi W/o Ozair Faisal Anis NIC No.611018-704201-8.	4. Mrs. Umama Rizvi Walana W/o Muhammad Faisal Amir Walana CNIC No.61101-1824396-2. 5. Mrs. Maliha Rizvi W/o Ozair Faisal Anis NIC No.611018-704201-8.

Case No. 10. CHANGE OF MANAGEMENT OF M/S MARTIN DOW LTD., PLOT NO. 37 SECTOR 19 KORANGI INDUSTRIAL AREA KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000267 BY WAY OF (FORMULATION).

M/s Martin Dow Ltd., Plot No. 37 Sector 19 Korangi Industrial Area Karachi, Drug Manufacturing License No.000267 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under:

Previous Management as per Form-29	New Management as per Form-29
1. Mr. Ali Akhai S/o Muhammad Jawed Akhai CNIC No.42000-3326827-5. 2. Mr. Muqtadir M. A. Jawad S/o Shafiq Ahmed CNIC No.42201-5392112-5. 3. Mr. Syed Dawood S/o Syed Fasih Uddin Ahmed, LB-9262870. 4. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad CNIC No. 42201-0556944-9.	1. Mr. Ali Akhai S/o Muhammad Jawed Akhai CNIC No.42000-3326827-5. 2. Mr. Abdul Samad S/o Haroon CNIC No.42301-5079532-3. 3. Mr. Syed Dawood S/o Syed Fasih Uddin Ahmed, LB-9262870. 4. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad CNIC No. 42201-0556944-9.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Martin Dow Ltd., Plot No. 37 Sector 19 Korangi Industrial Area Karachi, Drug Manufacturing License No.000267 by way of formulation as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:-

Previous Management as per Form-29	New Management as per Form-29
5. Mr. Ali Akhai S/o Muhammad Jawed Akhai CNIC No.42000-3326827-5. 6. Mr. Muqtadir M. A. Jawad S/o Shafiq Ahmed CNIC No.42201-5392112-5. 7. Mr. Syed Dawood S/o Syed Fasih Uddin Ahmed, LB-9262870. 8. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad CNIC No. 42201-0556944-9.	5. Mr. Ali Akhai S/o Muhammad Jawed Akhai CNIC No.42000-3326827-5. 6. Mr. Abdul Samad S/o Haroon CNIC No.42301-5079532-3. 7. Mr. Syed Dawood S/o Syed Fasih Uddin Ahmed, LB-9262870. 8. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad CNIC No. 42201-0556944-9.

Case No. 11. CHANGE OF MANAGEMENT OF M/S PFIZER PAKISTAN LTD., B-2-SITE KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000025 BY WAY OF (FORMULATION).

M/s Pfizer Pakistan Ltd., B-2-SITE Karachi, Drug Manufacturing License No.000025 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under:-

Previous Management as per Form-29	New Management as per Form-29
1. Mr. S.M. Wajeehuddin S/o Muhammad Fasihuddin CNIC No.42201-4564592-3. 2. Mr. Tafazull Khan S/o Habibullah CNIC No.42201-878585-1. 3. Mr. Rashid Mohammad Khan S/o FaiyazKhan CNIC No.42401-9462658-5.	1. Mr. S.M. Wajeehuddin S/o Muhammad Fasihuddin CNIC No.42201-4564592-3. 2. Mr. Tafazull Khan S/o Habibullah CNIC No.42201-878585-1. 3. Mr. Fida Hussain S/o Nazir Hussain Awan CNIC No.42201-7476012-5.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Pfizer Pakistan Ltd., B-2-SITE Karachi, Drug Manufacturing License No.000025 by way of formulation as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:

Previous Management as per Form-29	New Management as per Form-29
1. Mr. S.M. Wajeehuddin S/o Muhammad Fasihuddin CNIC No.42201-4564592-3. 2. Mr. Tafazull Khan S/o Habibullah CNIC No.42201-878585-1. 3. Mr. Rashid Mohammad Khan S/o Faiyaz Khan CNIC No.42401-9462658-5.	1. Mr. S.M. Wajeehuddin S/o Muhammad Fasihuddin CNIC No.42201-4564592-3. 2. Mr. Tafazull Khan S/o Habibullah CNIC No.42201-878585-1. 3. Mr. Fida Hussain S/o Nazir Hussain Awan CNIC No.42201-7476012-5.

CASE NO. 12. CHANGE IN MANAGEMENT OF M/S SANOFI-AVENTIS PAKISTAN LTD. PLOT NO. 23 SECTOR 22 KORANGI INDUSTRIAL AREA KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000007 BY WAY OF (FORMULATION).

M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23 Sector 22 Korangi Industrial Area Karachi, Drug Manufacturing License No.000007 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under:-

Previous Management as per Form-29 of SECP	New Management as per Form-29 of SECP
1. Mr. Rehmatullah Khan S/o Bangay Khan CNIC No.42301-6301459-3 2. Mr. Shahid Zaki S/o Sheikh Muhammad Zaki CNIC No.42301-0952120-9 3. Mr. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 4. Mr. Hermes Martet Passport No.13BP46775 5. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3.	1. Mr. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 2. Mr. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1. 3. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3. 4. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3

6. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3 7. Mr. Marc Antoine Lucchini 8. Mr. Yasser Pir Muhammad S/o Pir Muhammad Suleman CNIC No.42201-9620109-1 9. Mr. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1. 10. Ms. Naira Adamyan Passport No.75 9183818 11. Mr. Asim Jamal S/o Sharafat Ali CNIC No.42301-9423760-7	5. Mr. Muhammad Salman Burney S/o Ashfaq Azim Burney CNIC No. 42301-0193986-7 6. Mr. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No. 42301-4602118-1 7. Mr. Sajjad Iftikhar S/o Qazi Iftikhar un Nabi CNIC No. 35202-9162960-1 8. Ms. Saadia Naveed W/o Naveed Ahmed Khan CNIC No. 42301-2690950-6

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23 Sector 22 Korangi Industrial Area Karachi, Drug Manufacturing License No.000007 by way of formulation as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020: -

Previous Management as per Form-29 of SECP dated: 15-06-2023	Previous Management as per Form-29 of SECP dated 19-07-2023	New Management as per Form-29 of SECP dated 14-09-2023
1. Mr. Shahid Zaki S/o Sheikh Muhammad Zaki CNIC No.42301-0952120-9 2. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 3. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No.42301-5510501-3 4. Mr. Imtiaz Ahmed Husain Laliwala S/o Hussain Ahmed Laliwala CNIC No.42201-5114451-3 5. Mr. Yasser Pir Muhammad S/o Pir Muhammad Suleman CNIC No.42201-9620109-1 6. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1.	1. Mr. Asim Jamal S/o Sharafat Ali CNIC No.42301-9423760-7 2. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No.42301-5510501-3 3. Mr. Imtiaz Ahmed Husain Laliwala S/o Hussain Ahmed Laliwala CNIC No.42201-5114451-3 4. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 5. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1. 6. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No. 42301-4602118-1	1. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 2. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1. 3. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3. 4. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3 5. Mr. Muhammad Salman Burney S/o Ashfaq Azim Burney CNIC No. 42301-0193986-7 6. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No. 42301-4602118-1 7. Mr. Sajjad Iftikhar S/o Qazi Iftikhar un Nabi

7. Mr. Asim Jamal S/o Sharafat Ali CNIC No.42301-9423760-7 8. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No. 42301-4602118-1 9. Mr. Sajjad Iftikhar S/o Qazi Iftikhar un Nabi CNIC No. 35202-9162960-1 10. Ms. Iqra Sajjad W/o Ibrahim Ahmed Zahidie CNIC No.42101-8078335-4	7. Mr. Sajjad Iftikhar S/o Qazi Iftikhar un Nabi CNIC No. 35202-9162960-1 8. Ms. Saadia Naveed W/o Naveed Ahmed Khan CNIC No. 42301-2690950-6 9. Mr. Muhammad Salman Burney S/o Ashfaq Azim Burney CNIC No. 42301-0193986-7	CNIC No. 35202-9162960-1 8. Ms. Saadia Naveed W/o Naveed Ahmed Khan CNIC No. 42301-2690950-6

Case No. 13. **CHANGE OF MANAGEMENT OF M/S SANOFI-AVENTIS PAKISTAN LTD. PLOT NO. 23 SECTOR 22 KORANGI INDUSTRIAL AREA KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000368 BY WAY OF (FORMULATION).**

M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23 Sector 22 Korangi Industrial Area Karachi, Drug Manufacturing License No.000368 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under:-

Previous Management as per Form-29 of SECP	New Management as per Form-29 of SECP
1. Mr. Rehmatullah Khan S/o Bangay Khan CNIC No.42301-6301459-3 2. Mr. Shahid Zaki S/o Sheikh Muhammad Zaki CNIC No.42301-0952120-9 3. Mr. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 4. Mr. Hermes Martet Passport No.13BP46775 5. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3. 6. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3 7. Mr. Marc Antoine Lucchini 8. Mr. Yasser Pir Muhammad S/o Pir Muhammad Suleman CNIC No.42201-9620109-1 9. Mr. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1. 10. Ms. Naira Adamyan Passport No.75 9183818	1. Mr. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 2. Mr. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1. 3. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3. 4. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3 5. Mr. Muhammad Salman Burney S/o Ashfaq Azim Burney CNIC No. 42301-0193986-7 6. Mr. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No. 42301-4602118-1 7. Mr. Sajjad Iftikhar S/o Qazi Iftikhar un Nabi CNIC No. 35202-9162960-1 8. Ms. Saadia Naveed W/o Naveed Ahmed Khan CNIC No. 42301-2690950-6

11. Mr. Asim Jamal S/o Sharafat Ali CNIC No.42301-9423760-7	

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23 Sector 22 Korangi Industrial Area Karachi, Drug Manufacturing License No.000368 by way of formulation as under 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:-

Previous Management as per Form-29 of SECP dated: 15-06-2023	Previous Management as per Form-29 of SECP dated 19-07-2023	New Management as per Form-29 of SECP dated 14-09-2023
1. Mr. Shahid Zaki S/o Sheikh Muhammad Zaki CNIC No.42301-0952120-9 2. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 3. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No.42301-5510501-3 4. Mr. Imtiaz Ahmed Husain Laliwala S/o Hussain Ahmed Laliwala CNIC No.42201-5114451-3 5. Mr. Yasser Pir Muhammad S/o Pir Muhammad Suleman CNIC No.42201-9620109-1 6. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1. 7. Mr. Asim Jamal S/o Sharafat Ali CNIC No.42301-9423760-7 8. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No. 42301-4602118-1 9. Mr. Sajjad Iftikhar S/o Qazi Iftikhar un Nabi CNIC No. 35202-9162960-1 10. Ms. Iqra Sajjad W/o Ibrahim Ahmed Zahidie	1. Mr. Asim Jamal S/o Sharafat Ali CNIC No.42301-9423760-7 2. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No.42301-5510501-3 3. Mr. Imtiaz Ahmed Husain Laliwala S/o Hussain Ahmed Laliwala CNIC No.42201-5114451-3 4. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 5. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1. 6. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No. 42301-4602118-1 7. Mr. Sajjad Iftikhar S/o Qazi Iftikhar un Nabi CNIC No. 35202-9162960-1 8. Ms. Saadia Naveed W/o Naveed Ahmed Khan CNIC No. 42301-2690950-6 9. Mr. Muhammad Salman Burney S/o Ashfaq Azim Burney	1. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9. 2. Syed Hyder Ali S/o Syed Babar Ali CNIC No. 35201-1655225-1. 3. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3. 4. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3 5. Mr. Muhammad Salman Burney S/o Ashfaq Azim Burney CNIC No. 42301-0193986-7 6. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No. 42301-4602118-1 7. Mr. Sajjad Iftikhar S/o Qazi Iftikhar un Nabi CNIC No. 35202-9162960-1 8. Ms. Saadia Naveed W/o Naveed Ahmed Khan CNIC No. 42301-2690950-6

CNIC No.42101-8078335-4	CNIC No. 42301-0193986-7	

Case No. 14. **CHANGE OF MANAGEMENT OF M/S SAFE PHARMACEUTICALS (PVT) LTD., PLOT NO.C-120, SECTOR 6-B, NORTH KARACHI INDUSTRIAL AREA, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000368 BY WAY OF (FORMULATION).**

M/s Safe Pharmaceuticals (Pvt) Ltd., Plot No.C-120, Sector 6-B, North Karachi Industrial Area, Karachi, Drug Manufacturing License No.000349 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under:-

Previous Management as per Form-29 of SECP	New Management as per Form-29 of SECP
1. Mr. Muhammad Farooq Memon CNIC No. 42201-0622163-1 2. Mr. Muhammad Saleem Memon CNIC No. 42000-0524844-3	1. Mr. Muhammad Ali Chandna S/o Ghulam AhmedChandna CNIC No. 42201-4467225-9. 2. Mr. Muhammad Saad S/o Muhammad Naseem CNIC No. 42000-5375650-3.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Safe Pharmaceuticals (Pvt) Ltd., Plot No.C-120, Sector 6-B, North Karachi Industrial Area, Karachi, Drug Manufacturing License No.000349 by way of formulation as under:-

Previous Management as per Form-29 of SECP	New Management as per Form-29 of SECP
1. Mr. Muhammad Farooq Memon CNIC No. 42201-0622163-1 2. Mr. Muhammad Saleem Memon CNIC No. 42000-0524844-3	1. Mr. Muhammad Ali Chandna S/o Ghulam AhmedChandna CNIC No. 42201-4467225-9. 2. Mr. Muhammad Saad S/o Muhammad Naseem CNIC No. 42000-5375650-3.

Case No. 15 **CHANGE OF TITLE & MANAGEMENT OF M/S BAYER PAKISTAN (PVT) LTD, 108- QUAID E AZAM INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE UNDER DML NO 000243 (BY WAY OF FORMULATION)**

M/s Bayer Pakistan (Pvt) Ltd, 108-Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore submitted the documents for change in management & title. The firm has deposited fee of Rs.150,000/- for change of title & management. Detail of the documents is as under;

1. Asset Purchase Agreement by and among Bayer Pakistan (Pvt) Limited and OBS Pharma (Pvt) Ltd.
2. Sale deed
3. Certificate of incorporation
4. Form-II, Form-29 & Form 21 of OBS Pharma (Pvt) Ltd signed and stamped by SECP.

5. Memorandum & Articles of Association of OBS Pharma (Pvt) Ltd.
6. Attested copies of CNICs
7. No Objection Certificate for change of Management
8. Nothing Due Certificate
9. Undertaking on stamp Paper for change of management.

i. <u>Change of Title.</u>

Previous Title	New Title
M/s Bayer Pakistan (Pvt) Ltd, 108- Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore.	**M/s OBS Pharma (Pvt) Ltd,** 108- Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore.

ii. <u>Change of Management.</u>

Previous Management as per Form-A	New Management as per Form-29
i. Imran Ahmad Khan S/o Anwar Ahmad Khan CNIC#35202-0840996-1. ii. Muhammad Shafiq S/o Muhammad Rafiq Moti CNIC#42301-5878799-9.	i. Shahzad Khan S/o Shahbaz Ahmed Khan CNIC#35202-3335871-1. ii. Adeela Tariq Khan w/o Tariq Moin Uddin Khan CNIC#42301-0683642-2. iii. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb CNIC#35502-2435463-3. **iv.** Abdul Qadeer S/o Abdul Samad CNIC#42101-1665207-1. v. Bosco Firmin Dominic Sales S/o Joseph Jerome Sales CNIC#42301-9560930-5. vi. Tariq Moinuddin Khan S/o K A Moinuddin Khan CNIC#42301-07525070-1. vii. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC#42301-9154917-3.

<u>Decision of the Central Licensing Board in 292nd meeting</u>

The Board considered and accepted for record the change of title of M/s OBS Pharma (Pvt) Ltd, 108-Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore [*Formerly* M/s Bayer Pakistan (Pvt) Ltd] DML No.000243 (By way of Formulation) as under;

Previous Title	New Title
M/s Bayer Pakistan (Pvt) Ltd, 108- Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore.	**M/s OBS Pharma (Pvt) Ltd,** 108- Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore.

The Board considered and accepted for record the change of management of M/s OBS Pharma (Pvt) Ltd,, 108-Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore [*Formerly* M/s Bayer Pakistan (Pvt) Ltd] DML No.000243 (By way of Formulation) as under**;**

Previous Management as per Form-A	New Management as per Form-29
i. Imran Ahmad Khan S/o Anwar Ahmad Khan CNIC#35202-0840996-1. ii. Muhammad Shafiq S/o Muhammad Rafiq Moti CNIC#42301-5878799-9.	1. Shahzad Khan S/o Shahbaz Ahmed Khan CNIC#35202-3335871-1. 2. Adeela Tariq Khan w/o Tariq Moin Uddin Khan CNIC#42301-0683642-2. 3. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb CNIC#35502-2435463-3. 4. Abdul Qadeer S/o Abdul Samad CNIC#42101-1665207-1. 5. Bosco Firmin Dominic Sales S/o Joseph Jerome Sales CNIC#42301-9560930-5. 6. Tariq Moinuddin Khan S/o K A Moinuddin Khan CNIC#42301-07525070-1. 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC#42301-9154917-3.

Case No.16 **CHANGE OF MANAGEMENT OF M/S HONIG PHARMACEUTICAL LABORATORIES, 14-KM ADYALA ROAD, RAWALPINDI UNDER DML NO 000550 (BY WAY OF FORMULATION)**

M/s Honig Pharmaceutical Laboratories, 14-Km Adyala Road, Rawalpindi submitted the documents for change in management. The firm has deposited fee of Rs.75,000/- for change of management. Detail of management and submitted documents is as under;

i. Amended partnership Deed
ii. Undertaking on stamp paper for change of management
iii. Form D & Form C from Registrar office.
iv. Attested copies of CNICs
v. No objection Certificate from previous management.
vi. Nothing Due Certificate

Previous Management as per Partnership Deed	New Management as per Amended Partnership Deed

i. Iftikhar Ahmed S/o Imtiaz Ahmed CNIC# 37405-6039992-3. ii. Muhammad Faisal Latif S/o Ch. Abdul Latif CNIC# 37405-5664181-3.	i. Iftikhar Ahmed S/o Imtiaz Ahmed CNIC# 37405-6039992-3. ii. Mr. Tariq Masood Ch. S/o Muhammad Yousaf CNIC# 37405-8993989-7.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Honig Pharmaceutical Laboratories, 14-Km Adyala Road, Rawalpindi 000550 (by way of formulation) as under;

Previous Management as per Partnership Deed	New Management as per Amended Partnership Deed
i. Iftikhar Ahmed S/o Imtiaz Ahmed CNIC# 37405-6039992-3. ii. Muhammad Faisal Latif S/o Ch. Abdul Latif CNIC# 37405-5664181-3.	i. Iftikhar Ahmed S/o Imtiaz Ahmed CNIC# 37405-6039992-3. ii. Mr. Tariq Masood Ch. S/o Muhammad Yousaf CNIC# 37405-8993989-7.

Case No. 17 CHANGE OF MANAGEMENT OF M/S LUCKY CORE (Frmerly M/s. ICI) INDUSTRIES LIMITED, 45-KM OFF MULTAN ROAD, LAHORE UNDER DML NO 000881 (BY WAY OF FORMULATION)

M/s Lucky Core Industries Limited, 45-Km Off Multan Road, Lahore submitted the documents for change in management. The firm has deposited fee of Rs. 75,000/- for change of management. Detail of management is as under;

i. Form 29 signed and stamped by SECP
ii. Nothing Due Certificate
iii. Attested copies of CNICs
iv. Letter of Change of tittle issued by CLB

Previous Management	Retiring Management	New Management as per Form-29
i. Asif Jooma S/o Omar Valli Jooma CNIC# 42301-3175078-7. ii. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tahawur Zaidi CNIC#42301-1740521-7. iii. Muhammad Abid Ganatra S/o Moosa	i. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC#42301-8986425-7.	i. Asif Jooma S/o Omar Valli Jooma CNIC# 42301-3175078-7. ii. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tahawur Zaidi CNIC#42301-1740521-7. iii. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC#42201-5355492-7.

Ganatra CNIC#42201-5355492-7. iv. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC#42000-0568372-5. v. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC#42201-6464247-3. vi. Jawed Yunus Tabba S/o Muhammad Yunus CNIC#42201-2111104-7. vii. Amina Abdul Aziz Bawany w/o Abdul Aziz Bawany CNIC#42000-3004991-0. viii. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC#42301-8986425-7.		iv. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC#42000-0568372-5. v. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC#42201-6464247-3. vi. Jawed Yunus Tabba S/o Muhammad Yunus CNIC#42201-2111104-7. vii. Amina Abdul Aziz Bawany w/o Abdul Aziz Bawany CNIC#42000-3004991-0. viii. Adnan Afridi S/o Iqbal Afridi CNIC#42301-3039230-3.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Lucky Core (Frmerly M/s. ICI) Industries Limited, 45-Km Off Multan Road, Lahore DML No. 000881(by way of formulation) as under;

Previous Management	Retiring Management	New Management as per Form-29
i. Asif Jooma S/o Omar Valli Jooma CNIC# 42301-3175078-7. ii. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tahawur Zaidi CNIC#42301-1740521-7. iii. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC#42201-5355492-7. iv. Muhammad Sohail Tabba S/o Muhammad	i. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC#42301-8986425-7.	i. Asif Jooma S/o Omar Valli Jooma CNIC# 42301-3175078-7. ii. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tahawur Zaidi CNIC#42301-1740521-7. iii. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC#42201-5355492-7. iv. Muhammad Sohail Tabba S/o Muhammad Yunus

Yunus Tabba CNIC#42000-0568372-5. v. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC#42201-6464247-3. vi. Jawed Yunus Tabba S/o Muhammad Yunus CNIC#42201-2111104-7. vii. Amina Abdul Aziz Bawany w/o Abdul Aziz Bawany CNIC#42000-3004991-0. viii. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC#42301-8986425-7.		Tabba CNIC#42000-0568372-5. v. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC#42201-6464247-3. vi. Jawed Yunus Tabba S/o Muhammad Yunus CNIC#42201-2111104-7. vii. Amina Abdul Aziz Bawany w/o Abdul Aziz Bawany CNIC#42000-3004991-0. viii. Adnan Afridi S/o Iqbal Afridi CNIC#42301-3039230-3.

Case No. 18. <u>CHANGE OF MANAGEMENT OF M/S UNIMARK PHARMACEUTICALS (PVT) LTD. PLOT NO. 7-A, STREET NO. S-7, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD. UNDER DRUG MANUFACTURING LICENSE NO. 000557 BY WAY OF (FORMULATION)</u>

M/s Unimark Pharmaceuticals (Pvt) ltd. Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, DML No.000557 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 as per form 29	New management as per form 29
1. Talat Munir Baig S/o Sadiq Hussain Baig, CNIC No. 37405-1017139-3 2. Ms. Zarqa W/o Riaz Ahmed, CNIC No. 16202-5656628-0	1. Muhammad Qasim S/o Munir Hussain Qureshi, CNIC No. 37405-0287918-5 2. Pir Kifayat Ur Rehman S/o Pir Karim Ur Rehman, CNIC No. 17102-1178727-5 3. Syed Muhammad Ahmed Pasha, S/o Muhammad Younis Gillani CNIC No. 61101-6509197-3 4. Syed Munir-Ud-Din S/o Syed Zain Ul Abidin, CNIC No. 61101-1986111-9

<u>Decision of the Central Licensing Board in 292nd meeting</u>

The Board considered and accepted for record the change of management of M/s Unimark Pharmaceuticals (Pvt) Ltd. Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, DML No.000557 by way of formulation as under:

Existing management as per form 29	New management as per form 29

1. Talat Munir Baig S/o Sadiq Hussain Baig, CNIC No. 37405-1017139-3 2. Ms. Zarqa W/o Riaz Ahmed, CNIC No. 16202-5656628-0	1. Muhammad Qasim S/o Munir Hussain Qureshi, CNIC No. 37405-0287918-5 2. Pir Kifayat Ur Rehman S/o Pir Karim Ur Rehman, CNIC No. 17102-1178727-5 3. Syed Muhammad Ahmed Pasha, S/o Muhammad Younis Gillani CNIC No. 61101-6509197-3 4. Syed Munir-Ud-Din S/o Syed Zain Ul Abidin, CNIC No. 61101-1986111-9

Case No. 19. <u>CHANGE OF MANAGEMENT OF M/S P.D.H. LABORATORIES (PVT) LTD, 9.5-KM, SHIEKHUPURA ROAD, LAHORE. UNDER DRUG MANUFACTURING LICENSE NO. 000039 BY WAY OF (FORMULATION).</u>

M/s P.D.H. Laboratories (Pvt) Ltd, 9.5-Km, Sheikhupura road, Lahore. Under drug manufacturing license no. 000039 by way of (Formulation) has submitted request for change in management of the firm as per SECP Form-29 with prescribed fee. The detail of management of the firm is as under:-

Existing management as per Form-29	New management as per Form-29
1. Mr. Sajid Ullah Ghumman S/o Chaudhry Sanaullah Ghumman Qadri CNIC No. 34601-8991701-1 2. Ms. Zaineb Aleem Khan D/o Abdul Aleem Khan CNIC No. 35201-6656509-0 3. Mr. Abdur Rehman Khan S/o Abdul Aleem Khan CNIC No. 35201-7643531-3 4. Abdur Rafay Khan S/o Abdul Aleem Khan CNIC No. 35201-7548436-3 5. Mr. Abdul Khabir S/o Salim Ud Din Akhtar CNIC No. 35202-9376166-3	1. Dr. Shahzad Zaheer Qureshi S/o Zaheer ud Din Qureshi CNIC No. 35202-2959896-7 2. Ms. Zaineb Ali Khan D/o Abdul Aleem Khan CNIC No. 35201-6656509-0 3. Mr. Abdur Rehman Khan S/o Abdul Aleem Khan CNIC No. 35201-7643531-3 4. Abdur Rafay Khan S/o Abdul Aleem Khan CNIC No. 35201-7548436-3 5. Mr. Atif Iftikhar S/o Muhammad Iftikhar CNIC No. 35202-5848206-5

<u>Decision of the Central Licensing Board in 292nd meeting</u>

The Board considered and accepted for record the change of management of M/s P.D.H. Laboratories (Pvt) Ltd, 9.5-Km, Sheikhupura road, Lahore. Under drug manufacturing license no. 000039 by way of (Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:

Existing management as per Form-29	New management as per Form-29
1. Mr. Sajid Ullah Ghumman S/o Chaudhry Sanaullah Ghumman Qadri CNIC No. 34601-8991701-1	1. Dr. Shahzad Zaheer Qureshi S/o Zaheer ud Din Qureshi CNIC No. 35202-2959896-7 2. Ms. Zaineb Ali Khan D/o Abdul Aleem Khan CNIC No. 35201-6656509-0

2. Ms. Zaineb Aleem Khan D/o Abdul Aleem Khan CNIC No. 35201-6656509-0 3. Mr. Abdur Rehman Khan S/o Abdul Aleem Khan CNIC No. 35201-7643531-3 4. Abdur Rafay Khan S/o Abdul Aleem Khan CNIC No. 35201-7548436-3 5. Mr. Abdul Khabir S/o Salim Ud Din Akhtar CNIC No. 35202-9376166-3	3. Mr. Abdur Rehman Khan S/o Abdul Aleem Khan CNIC No. 35201-7643531-3 4. Abdur Rafay Khan S/o Abdul Aleem Khan CNIC No. 35201-7548436-3 5. Mr. Atif Iftikhar S/o Muhammad Iftikhar CNIC No. 35202-5848206-5

Case No. 20. <u>CHANGE OF MANAGEMENT OF M/S SCHAZOO ZAKA (PVT) LTD, 20-KM, LAHORE-JARANWALA ROAD, DISTRICT SHEIKHUPURA. UNDER DRUG MANUFACTURING LICENSE NO. 000636 BY WAY OF (FORMULATION).</u>

M/s Schazoo Zaka (Pvt) Ltd, 20-Km, Lahore-Jaranwala road, district Sheikhupura. Under drug manufacturing license no. 000636 by way of (formulation) have 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. Mian Muhammad Zaka-ur-Rehman S/o Mian Zaka-ur-Rehman, CNIC No. 35202-7072045-5 2. Begum Almas Zaka-ur-Rehman W/o Mian Zaka-ur-Rehman, CNIC No. 35202-8700873-8 3. Mian Ahmed Zaka-ur-Rehman S/o Mian Zaka-ur-Rehman, CNIC No. 35202-4360735-9 4. Ms. Aasia Saail Khan W/o Saail Ahmed Khan, CNIC No. 35202-2849644-8 5. Ms. Zeba Ahmed Shuja W/o Mian Ahmed Shuja-ur-Rehman, CNIC No. 35202-6923636-0 6. Ms. Sumaira Shahzad W/o Shahzad Akbar, CNIC No. 35201-1456826-0	1. Begum Almas Zaka-ur-Rehman W/o Mian Zaka-ur-Rehman, CNIC No. 35202-8700873-8 2. Mian Ahmed Zaka-ur-Rehman S/o Mian Zaka-ur-Rehman, CNIC No. 35202-4360735-9 3. Ms. Aasia Saail Khan W/o Saail Ahmed Khan, CNIC No. 35202-2849644-8 4. Ms. Zeba Ahmed Shuja W/o Mian Ahmed Shuja-ur-Rehman, CNIC No. 35202-6923636-0 5. Ms. Sumaira Shahzad W/o Shahzad Akbar, CNIC No. 35201-1456826-0

<u>Decision of the Central Licensing Board in 292nd meeting</u>

The Board considered and accepted for record the change of management of M/s Schazoo Zaka (Pvt) Ltd, 20-Km, Lahore-Jaranwala road, district Sheikhupura. Under drug manufacturing license no. 000636 by way of (formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:-

Existing management	New management
1. Mian Muhammad Zaka-ur-Rehman S/o Mian Zaka-ur-Rehman, CNIC No. 35202-7072045-5 2. Begum Almas Zaka-ur-Rehman W/o Mian Zaka-ur-Rehman, CNIC No. 35202-8700873-8 3. Mian Ahmed Zaka-ur-Rehman S/o Mian Zaka-ur-Rehman, CNIC No. 35202-4360735-9 4. Ms. Aasia Saail Khan W/o Saail Ahmed Khan, CNIC No. 35202-2849644-8 5. Ms. Zeba Ahmed Shuja W/o Mian Ahmed Shuja-ur-Rehman, CNIC No. 35202-6923636-0 6. Ms. Sumaira Shahzad W/o Shahzad Akbar, CNIC No. 35201-1456826-0	1. Begum Almas Zaka-ur-Rehman W/o Mian Zaka-ur-Rehman, CNIC No. 35202-8700873-8 2. Mian Ahmed Zaka-ur-Rehman S/o Mian Zaka-ur-Rehman, CNIC No. 35202-4360735-9 3. Ms. Aasia Saail Khan W/o Saail Ahmed Khan, CNIC No. 35202-2849644-8 4. Ms. Zeba Ahmed Shuja W/o Mian Ahmed Shuja-ur-Rehman, CNIC No. 35202-6923636-0 5. Ms. Sumaira Shahzad W/o Shahzad Akbar, CNIC No. 35201-1456826-0

Case No. 21. **CHANGE OF MANAGEMENT OF M/S SKIMS HARMACEUTICALS.10-B, VALUE ADDITION CITY, KHURRIANWALA, FAISALABAD UNDER DRUG MANUFACTURING LICENSE NO. 000175 BY WAY OF (FORMULATION).**

M/S Skims Pharmaceuticals 10-B, Value Addition City, Khurrianwala, Faisalabad. Under drug manufacturing license no. 000175 by way of (formulation) has submitted request for change in management of the firm with prescribed fee. The detail of management of the firm is as under: -

Management as per partenership deed dated 10 Sep 2013	Management as per partenership deed dated 15 Oct 2016	Management as per partenership deed dated 5 Aug 2022	New Management as per partenership deed dated 8 June 2023
I	II	III	IV
1. Kamran Anwar S/o Muhammad Anwar 2. Muhammad Rizawan S/o Abdul Majeed 3. Mrs. Samina Khalid W/o Khalid Mahmood	1. Kamran Anwar S/o Muhammad Anwar 2. Mrs. Samina Khalid W/o Khalid Mahmood 3. Muhammad Arif S/o Nazam Din 4. Mr. Usman Majeed S/o Abdul Majeed	1. Mrs. Samina Khalid W/o Khalid Mahmood, CNIC No. 33100-0626702-6 2. Mr. Usman Majeed S/o Abdul Majeed, CNIC No. 33102-0224932-5 3. Mr. Muhammad Mustafa S/o Muhammad Javed, CNIC No. 42201-9928918-3 4. Mr. Muzammil Jawaid S/o Muhammad	1. Mr. Muhammad Mustafa S/o Muhammad Javed, CNIC No. 42201-9928918-3 2. Mr. Muzammil Jawaid S/o Muhammad Jawaid, CNIC No. 42201-7413674-1 3. Mr. Muhammad Mehroze Daroowala S/o Abdul Razzaque Daroowala, CNIC No.

		Jawaid, CNIC No. 42201-7413674-1 5. Mr. Muhammad Mehroze Daroowala S/o Abdul Razzaque Daroowala, CNIC No. 42201-6441172-7	42201-6441172-7

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/S Skims Pharmaceuticals.10-B, Value Addition City, Khurrianwala, Faisalabad as per period mention in below table under drug manufacturing license no. 000175 by way of (formulation) as under: -

Management as per partenership deed dated 10 Sep 2013	Management as per partenership deed dated 15 Oct 2016	Management as per partenership deed dated 5 Aug 2022	New Management as per partenership deed dated 8 June 2023
I	II	III	IV
1. Kamran Anwar S/o Muhammad Anwar 2. Muhammad Rizawan S/o Abdul Majeed 3. Mrs. Samina Khalid W/o Khalid Mahmood	1. Kamran Anwar S/o Muhammad Anwar 2. Mrs. Samina Khalid W/o Khalid Mahmood 3. Muhammad Arif S/o Nazam Din 4. Mr. Usman Majeed S/o Abdul Majeed	1. Mrs. Samina Khalid W/o Khalid Mahmood, CNIC No. 33100-0626702-6 2. Mr. Usman Majeed S/o Abdul Majeed, CNIC No. 33102-0224932-5 3. Mr. Muhammad Mustafa S/o Muhammad Javed, CNIC No. 42201-9928918-3 4. Mr. Muzammil Jawaid S/o Muhammad Jawaid, CNIC No. 42201-7413674-1 5. Mr. Muhammad Mehroze Daroowala S/o Abdul Razzaque Daroowala, CNIC No. 42201-6441172-7	1. Mr. Muhammad Mustafa S/o Muhammad Javed, CNIC No. 42201-9928918-3 2. Mr. Muzammil Jawaid S/o Muhammad Jawaid, CNIC No. 42201-7413674-1 3. Mr. Muhammad Mehroze Daroowala S/o Abdul Razzaque Daroowala, CNIC No. 42201-6441172-7

Case No. 22. CHANGE OF MANAGEMENT OF M/S GLOBAL PHARMACEUTICALS (PVT) LTD, PLOT NO. 204-205, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD UNDER DRUG MANUFACTURING LICENSE NO. 000417 BY WAY OF (FORMULATION).

M/s Global Pharmaceuticals (Pvt) Ltd, Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Drug Manufacturing License No.000417 by way of formulation has submitted request for change in management of the firm as per Form-29 with the prescribed fee. The detail of the management of the firm is as under : -

Previous Management as per Form-29	New Management as per Form-29
1. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 2. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 3. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	1. Mr. Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Global Pharmaceuticals (Pvt) Ltd, Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Drug Manufacturing License No.000417 by way of (formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:

Previous Management as per Form-29	New Management as per Form-29
1. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 2. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 3. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	1. Mr. Muhammad Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Case No. 23. CHANGE OF MANAGEMENT OF M/S LUCKY CORE (Frmerly M/s. ICI) INDUSTRIES LIMITED, 32/2A, PHASE-III, INDUSTRIAL ESTATE, HATTAR UNDER DRUG MANUFACTURING LICENSE NO. 000363 BY WAY OF (FORMULATION).

M/s Lucky Core Industries Limited, 32/2A, Phase-III, Industrial Estate, Hattar, Drug Manufacturing License No.000363 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-29.	Retiring Management	New Management as per Form-29.
1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. 3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927. 4. Mr. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC No. 4220164642473. 6. Mr. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No. 4230130392303.	Mr. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No. 4230130392303.	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. 3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927. 4. Mr. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC No. 4220164642473. 6. Mr. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Lucky Core (Frmerly M/s. ICI) Industries Limited, 32/2A, Phase-III, Industrial Estate, Hattar, Drug Manufacturing License No.000363 by way of formulation as under 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: -

Previous Management as per Form-29	Retiring Management	New Management as per Form-29
1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. 3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927.	1. Mr. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No. 4230130392303.	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217.

4. Mr. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC No. 4220164642473. 6. Mr. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No. 4230130392303.		3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927. 4. Mr. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC No. 4220164642473. 6. Mr. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.

Case No. 24. <u>CHANGE OF MANAGEMENT OF M/S SEATLE (PVT) LTD,45-KM, MULTAN ROAD, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000481 BY WAY OF (FORMULATION).</u>

M/S Seatle (Pvt) Ltd,45-Km, Multan Road, Lahore, under drug manufacturing license no. 000481 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 as per Form-29	New management as per Form-29
1. Mr. Muhammad Ali Akhai S/o Muhammad Javed Akhai, CNIC No. 42000-3326827-5 2. Mr. Muqtadir M. Ali Jawad S/o Shafiq Ahmed, CNIC No. 42201-5392112-5 3. Mr. Syed Dawood S/o Syed Fasih Uddin, Passposrt No. LB9262870 4. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad, CNIC No. 42201-0556944-9	1. Mr. Muhammad Ali Akhai S/o Muhammad Javed Akhai, CNIC No. 42000-3326827-5 2. Mr. Abdul Samad S/o Mr. Haroon, CNIC No. 42301-5079532-3 3. Mr. Syed Dawood S/o Syed Fasih Uddin, Passposrt No. LB9262870 4. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad, CNIC No. 42201-0556944-9

<u>Decision of the Central Licensing Board in 292nd meeting</u>

The Board considered and accepted for record the change of management of M/S Seatle (Pvt) Ltd,45-Km, Multan Road, Lahore, under drug manufacturing license no. 000481 by way of

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

Existing management as per Form-29	New management as per Form-29
1. Mr. Muhammad Ali Akhai S/o Muhammad Javed Akhai, CNIC No. 42000-3326827-5 2. Mr. Muqtadir M. Ali Jawad S/o Shafiq Ahmed, CNIC No. 42201-5392112-5 3. Mr. Syed Dawood S/o Syed Fasih Uddin, Passposrt No. LB9262870 4. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad, CNIC No. 42201-0556944-9	1. Mr. Muhammad Ali Akhai S/o Muhammad Javed Akhai, CNIC No. 42000-3326827-5 2. Mr. Abdul Samad S/o Mr. Haroon, CNIC No. 42301-5079532-3 3. Mr. Syed Dawood S/o Syed Fasih Uddin, Passposrt No. LB9262870 4. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad, CNIC No. 42201-0556944-9

Case No. 25. <u>CHANGE OF MANAGEMENT OF M/S CCL PHARMACEUTICALS (PVT) LTD, 62-INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000052 BY WAY OF (FORMULATION)</u>

M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore under drug manufacturing license no. 000052 by way of (formulation). has submitted request for change in management of the firm as per SECP Form-29. The firm has deposited the fee of Rs.75000/- . The detail of management of the firm and documents submitted is as under: -

i. Form 29 signed and stamped by SECP
ii. Form-A
iii. Attested copies of CNICs

Previous Management as per Form-29 (Year-2022)	New Management as per Form-A & Form-29 (Year-2023)
1. Mr. Shahzad Khan S/o Shahbaz Ahmad Khan CNIC No. 35202-3335871-1. 2. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 3. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 4. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 5. Mr. Nadeem B. J. Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3.	1. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 2. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 3. Mr. Nadeem B. J. Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3. 4. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7.

<u>Decision of the Central Licensing Board in 292nd meeting</u>

The Board considered and accepted for record the change of management of M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore under drug manufacturing license No. 000052 by way of (formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020:

Previous Management as per Form-29 (Year-2022)	**New Management as per Form-A & Form-29 (Year-2023)**
1. Mr. Shahzad Khan S/o Shahbaz Ahmad Khan CNIC No. 35202-3335871-1. 2. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 3. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 4. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 5. Mr. Nadeem B. J. Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3.	1. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 2. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 3. Mr. Nadeem B. J. Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3. 4. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7.

Case No. 26. <u>CHANGE OF MANAGEMENT OF M/S VISION PHARMACEUTICALS (PVT) LTD, PLOT NO. 22-23, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD UNDER DRUG MANUFACTURING LICENSE NO. 000517 BY WAY OF (FORMULATION).</u>

M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad (000517) by way of formulation has submitted request for change in management of the firm as per Form-29 with the prescribed fee. The detail of the management of the firm is as under:

Previous Management as per form 29	**Current management as per Form-29**
1. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 2. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 3. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	1. Mr. Muhammad Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

<u>Decision of the Central Licensing Board in 292nd meeting</u>

The Board considered and accepted for record the change of management of M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad (000517) by way of formulation as under:

Previous Management as per form 29	**Current management as per Form-29**
1. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 2. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 3. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	1. Mr. Muhammad Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Case No. 27. <u>CHANGE OF MANAGEMENT OF M/S VISION PHARMACEUTICALS (PVT) LTD, PLOT NO. 22-23, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD UNDER DRUG MANUFACTURING LICENSE NO. 000806 BY WAY OF (SEMI BASIC MANUFACTURING).</u>

M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad (Semi Basic Manufacture 000806) has submitted request for change in management of the firm as per Form-29 with the prescribed fee. The detail of the management of the firm is as under:

Previous Management as per form 29	**Current management as per Form-29**
1. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 2. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 3. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	1. Mr. Muhammad Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

<u>Decision of the Central Licensing Board in 292nd meeting</u>

The Board considered and accepted for record the change of management of M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad (Semi Basic Manufacture 000806) as under:

Previous Management as per form 29	**Current management as per Form-29**

1. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 2. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 3. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	1. Mr. Muhammad Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Case No. 28. **GRANT OF DRUG MANUFACTURING LICENSE TO M/S AIR PHARMACEUTICALS (PVT) LTD, PLOT NO.74-75-A, SMALL INSUTRIAL ESTATE, KASUR.**

1	M/s Air Pharmaceuticals (Pvt) Ltd, Plot No.74-75-A, Small Industrial Estate, Kasur.	16-05-2023	Good	1. Mr. Muhammad Shamoon Chaudhary, Expert Member. 2. Mrs. MajidaMujahid, Additional Director, DRAP, Lahore. 3. Mr. Nafees Ur Rehman, Assistant Director (I&E), DRAP, Lahore.

Recommendations of the panel: -

Based on the areas inspected, technical staff met, discussion held during inspection, the documents reviewed and considering the findings of the inspection, the panel **recommends** the grant of Drug Manufacturing License (By way of formulation) to M/s Air Pharmaceuticals (Pvt) Ltd, Plot No.74-75-A, Small Industrial Estate, Kasur, for Syrup Section (General) only.

It is pertinent to mention here that a notice has been received from Assistant Registrar (Writ), Islamabad High Court, Islamabad that W.P 824/2023 has been filed by Abdul Ghaffar S/o Muhammad Yousaf Vs FOP etc. He pleaded that DRAP may be directed to cancel the approval/license issued in favor of M/s Air Pharmaceuticals (Pvt.) Ltd., Kasur as the proposed pharmaceutical unit is only at the distance of 50feet from the building of waste management Disposal where the waste of hospitals of Punjab is being disposed of and the proposed site is also surrounded by brick kilns, the smoke of which is harmful for human life.
The case was fixed on 17-05-2023in the Islamabad High Court but was not listed.

Decision of the Central Licensing Board in 291st meeting:

The Board considered the facts and deferred the grant of Drug Manufacturing License by way of Formulation in the name of M/s Air Pharmaceuticals (Pvt) Ltd, Plot No.74-

	75-A, Small Industrial Estate, Kasur for taking legal opinion from Mr Abid Ali, member CLB.

Court case has been received from Islamabad High Court, Islamabad W.P.824/2023 Misc. Other (SB). Accordingly, para wise comments have been submitted in the Honorable court. The firm has submitted the reply which is reproduce as under:

Reply of the Firm:

"This is to bring to your kind notice that our Company in the name and style of Air Pharmaceuticals (Pvt.) Ltd had been qualified for the grant of Drug Manufacturing License (DML) after all necessary codal formalities and other requisite procedure was complied with, by us and after our factory inspection was conducted by panel of experts on dated 16-05-2023,Accordingly the panel has recommends the grant of Drug Manufacturing License for its approval by the Licensing Board and finalized report has been submitted to DRAP Licensing Division.

Prior inspection of our factory we hired highly paid technical staff to meet the perquisite of the issuance of Drug Manufacturing License. We are constantly paying monthly salaries to our staffers whereas electricity bills of the factory are also being paid regularly amounting to Rs. 0.3 to 0.5 Million per month. (Copy of bill is attached herewith for your kind perusal and reference).

We have already written to DRAP vide letter dated 14/07/2023 and sought the permission for the development studies of our product range so that the product quality data with its stability studies could be submitted timely to DRAP without any delays. (Copy of letter attached)

Needless to mention about the huge investment spent on our new project of Air Pharmaceuticals, however, surprisingly Authority instead of encouraging us to begin the manufacturing process of our medicines as early as possible has deferred the grant of Drug Manufacturing License (DML) to us till decision of Writ Petition No.824/23 pending adjudication before the Honorable Islamabad High Court contrary to the settled law.

As It is settled law that if there is no Stay or Injunction Order then there is no hurdle or obstruction in the smooth running of routine business.

Our Manufacturing Plant is in the Industrial Estate Kasur which is under the control of the Punjab Government and where as many as 8/9 other Pharmaceuticals plants are already operational and manufacturing medicines.

In the light of above narrated facts the withholding of grant of Drug Manufacturing License (DML) to Air Pharmaceuticals by the DRAP is against the settled law of the Honorable Supreme Court of Pakistan as well as the provisions of Fundamental Rights guaranteed to citizens of Pakistan

In these circumstances, we therefore request and urge your good-self to issue us Drug Manufacturing License as early as possible to start manufacturing and production of medicines failing which we will be having no choice except to say Good Bye to all of our staffers hired so far and suspend the project at least for the time being.

It is further requested that the contents of our written statement submitted in the Islamabad High Court as well as of the written statement of your own Department deposited with the Honorable Islamabad High Court may also be examined/ considered accordingly."

Decision of the Central Licensing Board in 292nd meeting

The Board was apprised by Mr. Hafiz Bilal Akbar DD Legal that only notice has been issued by the Honourable Court and there are no restraining orders or stay by the Honorable Court, hence CLB may consider the grant of license to M/s. Air Pharma. The Board while considering the facts and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Air Pharmaceuticals (Pvt.) Ltd, Plot No.74-75-A, Small Industrial Estate, Kasur on the recommendations of the panel of experts for the following section.

1. Syrup Section (General) only.

CASE NO. 29. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S PACIFIC PHARMACEUTICALS LTD, PLOT NO. 30-KM, MULTAN ROAD, LAHORE (DML# 000295)

M/s Pacific Pharmaceuticals Ltd, Plot No. 30-KM, Multan Road, Lahore, submitted application for renewal of Drug Manufacturing License No. 000295 (by way of Formulation) for the period 22-07-2020 to 21-07-2025. The application was received on 13-07-2020 and due date of renewal of DML 22-07-2020.

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 29th December, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
ii. Partnership Deed along with CNIC's of all partners.
iii. Detail of premises including layout plan
iv. Proof of licensed sections from CLB.
v. Name and Qualification of Quality Control In-charge.
vi. Up-to-date nothing due certificate regarding CRF from STO.

The firm submitted their reply to above mentioned letter and same was evaluated and following shortcoming were observed for which final reminder issued to the firm on 18th June, 2021;

i. Latest certified true copy of form-29.
ii. Proof of licensed sections from CLB.
iii. Up-to-date nothing due certificate regarding CRF from STO.

In repose to final reminder the firm submitted their reply which is summarized as under;

a. Trust this letter finds you safe and in the best of health. I hope there will be no need to reintroduce Pacific Pharmaceuticals Ltd to your good self. We are being the MHRA certified company always tried our level best to represent Pakistan globally in the best possible way. Pacific Pharmaceuticals Ltd is the company, which is always strictly following the rules and regulations set by DRAP and other international regulatory bodies. Sir, I am writing this letter for the need of your kind support and attention to the subject matter. The brief detail is provided below for your kind attention.
b. Dear Sir, Pacific Pharmaceuticals applied for the renewal of Drug Manufacturing License (DML) in 13-07-2020 (copy enclosed) but inspection is still pending what we have been told by Licensing Division due to pending CRF NOC. I would like to bring it into your kind notice that we applied for NOC against CRF for the year 2019-2020 on 8-9-2020 (copy enclosed). We received letter from B&A Division on 4-11-2020 for payment of differential amount (copy enclosed). The differential amount was paid and response was submitted on 12-02-2021 received at DRAP on 19-2-2021 (copy enclosed). We have been telephonically advised by B&A Division to submit auditor's attested financial statements which were submitted on 3-8-2021 (copy enclosed). However, we received another query on 6-8-2021 and demanded huge amount which was not calculated according to the original financial statements. We were told by B&A Division that two types of financial statements were submitted by Pacific and they have considered the highest values.
c. Dear Sir, it took us four months to probe this issue because it really hit our integrity. We have reached to the culprits and found out that elevated financial statements were submitted to DRAP but those statements are incorrect. We are in contact with B&A Division to justify our case with solid evidences of auditor's attested financial statements. We are willing to pay any sort of amount provided, it is justified with the financial statements. We have always tried to work through and proper channels.
d. Dear Sir, keeping in view the above provided background, I request your competent authority to look into this matter and advised Licensing Division not to take further action until the matter is amicably resolved. You have always been kind enough to support Pacific Pharmaceuticals not for the uplift of pharmaceutical industry but also for the prestige of Pakistan globally.

In light of above, Division of Budget and Account, DAP was requested to submit updated status of the firm regarding nothing due certificate (CRF). Division of Budget and Account, DAP informed that the CRF certificate valid up to 31-12/2017 was issued to the firm.

It is pertinent to mention that application for renewal of Drug Manufacturing License for the period of 22-07-2020 to 21-07-2025 is still deficient due non availability of up to date nothing due certificate (CRF)

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 287th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the

Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000295 (by way of formulation) of M/s Pacific Pharmaceuticals Ltd, Plot No. 30-KM, Multan Road, Lahore may not be suspended by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

The firm has replied and submitted all the required documents for renewal of DML.

Decision of the Central Licensing Board in 292nd meeting

Since, the firm has completed the application for the Renewal of DML No. 000295, the Board while considering the facts on the record decided to cease the operation of Show Cause Notice for the further period issued in the name of M/s Pacific Pharmaceuticals Ltd, Plot No. 30-KM, Multan Road, Lahore.

The Board further decided that in future, the Chairman of CLB is authorized to issue/cease/revoke the Show Cause Notice issued to the firms regarding incomplete renewal/technical persons applications and later the complete case will be placed before the CLB in its meeting for final decision.

CASE NO. 30. CHANGE OF MANAGEMENT OF M/S ZETA PHARMACEUTICALS, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000818 BY WAY OF (FORMULATION).

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

Previous Management as per Partnership Deed	Current Management as per Partnership Deed
i. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. ii. Mr. Atiq Qamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5, iii. Mr. Zahid Masood Nasir S/o Basharat Ali CNIC No. 35202-5632630-7,	i. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. ii. Mr. Atiq Qamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5,

Decision of the Central Licensing Board in 288th meeting:

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

Decision of the Central Licensing Board in 292nd meeting

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

Previous Management as per Partnership Deed	Current Management as per Partnership Deed
i. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. ii. Mr. Atiq Qamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5. iii. Mr. Zahid Masood Nasir S/o Basharat Ali CNIC No. 35202-5632630-7.	i. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. ii. Mr. Atiq Qamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5,

Case No.31. CORRECTION IN MINUTES OF 291st MEETING.

The case for renewal of DML No.000503 (Formulation) of M/s Medisure Laboratories Pakistan (Pvt) Ltd., A-115, S.I.T.E., Super Highway, Karachi. Details are as under:

1	M/s Medisure Laboratories Pakistan (Pvt) Ltd., A-115, S.I.T.E., Super Highway, Karachi. DML No.000503 (Formulation) **Period:** Commencing on 06-10-2022& ending on 05-10-2027.	18-05-2023	Good	1. Chief Drug Inspector, Sindh. 2. Area FID, DRAP, Karachi. 3. Assistant Director, DRAP, Karachi.
	Recommendations of the panel: As per instructions contained in DRAP, Islamabad Letter No.F.2-2/2001-Lic (Vol-III) Dated: 12thMay, 2023, a detailed inspection of Medisure Laboratories Pakistan (Pvt) Ltd. situated at A-115, S.I.T.E., Super Highway, Karachi was carried out on 18th May, 2023. During opening meeting their Organogram, JDs, SMF, approved design, HVAC provision and design, an APQR of frequently manufactured product, Self- audit report, medical reports of employees, training records and several working SOPs were discussed at length and found an adequate level of compliance and an appropriate maintenance of necessary documents. The firm is found built as			

per approved design and necessary changes as per current design are satisfactorily carried out. AHUs are provided as required in production areas for better compliance & to control the hazards of contamination. Equipment's were adequately validated. Lab equipment's were seen calibrated and with proper log books. Quality manuals, IP testing records and line clearance documents were also in place.

Keeping in view the above stated facts and based on the attitude of the management towards continuous improvements, the panel unanimously recommends the grant of renewal of their DML No.000503 (By way of formulation) for next five years for the following sections;

S.#	Sections	S.#	Sections
1.	Tablet (General)	2.	Capsule (General)
3.	Dry Powder Suspension (General)	4.	Sterile Dry Powder Injectable/General, Sterile Liquid Injectable (Ampoule & Vial)/Sterile Ophthalmic Ear and Nasal Drops
5.	Oral Liquid (General)	6.	Cream/Ointment
7.	Sachet (General)	8.	Cephalosporin (Dry Powder Suspension and Capsule)
9.	External Preparations Powder (General)	**********	

Decision of the Central Licensing Board in 291st meeting

The Board considered and approved the grant of renewal of DML No. 000503 by way of Formulation in the name of M/s Medisure Laboratories Pakistan (Pvt) Ltd., A-115, S.I.T.E., Super Highway, Karachi on the recommendations of the panel of experts for the period Commencing on 06-10-2022& ending on 05-10-2027 for the following sections subject to verification of necessary testing equipment.

S.#	Sections	S.#	Sections
1.	Tablet (General)	2.	Capsule (General)
3.	Dry Powder Suspension (General)	4.	Sterile Dry Powder Injectable/General, Sterile Liquid Injectable (Ampoule & Vial)/Sterile Ophthalmic Ear and Nasal Drops
5.	Oral Liquid (General)	6.	Cream/Ointment
7.	Sachet (General)	8.	Cephalosporin (Dry Powder Suspension and Capsule)

		9.	External Preparations Powder (General)	**********	

In the inspection report, one section namely "Sterile Dry Powder Injection (Cephalosporin)" was inadvertently missed in the final recommendations of the inspection report. However, the name of the said section was mentioned in section wise report. Now Area FID, DRAP, Karachi has informed vide letter No.F.000503/2018-FID-VI (K) (Medisure) dated 27-07-2023 that the said section was inadvertently missed in final comments of the inspection report.

Decision of the Central Licensing Board in 292nd meeting

The Board considered the case and decided to approve the correction and approved renewal of following section:

i. Sterile Dry Powder Injection (Cephalosporin)

Case No.32 CHANGE OF MANAGEMENT M/S NEWTON HEALTH CARE (PVT) LTD., PLOT NO. N-8&9, HITE, HUB, BALOCHISTAN

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

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

Decision of the Central Licensing Board in 288th meeting:

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

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

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

Decision of the Central Licensing Board in 290th meeting:

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

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

In the decision of the 290th meeting of CLB the name of Mr. Farooq Ahmed Qazi S/o Abdul Ghafoor CNIC No.43203-9496796-7 was inadvertently missing. The correct detail of management is as under;

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

Decision of 292nd meeting of the CLB

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

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

Case No.33 **GRANT OF REVISED FLOW CHART FOR MANUFACTURING OF CIPROFLOXACIN-HCL (API) BY WAY OF SEMIS BASIC MANUFACTURE DML NO. 000959 M/S ANTHRO API-GEN (PVT) LTD, PLOT NO.04, STREET NO.N-4, RCCI INDUSTRIAL ESTATE RAWAT.**

The firm M/s. Anthro API-Gen (Pvt.) Ltd, Rawat submitted application for approval of revised process flow chart for manufacturing of "Ciprofloxacin HCL"

It is submitted for information that said API was approved by CLB in its 287th meeting held on 24/06/2022. Accordingly following panel was constituted for verification of revised flow chart of the already approved "Ciprofloxacin HCL"

1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad.
2. Mrs. Tehreem Sara, Area FID-IV, DRAP, Islamabad.
3. Mr. Abdullah, Assistant Director (Licensing), DRAP, Islamabad.

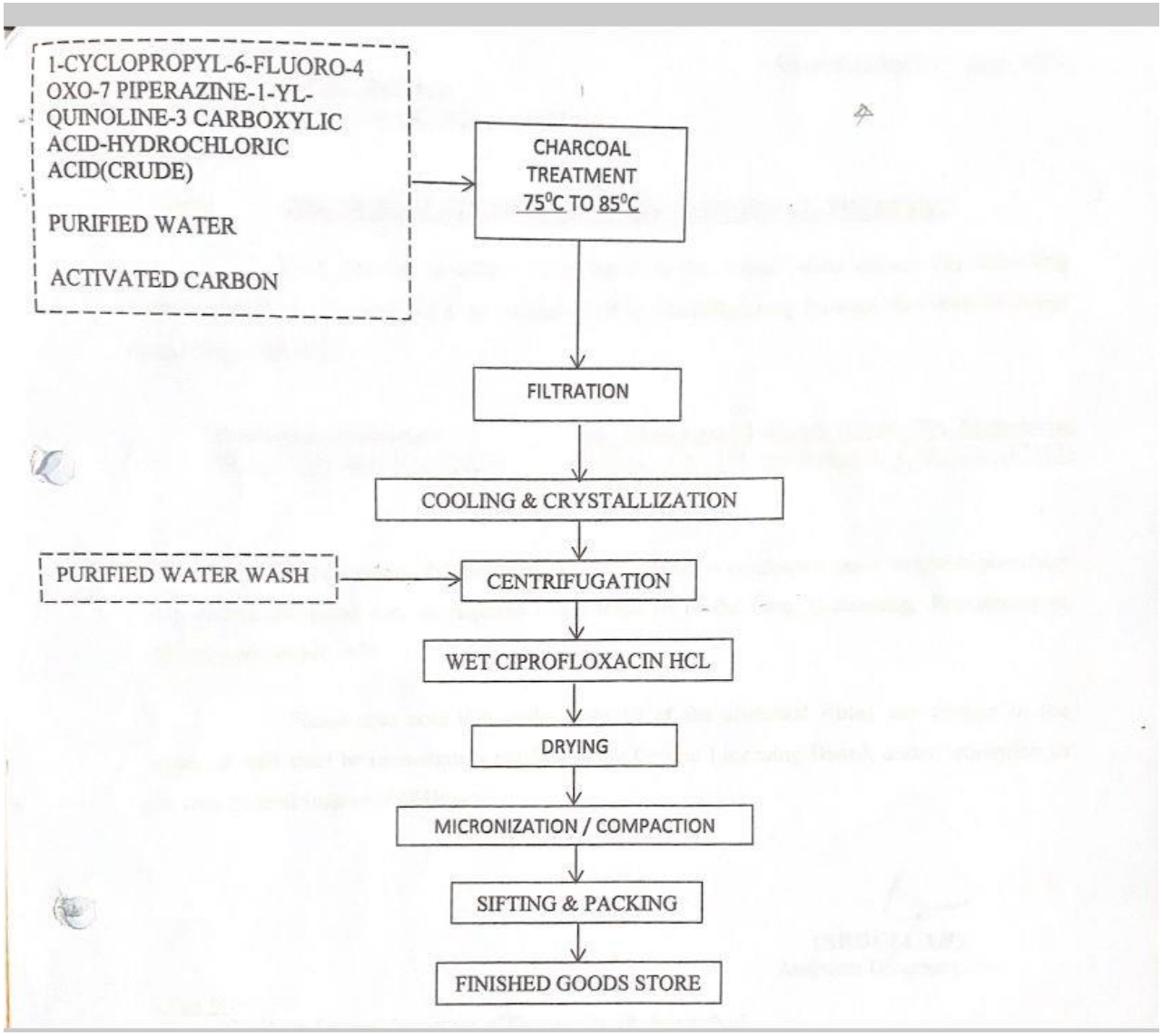
The said panel submitted following recommendation

Recommendations of the panel:

"In view of above, the panel verifies that the establishment possesses the facility for production and quality control testing /analysis which has already been approved by the Licensing Division. The matter may please be placed before the Licensing Board for its consideration of the New Formulation of API (as submitted by the firm) for Semi-Basic Manufacturing in the light of the previously approved formulation of "Ciprofloxacin API" for the other establishments.

Decision of the Central Licensing Board in 292nd meeting

The Board considered the case and decided to approve the revised flow chart for Ciprofloxacin HCl API of M/s. Anthro API-Gen (Pvt.) Ltd, Rawat DML No 000959 (by way of Semi Basic Manufacture).



Case No. 34. **CHANGE OF MANAGEMENT OF M/S RASCO PHARMA, 5.5-KM, NEAR ALI RAZA ABAD, HOLIDAY PARK, PLOT NO. 27-28, RAIWIND ROAD, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000175 BY WAY OF (FORMULATION).**

M/s Rasco Pharma, 5.5-Km, near Ali Raza Abad, Holiday Park, Plot No. 27-28, Raiwind Road, Lahore. Under drug manufacturing license no. 000530 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. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7	1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7 3. Mr. Zaid Jamshed S/o Jamshed Jamil, CNIC No. 35202-9206546-5

Decision of the Central Licensing Board in 292nd meeting

The Board considered and accepted for record the change of management of M/s Rasco Pharma, 5.5-Km, near Ali Raza Abad, Holiday Park, Plot no. 27-28, Raiwind Road, Lahore Under drug manufacturing license no. 000530 by way of (formulation) as under 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: -

Existing management	**New management**
1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7	1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7 3. Mr. Zaid Jamshed S/o Jamshed Jamil, CNIC No. 35202-9206546-5

Case No. 35. Requirement of R&D Laboratory / Lay out approvals

The Board observed that as per GMP guidelines the Research & Development laboratory is mandatory for a pharamceuical firm. The Board decided that in future all layout plans for new units/ additional sections/ regularizations and amendements shall be approved by the Chairman CLB with the requirement of having a R&D lab/facility.

QUALITY ASSURANCE CASES

(GMP NON-COMPLIANCE)

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. *Chief Drug Controller, Punjab or his Nominee.*
   b. *Mr. Younas Khattak, Chief Drug Inspector, Khyberpakhtunkhwa.*
   c. *Mr Muhammad Sarfaraz AD PE&R.*
   d. *Mr Noman Yousuf DD Pharmacy Services*

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 & CLB and also representative 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 within (05) working 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 within Seven (07) working days after the issuance of final reminder.*

Case No. 02: <u>UNREGISTERED DRUG "SUDOCREAM ANTISEPTIC HEALING CREAM" MANUFACTURED BY M/S. TOSARA PHARMA, LTD., IRELAND</u>

FID-III Karachi visited premises of M/s; Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi_on 20-05-2021 wherein following sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3

S. No.	Name of Drug	Reg. No.	Lot. No.	Mfg. Date	Exp. Date	Mfg. by
01	Sudocrem Antiseptic Healing cream	Nil	135838	Nil	09-04-2023	M/s. Tosara Pharma Ltd, Baldoyle Ind. Est, Dublin 13, Ireland.

02. The sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the purpose of test/analysis vide memorandum No. DHB-16/2021 to 17/2021-FID-111 (K) dated 20th, May, 2021.

03. Portion of Sealed sample was sent to Chairman, Registration Board, DRAP Islamabad vide this office letter of even number dated 20th, May, 2021.

04. M/s. Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi was asked to provide bill warranty in connection with the purchase of above said drug vide this office letter of even number dated 20th May 2021, Reminder-I on dated 21th June 2021, reminder-II on dated 16th July 2021 and reminder-III on dated 26th July 2021.

05. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared above said samples "Sudocream Antiseptic Healing Cream" sent to CDL Karachi by FID-III Karachi as **"Unregistered drug"** vide test report No. R.KQ.121/2020 dated 19-07-2021. Wherein Federal Government Analyst, CDL Karachi, has informed that the sample of product. Details of the test report are given as under:

"Description: Off white cream

Identification: Zinc (Oxide) identified

<u>Assay for Zinc Oxide:</u>

Determined amount/100gm: 15.8534gm

***Remarks: -** 1) The assay result for Zinc Oxide has been calculated as 15-8534gm per 100gm.*

2) Since, Zinc Oxide is an allopathic drug and the sample (Sudocream Antiseptic Healing Cream). Manufactured by M/S. Tosara Pharma Ltd. Ireland is not registered with DRAP (Directorate of Registration), Islamabad, Government of Pakistan.

*<u>Hence, the sample is declared "**Un-Registered Drug Product"** under the Drugs Act, 1976.</u>*"

06. An explanation letter of even number dated 20 *July 2021* was accordingly issued to M/s. Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi for explaining their position in the matter of manufacturing/selling of above mentioned UN-REGISTERD DRUG PRODUCT.

07. M/s; Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi vide their letter No. Nil dated 13th, August 2021 Provided the Bill/warranty No. 746 dated 17 May 2021 from Mr. Muhammad Hussain (Owner) Haroon center 1st, Floor Marriot Road near chat lane Boulton Market Karachi in connection with the purchase of above said drug

08. Undersigned vide this office letter of even number dated 20th August 2021, Reminder -01 on dated 03rd September 2021 and Reminder -02 on dated 04th, February 2022 was asked Mr. Muhammad Hussain (Owner) Haroon center lst, Floor Marriot Road near chat Laine Boulton Market Karachi to verify the same and provide subsequent bill warranty in connection with purchase of above said drug. (Annexure-M, N, & 0) But no any reply has been received till date.

09. FID reported in the light of Federal Government Analyst, Central Drug Laboratory test report No. R. KQ.121/2021 dated 19th July 2021 M/s. Danish Brothers, Shop #14, Maji Market, Marriot Road, Kuichi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi was found involved in selling UNREGISTERD DRUG PRODUCT and violated the section 23(1)(a)(vii), 23(1)(i) of the Drugs Act 1976, punishable under section 27(1)(a) and 27(4) of the Drugs Act 1976 and rules framed thereunder.

Recommendation: -

Following accused may kindly be prosecuting in Drug Court of Sindh, Karachi: -

1. M/s. Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi.

2. Danish S/o Abid Hussain, Proprietor of M/s. Danish Brothers, Shop #14, Maji Market, Marriot Road, Kutchi Gali No. 01, Denso Hall M.A. Jinnah Road, Karachi
   CNIC No.42301-8035242-9

10. M/s. Danish Brothers was Show caused vide letter no. 04-03/2021-QC dated , *December 9, 2022* in the light of above-mentioned laboratory report, found involved in selling Un-registered drug which is a prohibited under Section 23(1)(a)(vii) of the Drugs Act 1976 read with Schedule-II of the DRAP Act, 2012 and punishable under Section 27(1)(a) and 27(4) of the Drugs Act 1976 read with Schedule-III of the DRAP Act, 2012, therefore, you are hereby required to show cause in writing that, why the following action(s) should not be initiated against you.

   i. Prosecution in Drug court.

   ii. Any other action the Board may deem fit.

11. Reply of M/s; Danish Brothers was received vide letter No.892/22 dated 19-12-22 in reply to show cause in which he briefed that he was ignorant of the fact that the said item is an allopathic medicine and considered it as a general item. He has now stopped the selling of this item and ensures he will not be involved in its selling again.

Proceedings and decision of 289th meeting of CLB held on 23-01-2023:

"The Board after considering the facts of the case and thorough deliberation decided to show cause following accused and called them for personal hearing:

i. Ms. Danish Brothers, Shop#14, Maji Market, Marriot Road, Kutchi Gali no. 01, Denso Hall M.A. Jinnah Road, Karachi
ii. Danish S/o Abid Hussain, Proprietor of Ms. Danish Brother, Shop#14, Maji Market, Marriot Road, Kutchi Gali no. 01, Denso Hall M.A. Jinnah Road, Karachi
iii. Muhammad Hussain, Harron Center 1st Floor, Marriot Road near Chat Lane Boulton Market Karachi."

12. In compliance to the decision of 289th meeting of the Central Licensing Board, the accused are called for personal hearing.

Proceedings of the meeting:

13. Danish S/o Abid Hussain, proprietor of M/s. Danish Brothers, Karachi appeared before the Board along with his father Mr. Abid Hussain and informed the Board that he purchased a few units of Sudocream on customer demand and was unaware of the fact that the product contained any allopathic ingredients since this product is freely available in the market as a general/consumer product. He provided the same stance in written form to the Board.

Decision of the Board:

The Board after thorough deliberations and keeping in view the statement of Danish S/o Abid Hussain (Proprietor) of M/s. Danish Brothers Karachi decided to issue warning to the accused. Moreover, the Board decided to issue an advisory to the importers/wholesalers regarding the sale of products containing allopathic products.

Case No. 03: RENEWAL OF DRUG MANUFACTURING LICENSE UNDER THE DRUGS ACT, 1976 OF M/S HAMAZ PHARMACEUTICAL (PVT) LTD., 13-K.M, LUTAFABAD BOSAN ROAD, MULTAN

01. Secretary Central Licensing Board vide letter No. 1-37/93-Lic(Vol-II) dated 02.12.2022 communicated the decision of the 288th meeting of the Board which is given as under:

> *"Mr. Azher Jamal Saleemi, member CLB, informed the board that M/s Hamaz Pharmaceutical (Pvt) Ltd., 13-K.M, Lutafabad Bosan Road, Multan for renewal of DML No.000427 (Formulation) has been found involved in manufacturing of Citalem 10 mg Tab (Escitalopram) Batch No. 46201 adulterated with other drug i.e. Sildenafil. He also shared a copy of case report. The board decided to defer the renewal application and referred the case to QA&LT division for further investigation in the instant matter and to submit the report to the CLB."*

02. In compliance to the decision of Board, the division of QA&LT vide letter No. F. 4-32/2022-QC dated 13-12-2022 wherein field offices of DRAP and Provincial Health Departments were requested to investigate the matter.

03. In response to the above-mentioned letter of the division of QA&LT, panel consisting of Area Federal Inspector of Drugs Lahore and Assistant Director Lahore submitted an investigation report, conclusion of which is given as under:

> "7. In light of the aforesaid investigation, apparently, no evidence of adulteration was found. However, it is proven and also owned by the firm that they had manufactured substandard drug as per their own test reports. So, the firm committed that they engaged in manufacturing of substandard drug (Citalem 3H 10 mg tablet registration number 040726).

So, the drug/product may be cancelled/suspended or any other action as deemed fit may be taken by the competent authorities."

04. Keeping in view the above-mentioned report and decision of 288th meeting of the Board, letter vide No. F. 03-31/2023-QC dated 25-07-2023 was issued addressed to the Secretary, PQCB requiring the current status of case of Citalem tablet (Escitalopram) pending at the end of PQCB. The Secretary provided the updated status of cases as under:

S#	Name of Drug	B. No.	DTL report	Status of case
01	Film Coated Tablet. Citalem (Escitalopram Oxalate 12.7mg eq. to Escitalopram 10mg) R.No.: R-114/2022	46201	Adulterated and Substandard	Retesting request of the firm was turned down by the Board in its 251st meeting dated 20-10-2022. Drug inspector sought permission for registration of F.I.R, Showcause notice was issued dated 04-11-2022, The Board granted permission for registration of F.I.R to the drug inspector in its 253rd meeting dated 29-11-2022. The firm challenged the order of turn-down of retesting request in the Lahore High Court. Court disposed-off the writ petition with directions to decide the review petition of the firm. The Board decided the review application of the firm on the retesting request on the directions of High Court in its 257th meeting dated 07-02-2023 and upheld its decision taken in PQCB 251st meeting to turn down the retesting request. Firm filed review against the orders of permission of F.I.R. that is ready to place in the upcoming meeting of the Board.
02	Film Coated Tablet. Citalem (Escitalopram Oxalate 12.7mg eq. to Escitalopram 10mg) R.No.: R-112/2022	-do-	-do-	
03	Film Coated Tablet. Citalem (Escitalopram Oxalate 12.7mg eq. to Escitalopram 10mg) R.No.: R-113/2022	-do-	-do-	
04	Film Coated Tablet. Citalem (Escitalopram Oxalate 12.7mg eq. to Escitalopram 10mg) SM-20-09/2022, SM-26-11/2022, R.No.: R-194/2022	-do-	-do-	Showcause notice was issued to the firm on 23-12-2022. The firm requested for retest of the drug sample. The retesting request of the firm was turn-down by the Board in its 259th meeting dated 18-04-2023. The case is ready to be placed in upcoming meeting of the Board.

05. Matter is placed before the Board under the light of investigation report of Area FID Lahore and information provided by the Secretary, PQCB Lahore.

Proceedings and decision of the Board:

06. The Division of QA&LT presented the case before the Board, the detailed investigation of the matter as submitted by DRAP Lahore and current status of the case of M/s. Hamaz Pharmaceutical, Multan at PQCB Punjab Lahore as directed by the Board in its 288th meeting. The Board discussed the matter in detail and directed the division of QA&LT to submit both the investigation and current status of case to the Division of Licensing, for further processing of the matter.