MINUTES OF 277th MEETING OF CENTRAL LICENSING BOARD HELD ON OCTOBER 15-16, 2020

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277th meeting of the Central Licensing Board (CLB) was held on October 15-16, 2020 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Dr. Masud ur Rehman, Director Drug Licensing, Drug Regulatory Authority of Pakistan, Islamabad. Following members attended the meeting: -

S.No	Name & Designation	Status
1	Dr Ikram Ul Haq, Quality Control Expert	Member
2	Prof. Dr. Abdullah Dayo, Dean Faculty of Pharmacy, University of Sindh, Jamshoro	Member
3	Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar.	Member
4	Mr. Muhammad Israr, Law Expert, Ministry of Law & Justice Division, Islamabad	Member
5	Mr. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore	Member
6	Mr Saleem Shah, Chief Inspector of Drugs, Government of Balochistan, Quetta	Member
7	Mr Shoaib Ahmed Ansari, Chief Inspector of Drugs, Government of Sindh, Karachi	Member
8	Mr Zahid Khan, Chief Drug Inspector Peshawar, Department of Health, Govt of Khyber Pakhtunkhwa.	Member
9	Dr. Hafsa Karam Ellahi, Additional Director Representative Director (QA/LT), DRAP, Islamabad	Member
10	Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
11	Mr. Tipu Sultan Akram, Representative of PPMA.	Observer
12	Ms. Mahwish Siddiqui, Representative of PPMA.	Observer
13	Mr. Kamran Anwar, Representative, PCDA	Observer
14	Mr.Nadeem Alamgir Representative of Pharma Bureau.	Observer

The meeting started with the recitation of Holy verses. The Chairman Central Licensing Board welcomed the honorable members. He stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes thereof. The Central Licensing Board discussed and decided that initial draft minutes of the meeting would be prepared by concerned sections of Divisions and counter verified by the Secretary, Central Licensing Board before submitting to the members of the Board. Secretary Licensing Board presented the agenda before

the Board. Mr. Zeeshan Nazir, Deputy Director (QA), Mr. Muhammad Asad Malik, Deputy Director (Licensing), Mr. Muhammad Usman, AD (Lic), Mr. Abdullah Bangash, AD (Lic), Ms. Zunaira Faryad, AD (Lic), Ms. Haleema Shareef (Lic) Mr. Sanaullah Babar, AD (QC) and Mr. Muhammad Ashfaq, AD (QC) DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

DRUG LICENSING DIVISION

Item-I CONFIRMATION OF THE MINUTES OF 276th MEETING

The Central Licensing Board (CLB) formally confirmed the minutes of its 276th meeting of the Central Licensing Board (CLB) which was held on 3rd September, 2020.

Item-II: GRANT OF NEW DRUG MANUFACTURING LICENSES.

Following cases have been forwarded by the respective panel of experts for grant of new Drug Manufacturing Licenses. 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 Haarlods Pharmaceuticals (Pvt) Ltd., Plot No.60-64/C, Small Industrial Estate, Bhimber, AJK.	09-10-2020	Good	1. Dr. Hafsa Karam Elahi, Additional Director (QA/LT), DRAP, Islamabad. 2. Mr. Manzoor Ali Bozdar, Additional Director (Licensing), DRAP, Islamabad. 3. Mr. Hassan Afzaal, Area Federal Inspector of Drugs, DRAP, Islamabad.
	Recommendations of the panel: - *"Keeping in view of the above facts, detailed visit of the facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Haarolds Pharmaceuticals,(Pvt), Ltd, Plot No 60-64/C, small industrial Estate, Bhimber, AJ&K (By way of Formulation) for following sections;* *1. Bulk Powder Section–I (Veterinary) (General),* *2. Oral Liquid Section -I (Veterinary) (General),* *3. Bulk Powder Section–II (Veterinary) (General),*			

	4. *Oral Liquid Section -I (Veterinary) (General),* 5. *Liquid Injection Section (Veterinary) General,* 6. *Liquid Injectable Section (Veterinary) Penicillin,* 7. *Bulk Dry Powder Section (Veterinary) Penicillin,* 8. *Topical Spray section (Veterinary) General.* **Decision of the Central Licensing Board in 277th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Haarolds Pharmaceuticals,(Pvt), Ltd, Plot No 60-64/C, small industrial Estate, Bhimber, AJ&K (By way of Formulation) on the recommendations of the panel of experts for the following sections: **Sections (8)** 1. *Bulk Powder Section–I (Veterinary) (General),* 2. *Oral Liquid Section -I (Veterinary) (General),* 3. *Bulk Powder Section–II (Veterinary) (General),* 4. *Oral Liquid Section -I (Veterinary) (General),* 5. *Liquid Injection Section (Veterinary) General,* 6. *Liquid Injectable Section (Veterinary) Penicillin,* 7. *Bulk Dry Powder Section (Veterinary) Penicillin,* 8. *Topical Spray section (Veterinary) General.*			
2.	M/s Unichem Pharmaceuticals Pakistan (Pvt) Ltd., Plot No.310, Industrial Triangle Kahuta Road, Islamabad.	12.10.2020 (Semi Basic manufacture)	Good	1. Mr. Manzoor Ali Bozdar, Additional Director (Licensing), DRAP, Islamabad 2. Ch. Zeeshan Nazir, Additional Director (QALT/BER), DRAP, Islamabad 3. Mr. Babar Khan, Area Federal Inspector of Drugs, Islamabad
	RECOMMENDATIONS: Keeping in view the manufacturing and testing facility in place, the panel unanimously ***recommended the approval of drug manufacturing license by way of semi- basic manufacturing to M/s Unichem Pharmaceuticals Pakistan (Pvt) Ltd., Plot No.310, Industrial Triangle Kahuta Road, Islamabad,*** **for manufacturing of following 19 active pharmaceutical ingredient for Semi-basic manufacturing**. The responsibility lies with the manufacturer to ascertain the regulatory requirements during the validity period of DML.			

Cephalosporin Oral Non-sterile Section

1. Cefradine (USP/NF)
2. Cefixime trihydrate (BP)

Cephalosporin Sterile Section

3. Ceftriaxone sodium (BP)
4. Ceftazidime pentahydrate (BP)
5. Cefotaxime sodium (BP)

Multi-purpose (General) Non-sterile section

6. Paracetamol (BP)
7. Montelukast sodium (BP)
8. Moxifloxacin hydrochloride (BP)
9. Ciprofloxacin Base
10. Clarithromycin (BP)
11. Azithromycin (BP)
12. Ciprofloxacin hydrochloride (BP)
13. Levofloxacin hemihydrate (BP)
14. Dexlansoprazole (In-House Unichem Specifications)
15. Esomeprazole (BP)
16. Itraconazole (JP)
17. Omeprazole (BP)
18. Levitericetam (USP/NF)
19. Drotaverine hydrochloride (In-House Unichem Specifications)

Decision of the Central Licensing Board in 277th meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of ***M/s Unichem Pharmaceuticals Pakistan (Pvt) Ltd., Plot No.310, Industrial Triangle Kahuta Road, Islamabad*** (By way of Semi Basic Manufacture) on the recommendations of the panel of experts for the following Sections and Active Pharmaceutical Ingredients:

Cephalosporin Oral Non-sterile Section

1. Cefixime trihydrate (BP)

Cephalosporin Sterile Section

1. Ceftriaxone sodium (BP)
2. Ceftazidime pentahydrate (BP)
3. Cefotaxime sodium (BP)

	Multi-purpose (General) Non-sterile section 1. Paracetamol (BP) 2. Montelukast sodium (BP) 3. Ciprofloxacin Base (In-House Unichem Specifications) 4. Azithromycin (BP) 5. Ciprofloxacin hydrochloride (BP) 6. Levofloxacin hemihydrate (BP) 7. Dexlansoprazole (In-House Unichem Specifications) 8. Esomeprazole (BP) 9. Itraconazole (JP) 10. Omeprazole (BP) The Board also deferred the following Active Pharmaceutical Ingredients (API's) for further working on use of Methylene Chloride as solvent in these API's. **Cephalosporin Oral Non-sterile Section** 1. Cefradine (USP/NF) **Multi-purpose (General) Non-sterile section** 1. Moxifloxacin hydrochloride (BP) 2. Clarithromycin (BP) 3. Levitericetam (USP/NF) 4. Drotaverine hydrochloride (In-House Unichem Specifications)			
7	M/s Swat Pharmaceuticals, Valley Road, Sherari Gulkada No. 3, Saidu Sharif Swat Khyber Pakhtoonkhwa. [Grant/Transfer er of DML No. 000035 (Formulation) to new premises] **<u>SECTIONS</u>** 1. Tablet (General),	07-09-2020	**Good**	1. Dr. Jamshed Ali Khan, Member CLB. 2. Director DTL, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar.

	2. Tablet (Psychotropic), 3. Capsule (General), 4. Syrup (General), 5. Cream/ointment (General), 6. Sachet (General)			

Recommendations of the panel: -

Keeping in view the above, the panel unanimously **recommended the grant/transfer of DML by The Way of Formulation (000035)** of M/s Swat Pharmaceuticals, on new premises on Valley Road, Sherarai Gulkada No.3, Saidu Sharif Swat with the Section as per Layout Plan).

Decision of the Central Licensing Board in 277th meeting

The Board considered and approved the grant of Drug Manufacturing License **(000035)** by way of Formulation in the name of M/s Swat Pharmaceuticals at new premises Valley Road, Sherari Gulkada No. 3, Saidu Sharif Swat Khyber Pakhtoonkhwa on the recommendations of the panel of experts for the following sections:

Sections (6)

1. Tablet (General),
2. Tablet (Psychotropic),
3. Capsule (General),
4. Syrup (General),
5. Cream/ointment (General),
6. Sachet (General)

The said Drug Manuafcturing Licence shall stand cancelled at old premises M/s Swat Pharmaceuticals, Saidu Sharif Raod, Anankot, Mingora, Swat from the date of issuance of licence at new premises.

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

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Bosch Pharmaceuticals (Pvt) Ltd, Plot No. 209, Sector 23, Korangi Industrial Area, Karachi **DML No. 000707 (formulation)** **1.** Infusion Section General-II	**23-09-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director (E&M)/Area FID, DRAP, Karachi.
	Recommendations:- Based on the people met, documents reviewed and observations made during the inspection, panel recommends the grant of Additional Section Infusion Section General-II, as mentioned in aforementioned DRAP letter. **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of additional section in the name of M/s Bosch Pharmaceuticals (Pvt) Ltd, Plot No. 209, Sector 23, Korangi Industrial Area, Karachi under DML No. 000707(Formulation); **Section (1)** 1. Infusion Section SVP General-II			
2.	M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, **Karachi.** **DML No. 000597 (formulation)** **1.** Dry Powder Injection (Carbapenam)	**17-09-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Director CDL, Karachi 3. Additional Director (E&M)/Area FID, DRAP, Karachi.
	Recommendations:- Based on the people met, documents reviewed and observation made during the inspection, panel recommends the grant of additional section Dry Powder Injection (Carbapenem)			

<table>
<tr><td></td><td colspan="4"><u>Decision of the Central Licensing Board in 277th meeting</u>
The Board considered and approved the grant of additional section in the name of M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi under DML No. 000597 (Formulation);
<u>Section (1)</u>
1. Dry Powder Injection (Carbapenam)</td></tr>
<tr><td>3.</td><td>M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14Km, Adyala Road, Post Office, Dhagal, Rawalpindi.
DML No. 000333 (Formulation).
<u>Sections for inspection:</u>
QC Lab (Ground Floor).
Microbiological Lab (First Floor).
R&D Lab (First Floor).</td><td>17-09-2020</td><td>Good</td><td>3. Dr. Massud-ur-Rehman, Director (Lic), DRAP, Islamabad.
4. Mr. Zeeshan Nazir, Deputy Director (QA), DRAP, Islamabad.
5. Area Federal Inspector of Drugs, DRAP, Islamabad.</td></tr>
<tr><td></td><td colspan="4">Recommendations of the panel: -
In view of above, as per mandate given vide letter No. F.1-18/92-Lic (Vol-II) dated 19th of August, 2020. The panel unanimously recommends following three areas as per approved layout plan mentioned as under DML No. 000333 Formulation to M/s. Shaigan Pharmaceuticals Pvt. Ltd, 14-KM, Adyala Road, Rawalpindi.

<table>
<tr><td><u>Ground Floor.</u>
1. Quality Control Lab.</td><td><u>First Floor.</u>
1. Microbiology Lab.
2. R&D Lab.</td></tr>
</table>

<u>Decision of the Central Licensing Board in 277th meeting</u>
The Board considered and approved the grant of revised and additional section in the name of M/s Shaigan Pharmaceuticals (Pvt) Ltd,14Km, Adyala Road, Post Office, Dhagal, Rawalpindi. under DML No. 000333 (Formulation);
<u>Section/ and facilities (3)</u>

<table>
<tr><td><u>Ground Floor.</u>
1. Quality Control Lab.</td><td><u>First Floor.</u>
1. Microbiology Lab.
2. R&D Lab.</td></tr>
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4.	M/s OBS Pakistan (Pvt) Ltd, Plot No. C-14, Manghopir Road, S.I.T.E, Karachi. DML No. 000012 (Formulation) **Sections/Facilities (03):-** (i) Tablet (General) Section - Revised (ii) Liquid Vial SVP (General) Section - Revised (iii) Change Room (General) - Revised	**07-10-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Chief Drugs Inspector, Govt of Sindh, Karachi. 3. Area FID, DRAP, Karachi.

Recommendations of the panel: -

Keeping in view overall GMP compliance and positive intention towards improvements, Panel unanimously recommends the renewal of (DML No. 000012) by way of Formulation and Grant of Amendments in Sections (i) Tablet (General) Section (ii) Liquid Vial SVP (General) Section and (iii) Change Room (General) to the firm M/s. OBS Pakistan (Private) Limited, C-14, Manghopir Road Karachi. It is pertinent to mention that the Firm has approved section as Capsule (General), however in panel Inspection letter issued vide letter No. F.2-1/2004-Lic (Vol-II), dated 20th May 2020, it was mistakenly typed as Soft Gelatin Capsule (General), which may be corrected in Grant of DML letter.

Decision of the Central Licensing Board in 277th meeting

The Board considered and approved the grant of revised section in the name of M/s OBS Pakistan (Pvt) Ltd, Plot No. C-14, Manghopir Road, S.I.T.E, Karachi under DML No. 000012 (Formulation);

Sections/Facilities (03):-

(i) Tablet (General) Section - Revised

(ii) Liquid Vial SVP (General) Section - Revised

(iii) Change Room (General) - Revised

5.	M/s The Searle Company Limited, Plot No. F-319, Sindh Industrial Trading Estate, Karachi. DML No. 000016 (Formulation) **Amendments in sections:-** (i) Tablet (General) Section - Revised (ii) Injection ampoule (General) Section - Revised (iii) Capsule (General) – Revised (iv) Raw Material Store – Revised (v) Packaging Material Ware House- Expansion vi. Microbiology Laboratory- Revised vii. Research & Development Laboratory- Revised	**08-10-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director (E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.

Recommendations of the panel: -

Based on the stated observations, the panel recommends Renewal and Amendments/ Expansions as following:

1. Tablet (General)- Amendment
2. Capsule (General) – Amendment
3. Sachet (General)
4. Injection Ampoule (General) Amendment
5. Oral Liquid (General)
6. Raw Material Store – Amendment
7. Packaging Material Ware House- Expansion
8. Microbiology Laboratory- Amendment
9. Research & Development Laboratory- Amendment

Decision of the Central Licensing Board in 277th meeting

The Board considered and approved the grant of additional section in the name of M/s The Searle Company Limited, Plot No. F-319, Sindh Industrial Trading Estate, Karachi under DML No. 000016 (Formulation);

Section (9)

1. Tablet (General)- Amendment
2. Capsule (General) – Amendment
3. Sachet (General)
4. Injection Ampoule (General) Amendment
5. Oral Liquid (General)

	6. Raw Material Store – Amendment 7. Packaging Material Ware House- Expansion 8. Microbiology Laboratory- Amendment 9. Research & Development Laboratory- Amendment			
6.	M/s Martin Dow Ltd, Plot No. 37, Sector 19,Korangi Industrial Area, Karachi. DML No. 000267 (Formulation) **Sections (01):-** (i) Dry Powder Inhaler (General) Capsule section	**07-10-2020**	**Good**	1. Director CDL, Karachi. 2. Area FID, DRAP, Karachi.
	Recommendations of the panel: - Based on stated condition, personnel met, documents reviewed and keeping in view the attitude of the firm for attaining a better level of compliance the panel unanimously recommends the grant of additional section of Dry Powder Inhaler (G) Capsule of the firm Martin Dow Limited having DML NO. 000267 Formulations. **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of regularized section in the name of M/s Martin Dow Ltd, Plot No. 37, Sector 19,Korangi Industrial Area, Karachi under DML No. 000267 (Formulation); **Section (1)** 1. Dry Powder Inhaler (G) Capsule (Regularized)			
7.	M/s Alpha Chemicals (Pvt) Ltd, 65-Km, Lahore-Multan National Highway Jamber Kalan, Tehsil Patoki, District Kasur. DML No. 000373 (Basic Manufacture). API (01) 1. Tramadol HCl (USP 41/ Ph. EUR)	24-09-2020	Good	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3. Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore. Additional Director could not join due to other official engagements and he had nominated Majida Mujahid, FID, DRAP Lahore to join the panel.

	Recommendations of the panel: - "Firm M/s Alpha Chemicals (Pvt) Ltd 65 - Km Lahore - Multan National Highway, Jamber Kalan Kasur has Drug Manufacturing No. 000373 by way of Basic Manufacturing. Firm has presently established the facility for conversion of Tramadol nitrate to Tramadol HCl as semi basic manufacturing process. Firm informed that they have also already got approval of Central Licensing Board in its 238 meeting held on 19-11-2014 vide DRAP letter No. F.1.3/94 - Lic (Vol –I) dated 02-12-2014 to manufacture Pseudoephedrine HCl by way of semi Basic Manufacturing method from intermediate i.e.(+) -(IS.2S)-2- Methylamino -1- phenylpropan – 1-OL base (i.e pseudoephedrine base) (Copy of approval letter attached with the report for perusal. Panel is of the view that firm must manufacture pilot batches for trial before start of commercial manufacturing of Tramadol HCL upon its formal approval of Central Licensing Board as per law. Firm must have calculation and recording of theoretical and practical yield for every batch along with complete record of materials used and keep these records as part of BMR as well as in consolidated and tabulated form. Manufacturing processes, process flow chart list of material intended to be used, undertaking by the firm to ensure the authorize use of all material with proper records, details of equipment of production and quality control department and list of technical staff duly signed by the firm / panel members are attached with this report for perusal of Central Licensing Board. Based on the documentations revealed and submitted by the firm, description mentioned above , physical inspection of the unit and previous approval of Central Licensing Board to manufacture a product as cited above by way of semi basic manufacturing method, Panel has recommended the facility for grant of new API i.e Tramadol HCI (USP 41 / Ph. EUR) by way of semi basic manufacturing method" **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of one additional API in the name of M/s Alpha Chemicals (Pvt) Ltd, 65-Km, Lahore-Multan National Highway Jamber Kalan, Tehsil Patoki, District Kasur under DML No. 000373 (Formulation); **Section (1)** 1. Tramadol HCI (USP / Ph. EUR)			
8.	M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-5, National Industrial Zone, Rawat DML No. 000718 (Formulation) Section (02)	08-07-2020	Good	i. Dr. Hafa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad. ii. Prof. Dr. Muhammad Usman, Member CLB. iii. Mr. Hasan Afzaal, Federal Inspector of Drugs, DRAP,

	1. Cream / Ointment Section (General). 2. Oral Dry powder for Sachet (General).			Lahore.

Recommendations of the panel: -

Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously Recommended M/s Medisynth Pharmaceutical, Plot No. 55, Street No. S-5, RCCI, Rawat, Rawalpindi for the following sections namely;

Sections (2)

1. Cream / Ointment Section (General).
2. Oral dry powder for Sachet (General).

Upon the completion of inspection the panel agreed upon the above statement, however prior to the formal endorsement of the report one of the panel member (Prof. Dr. Usman Member CLB) passed away. Hence the report is being submitted for the consideration of the board.

Decision of the Central Licensing Board in 276th meeting

The Board considered and deferred the grant of additional section in the name of M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-5, National Industrial Zone, Rawat as inspection was carried out by two members instead of Three (full) member of the constituted panel. The Board decided to re-inspect the premises and panel will be constituted by the Chairman Central Licensing Board.

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

Chairman Central Licensing Board constituted following panel for re-inspection of the firm:

1. Prof. Dr. Gul Majeed, Quaid-e-Azam University.
2. Additional Director (QA), DRAP.
3. Area Federal Inspector of Drugs, DRAP.

Panel conducted inspection of the firm on 12-10-2020.

Recommendations of the panel: -

"Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously Recommends M/s Medisynth Pharmaceutical, Plot No. 55, S-5, RCCI, Rawat for the following sections namely.

i. Cream / Ointment Section (General).

	ii. Oral Dry Powder for sachet (General) Section.". **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of additional section in the name of M/s Medisynth Pharmaceutical, Plot No. 55, S-5, RCCI, Rawat under DML No. 000718 (Formulation); **Section (2)** i. Cream / Ointment Section (General). ii. Oral Dry Powder for sachet (General) Section.".			
9.	M/s Mallard Pharmaceuticals (Pvt) Ltd, 23-Km, Lahore Road, Multan. DML No. 000622 (Formulation) Section (02) 1. External Preparation section (Veterinary). 2. Bolus Section (Veterinary).	13-08-2020	Good	1. Dr. Farzana Chowdhary, Member. 2. Dr. Ikram ul Haq Member Central Licensing Board. 3. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 4. Mr. Akbar Ali, 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 and Microbiology Laboratory, testing facilities, Technical Personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation M/s Mallard Pharmaceuticals (Pvt) Ltd, 23-Km, Lahore Road, Multan for the following sections.* *i. Powder Section (General) (Veterinary).* *ii. Powder Section (Antibiotics) (Veterinary).* *iii. Powder Section (Antibiotics) (Veterinary).* *iv. Liquid Injection Section (Veterinary).* *v. Repacking Section. (Veterinary)."* The panel of inspectors also recommend the grant of following additional sections. i. External Preparation section (Veterinary). ii. Bolus Section ((Veterinary).			

<table>
<tr><td></td><td colspan="4"><u>Decision of the Central Licensing Board in 277th meeting</u>
The Board considered and approved the grant of additional section in the name of M/s Mallard Pharmaceuticals (Pvt) Ltd, 23-Km, Lahore Road, Multan under DML No. 000718 (Formulation);

<u>Section (2)</u>
i. External Preparation section (Veterinary).
ii. Bolus Section ((Veterinary).</td></tr>
<tr><td>10.</td><td>M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore.

DML No. 000155 (Formulation)

<u>Section (03)</u>
1. Dry Powder Inhaler Capsule (Steroid) Section (New)
2. Capsule (General) Section (Revised).
3. Tablet (General) Section (Revised).</td><td>30-09-2020</td><td>Good</td><td>1. Dr. Ikram ul Haq Member Central Licensing Board.
2. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab.
3. Ms. Uzma Barkat, Federal Inspector of Drugs, DRAP, Lahore.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel: -</u>

“In the light of inspection conducted by the panel and based on the findings, the panel of inspectors recommends the grant of following to M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore for the following sections.

<u>Section (3)</u>
i. Dry Powder Inhaler Capsule (Steroid) Section (New)
ii. Capsule (General) Section (Revised).
iii. Tablet (General) Section (Revised)except Compression VI area”
<u>Decision of the Central Licensing Board in 277th meeting</u>
The Board considered and approved the grant of additional/ revised section in the name of M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore under DML No. 000155 (Formulation);

<u>Section (3)</u>
i. Dry Powder Inhaler Capsule (Steroid) Section (New)
ii. Capsule (General) Section (Revised).
iii. Tablet (General) Section (Revised)except Compression VI area”</td></tr>
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11	M/s Zenith Chemical Industries (Pvt) Moza Donday, Jia Baga, Raiwind Road, Lahore DML No. 000733(Semi Basic). **Sections for inspection:** change of starting material for synthesis of Moxifloxacin Hydrochloride".	**26-08-2020**	**-**	1. Dr. Ikram ul Haq, Membr, CLB, Islamabad. 2. Dr. Farzana Chaudhary, Member Appellate Board, DRAP, Islamabad. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.

The panel was constituted for manufacturing of following API's under DML No. 000733 by way Semi Basic on 5th August, 2020:-

i. API Chloroquine Phosphate (for approval of API).
ii. Moxifloxacin Hydrochloride (For change of starting material for Synthesis Moxifloxacin Hydrochloride).

In response to this Division's panel inspection letter dated 5th August, 2020 Mr. Ajmal Sohail Asif, FID, DRAP, Lahore, has submitted inspection report for grant of API's under Drug Manufacturing License No. 000733 by way (Semi Basic) of M/s Zenith Chemical Industries (Pvt) Moza Donday, Jia Baga, Raiwind Road, Lahore with following remarks:-

Focus of the Inspection.

The inspection was focused on verification of complete manufacturing process for Chloroquine Phosphate and change of starting materials for synthesis of Moxifloxacin Hyrochloride along with endorsement of starting / raw materials used in manufacturing process as per process flow chart diagram.

The management of the firm informed the panel that they could not develop the facility for manufacturing of Chloroquine Phosphate and requested to defer the inspection with reference to verification of manufacturing facility for Chloroquine Phosphate. In this regard the firm also submitted a letter (copy enclosed).

Recommendations of the panel: -

"In the light of above observations, scrutiny of documents, discussion with technical personnel and submitted documents, the panel recommends the approval of change of starting material for synthesis of **Moxifloxacin Hydrochloride**".

Decision of the Central Licensing Board in 277th meeting

The Board considered and approved the grant of additional API in the name of M/s Zenith Chemical Industries (Pvt) Moza Donday, Jia Baga, Raiwind Road, Lahore under DML No. 000733 (Formulation) from new pathway.

	API (1) 1. **Moxifloxacin Hydrochloride**			
12.	M/s Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhupura Road, Lahore DML No. 000323 by way (Formulation) **Grant of Section (01).** **i.** Oral Dry Powder (Penicillin) Section (Veterinary).	28-10-2019 and 02-10-2020	**Good**	1.Dr. Ikram-ul-Haq, Member, CLB, Islamabad. 2.Dr. Mehmood Ahmed, Expert Member. 3.Abdul Rashid Sheikh, FID, DRAP, Lahore.
	"Keeping in view the manufacturing facility like, building, HVAC System, sanitation, production machinery, equipment in Quality Control and microbiology laboratory, testing facilities, technical personnel met and documentation reviewed, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation and regularization for the following sections as per approved layout plan to M/s Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhupura Road, Lahore:- i. Liquid Injectable Section (Vial) (Veterinary) (General). ii. Liquid Injectable (Steroidal) Vials (Veterinary). iii. Oral Liquid Section (Veterinary). iv. Oral Powder Section (General) (Veterinary). v. Bolus Section (Veterinary). vi. Repacking Liquid / Powder Section (Veterinary). The panel of inspectors also recommend the grant of following additional sections: i. Oral Dry Powder (Penicillin) Section (Veterinary). The Board considered and approved the grant of additional/ revised section in the name of M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore under DML No. 000155 (Formulation); **Section (1)** 1. Oral Dry Powder (Penicillin) Section (Veterinary).			

Item-III: **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.**

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Standard Drug Company Plot No. E-6-A, S.I.T.E. Hyderabad DML No. 000118 (Formulation) **Period**. 12-07-2019 till 11-07-2024	**28-08-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director (E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.

Recommendations of the panel: -

Based on the stated observations, the panel recommends the renewal of DML No. 000118 and regularization of manufacturing facility for following sections.

1. Tablet (General)
2. Capsule (General)
3. Syrup (General)
4. Dry Suspension (General)
5. Ointment/External Preparation (General)
6. Warehouse
7. QC laboratory.

Decision of the Central Licensing Board in 277th meeting

The Board considered and approved the grant of renewal of (DML No. 000118) by way of formulation in the name of M/s Standard Drug Company Plot No. E-6-A, S.I.T.E. Hyderabad on the recommendations of the panel of experts for the period commencing on 16-02-2020 and ending on 15-02-2025for the following sections:

Sections / Facilities (7):

1. Tablet (General)
2. Capsule (General)
3. Syrup (General)
4. Dry Suspension (General)
5. Ointment/External Preparation (General)
6. Warehouse
7. QC laboratory.

<table>
<tr><td>2.</td><td>M/s. Le Mendoza Pharmaceutical (Pvt) Ltd,
Plot No. 7, Sector 23, Korangi Industrial Area,
<u>Karachi.</u>

DML No. 000140 (Formulation)

Period. 18-03-2020 till 17-03-2025</td><td>25-09-2020</td><td>Good</td><td>1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Director DTL, Karachi
3. Area FID, DRAP, Karachi.</td></tr>
<tr><td></td><td colspan="4">Recommendations of the panel: -

Based on the stated observations, the panel recommends the renewal of DML No. 000140 (Formulation) for following sections.

<table>
<tr><th>Sr. No</th><th>Name of Sections</th><th>Sr. No</th><th>Name of Sections</th></tr>
<tr><td>i.</td><td>Tablet (General)</td><td>ii.</td><td>Capsule (General)</td></tr>
<tr><td>iii.</td><td>Syrup (Oral Liquid) General</td><td>iv.</td><td>Oral Dry Powder Suspension (General Antibiotic)</td></tr>
<tr><td>v.</td><td>Topical (Cream/Ointment/Gel)</td><td>vi.</td><td>Injection (Ampoule)</td></tr>
</table>

<u>Decision of the Central Licensing Board in 277th meeting</u>

The Board considered and approved the grant of renewal of (DML No. 000140) by way of formulation in the name of M/s. Le Mendoza Pharmaceutical (Pvt) Ltd, Plot No. 7, Sector 23, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 18-03-2020 and ending on 17-03-2025 for the following sections:

Sections / Facilities (6):

<table>
<tr><th>Sr. No</th><th>Name of Sections</th><th>Sr. No</th><th>Name of Sections</th></tr>
<tr><td>i.</td><td>Tablet (General)</td><td>ii.</td><td>Capsule (General)</td></tr>
<tr><td>iii.</td><td>Syrup (Oral Liquid) General</td><td>iv.</td><td>Oral Dry Powder Suspension (General Antibiotic)</td></tr>
<tr><td>v.</td><td>Topical (Cream/Ointment/Gel)</td><td>vi.</td><td>Injection (Ampoule)</td></tr>
</table>
</td></tr>
<tr><td>3.</td><td>M/s Batala Pharmaceuticals, 23/B, Small Industrial Estate No. 2, Near Wapda Town, Khiali Bye-Pass, Gujranwala</td><td>06-12-2019</td><td>Good</td><td>7. Dr. Ikram ul Haq, Member CLB.
8. Dr Munawar Hayat, Chief Drugs Controller, Punjab.
9. Mr Ajmal Sohail Asif,</td></tr>
</table>

	DML No. 000477(Formulation). **Period**: 03-06-2015 to 02-06-2020			Federal Inspector of Drugs, DRAP, Lahore
	Recommendations of the panel: - "Based on the areas inspected, the technical people met and the documents reviewed and considering the findings of the inspection the panel verified a satisfactorily maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirement of DML as per Drug (Licensing, Registering and Advertising) Rules, 1976 and capacity & capability of the firm in respect of manufacturing and quality control of all registered products and approved sections. The Panel of Inspectors **Recommends** the renewal bearing DML No. 000477in favour of M/s Batala Pharmaceuticals, 23/B, Small Industrial Estate No. 2, Near Wapda Town, Khiali Bye-Pass, Gujranwala". **Decision of the Central Licensing Board in 277th meeting** The Board perused the inspection report of the firm conducted by the panel for renewal of Drug Manufacturing Licence for the period which is already complete and application for next tenure is filed.			
4.	M/s Brookes Pharma (Pvt) Ltd, Plot No. 58-59, Sector-15, Korangi Industrial Area, Karachi. DML No. 000275 (Formulation) **Period**. 19-07-2020 till 18-07-2025	**18-08-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director (E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.
	Recommendations of the panel: - Based on the people met, documents reviewed and observation noted by the panel and intention of the management for obtaining WHO pre-qualification and PICs etc, the panel unanimously recommends the grant of renewal of their DML by way of formulation. **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of renewal of (DML No. 000275) by way of formulation in the name of M/s Brookes Pharma (Pvt) Ltd, Plot No. 58-59, Sector-15, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 19-07-2020 and ending on 18-07-2025for the following sections:			

	SECTIONS/ FACILITIES (19)

Tablet (General) Section	Cream/Ointment/Gel Section (General)
Dry Powder Suspension (General)	Capsule Section (Pellet Mfg & Filling)
Raw Material Warehouse	Capsule Powder Section (General)
Topical Liquid (Spray) Solution	Oral Liquid Syrup Section (General)
Liquid Injection Section (Psychotropic)	Dry Powder Sachet (General)
Packaging Material Store	Oral Tablet Psychotropic Section
Quality Control Laboratory	External Liquid Section (Pyodine) Manufacturing Filling & Packing.
Liquid Injectable (SVP)	Warehouse (Cephalosporin)
Sterile Topical Solution (General)	Injectable Section (Cephalosporin)
Ampoule Compact Line	

5.	M/s The Searle Company Limited, Plot No. F-319, Sindh Industrial Trading Estate, Karachi. DML No. 000016 (Formulation) **Period**. 31-03-2020 till 30-03-2025	**08-10-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director (E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.

Recommendations of the panel: -

Based on the stated observations, the panel recommends Renewal and Amendments/ Expansions as following:

1. Tablet (General)- Amendment
2. Capsule (General) – Amendment
3. Sachet (General)
4. Injection Ampoule (General) Amendment
5. Oral Liquid (General)
6. Raw Material Store – Amendment
7. Packaging Material Ware House- Expansion
8. Microbiology Laboratory- Amendment
9. Research & Development Laboratory- Amendment

	Decision of the Central Licensing Board in 277th meeting The Board considered and approved the grant of renewal of (DML No. 000016) by way of formulation in the name of M/s The Searle Company Limited, Plot No. F-319, Sindh Industrial Trading Estate, Karachi on the recommendations of the panel of experts for the period commencing on 31-03-2020 and ending on 30-03-2025 **Sections / Facilities (2):-** 1. Sachet (General) 2. Oral Liquid (General)			
6.	M/s OBS Pakistan (Pvt) Ltd, Plot No. C-14, Manghopir Road, S.I.T.E, Karachi. DML No. 000012 (Formulation) **Period**. 31-03-2020 till 30-03-2025	**07-10-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Chief Drugs Inspector, Govt of Sindh, Karachi. 3. Area FID, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view overall GMP compliance and positive intention towards improvements, Panel unanimously recommends the renewal of (DML No. 000012) by way of Formulation and Grant of Amendments in Sections (i) Tablet (General) Section (ii) Liquid Vial SVP (General) Section and (iii) Change Room (General) to the firm M/s. OBS Pakistan (Private) Limited, C-14, Manghopir Road Karachi. It is pertinent to mention the Firm has approved section as Capsule (General), however in panel Inspection letter issued vide letter No. F.2-1/2004-Lic (Vol-II), dated 20th May 2020, it was mistakenly typed as Soft Gelatin Capsule (General), which may be corrected in Grant of DML letter. **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of renewal of (DML No. 000012) by way of formulation in the name of M/s OBS Pakistan (Pvt) Ltd, Plot No. C-14, Manghopir Road, S.I.T.E, Karachi on the recommendations of the panel of experts for the period commencing on 31-03-2020 and ending on 30-03-2025 for the fowling sections: **SECTIONS (5)** 1. Tablet (General) 2. Tablet (Hormone) 3. Liquid Vial SVP (General) 4. Soft Gelatin Capsule (Hormone) 5. Sachet (Hormone/ Soft Gel) It was apprised to the Board that the lay out plan of the firm was regularized on 16th July, 2014 with the title Soft Gelatin Capsule (General) and panel for renewal of Licence was constituted on			

	30th March, 2015 which also mention the section as Soft Gelatin Capsule (General). The inspection report of the panel dated 8-4-2015 also mention Soft Gelatin Capsule (General). The Board, therefore, decided to defer the section for further clarification the matter.			
8.	M/s. Aries Pharmaceuticals (Pvt) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar **DML No 000565 (Formulation)** **Period**: 31-12-2019 to 30-12-2024 **SECTIONS** 1. Tablet (General/Antibiotics-I) 2. Tablet (General/Antibiotics-II), 3. Tablet (Psychotropic), 4. Tablet(Steroidal Hormone) 5. Capsule (General), 6. Capsule (Cephalosporin), 7. Dry Syrup (General), 8. Dry powder Suspension (General), 9. Oral Liquid (General), 10. Liquid Syrup (Psychotropic) 11. Liquid Infusion/Vail (General) 12. Liquid injectable (Psychotropic) 13. Liquid Ampoule Injectable (General) 14. Dry Powder Injection (General) 15. Dry Powder Vail Injectable (Cephalosporin)	04-09-2020	**Good**	1. Prof. Dr. Jamshed Ali Khan, Department of Pharmacy, Peshawar University, Peshawar (Member CLB) 2. Dr. Masud ur Rehman, Director (Lic), DRAP, Islamabad. 3. Area Federal Inspector of Drugs, DRAP, Peshawar. 4. Assistant Director-III, DRAP, Islamabad.
	Recommendations of the panel: - Keeping in view the above facts on record and the people met during the visit, the			

	panel unanimously recommended the renewal of DML by Way of Formulation (000565) of M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of renewal of (DML No. 000565) by way of formulation in the name of M/s. Aries Pharmaceuticals (Pvt) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar on the recommendations of the panel of experts for the period commencing on 31-12-2019 and ending on 30-12-2024 for the following sections:- **SECTIONS (15)** 1. Tablet (General/Antibiotics-I) 2. Tablet (General/Antibiotics-II), 3. Tablet (Psychotropic), 4. Tablet(Steroidal Hormone) 5. Capsule (General), 6. Capsule (Cephalosporin), 7. Dry Syrup (General), 8. Dry powder Suspension (General), 9. Oral Liquid (General), 10. Liquid Syrup (Psychotropic) 11. Liquid Infusion/Vail (General) 12. Liquid injectable (Psychotropic) 13. Liquid Ampoule Injectable (General) 14. Dry Powder Injection (General) 15. Dry Powder Vail Injectable (Cephalosporin)			
9.	M/s Shaheen Pharmaceuticals, 3-Km, Murghzar Road, Saidu Sharif, Swat DML No. 000562 (formulation) **Period**: 31-12-2019 to 30-12-2024 **SECTIONS** 1. Tablet (General/Antibiotics), 2. Tablet (Psychotropic), 3. Capsule (General), 4. Dry powder Suspension	18-09-2020 & 05-10-2020	**Good**	1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Dr. Masud ur Rehman Director (Licensing), DRAP, Islamabad. 3. Area Federal Inspector of Drugs, DRAP, Peshawar

<table>
<tr><td></td><td>(General),
5. Oral Liquid (General),</td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="4">Recommendations of the panel: -
Keeping in view the above the panel unanimously recommends the renewal of DML by The Way of Formulation (000562) of M/s Shaheen Pharmaceuticals, 3-Km, Murghzar Road, Saidu Sharif, Swat.

<u>Decision of the Central Licensing Board in 277th meeting</u>
The Board considered and approved the grant of renewal of (DML No. 000562) by way of formulation in the name of M/s Shaheen Pharmaceuticals, 3-Km, Murghzar Road, Saidu Sharif, Swat on the recommendations of the panel of experts for the period commencing on 31-12-2019 and ending on 30-12-2024 for the following sections:-

<u>SECTIONS (5)</u>

1. Tablet (General/Antibiotics),
2. Tablet (Psychotropic),
3. Capsule (General),
4. Dry powder Suspension (General),
5. Oral Liquid (General),</td></tr>
<tr><td>10.</td><td>M/s Mediate Pharmaceutical (Pvt) Ltd, Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi.

DML No. 000167 (Formulation)

Period.

18-11-2020 till 17-11-2025</td><td>09-10-2020</td><td>Good</td><td>1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Chief Drugs Inspector, Govt of Sindh, Karachi.
3. Area FID, DRAP, Karachi.</td></tr>
<tr><td></td><td colspan="4">Recommendations of the panel: -
Based on the people met, documents reviewed and observation made during the inspection, panel recommends the grant of renewal of Drug Manufacturing License No. 000167 by way of Formulation for following sections:-

<table>
<tr><th>Sr. No</th><th>Name of Sections</th><th>Sr. No</th><th>Name of Sections</th></tr>
<tr><td>1.</td><td>Tablet (General)</td><td>2.</td><td>Tablet (Quinolone)</td></tr>
<tr><td>3.</td><td>Tablet (Psychotropic)</td><td>4.</td><td>Liquid syrup (General)</td></tr>
</table>
</td></tr>
</table>

5.	Ointment	6.	Liquid ampoule (General)
7.	Liquid Injection (Psychotropic)	8.	Infusion (General Antibiotic)
9.	Dry Powder Injectable (Cephalosporin)	10.	Capsule (Cephalosporin)
11.	Oral Dry Powder Suspension (cephalosporin)	12.	Capsule(General)
13.	Oral Dry Powder Suspension antibiotic (General)	14.	Dry Powder (General) Injection
15.	Dry Powder Suspension (Penicillin)	16.	Capsule (Penicillin)

Decision of the Central Licensing Board in 277th meeting

The Board considered and approved the grant of renewal of (DML No. 000167) by way of formulation in the name of M/s Mediate Pharmaceutical (Pvt) Ltd, Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 18-11-2020 and ending on 17-11-2025 for the following sections:-

SECTIONS (16)

Sr. No	Name of Sections	Sr. No	Name of Sections
1.	Tablet (General)	2.	Tablet (Quinolone)
3.	Tablet (Psychotropic)	4.	Liquid syrup (General)
5.	Ointment	6.	Liquid ampoule (General)
7.	Liquid Injection (Psychotropic)	8.	Infusion (General Antibiotic)
9.	Dry Powder Injectable (Cephalosporin)	10.	Capsule (Cephalosporin)
11.	Oral Dry Powder Suspension (cephalosporin)	12.	Capsule(General)
13.	Oral Dry Powder Suspension antibiotic (General)	14.	Dry Powder (General) Injection
15.	Dry Powder Suspension (Penicillin)	16.	Capsule (Penicillin)

11.	M/s. Ferozsons Laboratories Ltd., Amangarh, Nowshera,	**02/10/2020**	**V. Good**	1. Prof. Dr. Jamshed Ali Khan, Department of

	Khyber Pakhtunkhwa **DML No 000038 (Formulation)** **Period**: **03-05-2020 to 02-05-2025** **<u>SECTIONS</u>** 1. Tablet (General) 2. Tablet (Psychotropic / Narcotics), 3. Capsule (General), 4. Dry Syrup / Dry powder for Suspension (General), 5. Liquid Syrup / Suspension (General), 6. Sachet (general) 7. Ointment / Cream (General) **8. Steroid Cream / Ointment / Gel (New Section)**			Pharmacy, Peshawar University, Peshawar (Member CLB) 2. Dr. Masud ur Rehman, Director (Lic), DRAP, Islamabad. 3. Area Federal Inspector of Drugs, DRAP, Peshawar.

<u>Recommendations of the panel: -</u>

"Based on the areas inspected, the people met, documents reviewed, the intension towards further improvement and the corrective and preventive action taken, M/s. Ferozsons Laboratories Ltd., Nawshera KPK is considered to be operating at very good level of compliance with cGMP guidelines as per Drugs Act 1976 and Rules framed thereunder.

*As per Manufacturing/Testing equipment installed in the production, quality control, microbial Labs, Products development Lab, utilities, engineering as well as the cGMP compliance status of the firm, the panel unanimously **recommended** the grant of renewal of DML No.000038 by way of Formulation and following one additional steroid section for ointment/Cream Manufacturing*

i. Cream/ointment/Gel Section (Steroid)

<u>Decision of the Central Licensing Board in 277th meeting</u>

The Board considered and approved the grant of renewal of (DML No. 000038) by way of formulation in the name of M/s. Ferozsons Laboratories Ltd., Amangarh, Nowshera, Khyber Pakhtunkhwa on the recommendations of the panel of experts for the period commencing on 03-05-2020 and ending on 02-05-2025 for the following sections:-

SECTIONS (07)

1. Tablet (General)
2. Tablet (Psychotropic / Narcotics),
3. Capsule (General),
4. Dry Syrup / Dry powder for Suspension (General),
5. Liquid Syrup / Suspension (General),
6. Sachet (general)
7. Ointment / Cream (General)

12.	M/s Amros Pharmaceuticals, Plot No. A-96, SITE, Super Highway, Karachi. DML No. 000406 (Formulation) **Period**. 19-06-2020 till 18-06-2025	**13-10-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director (E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.

***Recommendations of the panel**: -*

Keeping in view the stated condition, people met, documents reviewed and attitude of the firm for continuous improvements the panel unanimously recommends the grant of renewal of DML No. 000406 Formulation for the next five years due from 19/06/2020.

Decision of the Central Licensing Board in 277th meeting

The Board considered and approved the grant of renewal of (DML No. 000406) by way of formulation in the name of M/s Amros Pharmaceuticals, Plot No. A-96, SITE, Super Highway, Karachi on the recommendations of the panel of experts for the period commencing on 19-06-2020 and ending on 18-06-2025 for the following sections:-

SECTIONS / FACILITIES (18)

NAME OF SECTIONS IN GROUND FLOOR	NAME OF SECTIONS IN FIRST FLOOR

	Tablet Section (General) Tablet Section (Psychotropic) Cream / Ointment section (General) Oral Dry Powder Suspension Section (General anti biotic) Capsule Section (General) Injectable Section (General) Ear / Eye Drops Section (Sterile) Oral Liquid Section (General) Warehouse		Dry Powder Suspension Section (Cephalosporin)- Capsule Section (Cephalosporin) Injectable section (Cephalosporin) Warehouse (Cephalosporin) Dry Powder Suspension Section (Penicillin) Capsule Section (Penicillin) Injectable section (Veterinary) Tablet Section (Penicillin) Raw Material Store (Penicillin)	
13.	M/s Mallard Pharmaceuticals (Pvt) Ltd, 23-Km, Lahore Road, Multan. DML No. 000622 (Formulation) **Period**: 29-08-2017 to 28-07-2022.	13-08-2020	**Good**	1. Dr. Farzana Chowdhary, Member. 2. Dr. Ikram ul Haq Member Central Licensing Board. 3. Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 4. Mr. Akbar Ali, 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 and Microbiology Laboratory,*			

	testing facilities, Technical Personnel met and documentation, the panel of inspectors ***recommends*** *the renewal of Drug Manufacturing License by way of formulation M/s Mallard Pharmaceuticals (Pvt) Ltd, 23-Km, Lahore Road, Multan for the following sections.* 1. *Powder Section (General) (Veterinary).* 2. *Powder Section (Antibiotics) (Veterinary).* 3. *Powder Section (Antibiotics) (Veterinary).* 4. *Liquid Injection Section (Veterinary).* 5. *Repacking Section. (Veterinary).***"** The panel of inspectors also **recommend** the grant of following additional sections. i. External Preparation section (Veterinary). ii. Bolus Section ((Veterinary). **<u>Decision of the Central Licensing Board in 277th meeting</u>** The Board considered and approved the grant of renewal of (DML No. 000622) by way of formulation in the name of M/s Mallard Pharmaceuticals (Pvt) Ltd, 23-Km, Lahore Road, Multan on the recommendations of the panel of experts for the period commencing on 29-08-2017 and ending on 28-07-2022 for the following sections:- **<u>SECTIONS (05)</u>** 1. *Powder Section (General) (Veterinary).* 2. *Powder Section (Antibiotics) (Veterinary).* 3. *Powder Section (Antibiotics) (Veterinary).* 4. *Liquid Injection Section (Veterinary).* 5. *Repacking Section. (Veterinary).***"**			
14.	M/s Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhupura Road, Lahore DML No. 000323 by way (Formulation) **<u>Regularization of Sections (06)</u>** i. Liquid Injectable Section (Vial) (Veterinary) (General). ii. Liquid Injectable (Steroidal) Vials (Veterinary). iii. Oral Liquid Section (Veterinary). iv. Oral Powder Section (General)	28-10-2019 and 02-10-2020	**Good**	1. Dr. Ikram-ul-Haq, Member, CLB, Islamabad. 2. Dr. Mehmood Ahmed, Expert Member. 3. Abdul Rashid Sheikh, FID, DRAP, Lahore.

	(Veterinary). v. Bolus Section (Veterinary). vi. Repacking Liquid / Powder Section (Veterinary). **Grant of Section (01)** **i.** Oral Dry Powder (Penicillin) Section (Veterinary). **Period**: 18-10-2015 to 18-10-2020.			
	"Keeping in view the manufacturing facility like, building, HVAC System, sanitation, production machinery, equipment in Quality Control and microbiology laboratory, testing facilities, technical personnel met and documentation reviewed, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation and regularization for the following sections as per approved layout plan to M/s Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhupura Road, Lahore:- i. Liquid Injectable Section (Vial) (Veterinary) (General). ii. Liquid Injectable (Steroidal) Vials (Veterinary). iii. Oral Liquid Section (Veterinary). iv. Oral Powder Section (General) (Veterinary). v. Bolus Section (Veterinary). vi. Repacking Liquid / Powder Section (Veterinary). The panel of inspectors also recommend the grant of following additional sections: ii. Oral Dry Powder (Penicillin) Section (Veterinary). **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of renewal of (DML No. 000323) by way of formulation in the name of M/s Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhupura Road, Lahore on the recommendations of the panel of experts for the period commencing on 18-10-2015 and ending on 18-10-2020.			
15.	M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore DML No. 000799 by way (Formulation) **Sections (03)** i. Tablet Section (General). ii. Capsule Section (General). iii. Oral Liquid Section (General).	**30.09.2020**	**Good**	1. Dr. Farzanan Chaudhary Expert member, Lahore 2. Chief Drug Controller Punjab . 3. Area Federal Inspector of Drugs, Lahore .

	Period: 03-07-2019 to 02-07-2024.			
	"Keeping in view the facilities like Building, HVAC System, Purified Water, Other Utlities, Production Machinery & Equipments, Personnel, Documentation, Quality Control Instruments and Testing facilities; the panel of inspectors is of the opinion to recommend the renewal of Drug Manufacturing License to M/s Titlis Pharma, Lahore for the following sections". i. Tablet Section (General). ii. Capsule Section (General). iii. Oral Liquid Section (General). **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of renewal of (DML No. 000799) by way of formulation in the name of M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore on the recommendations of the panel of experts for the period commencing on 03-07-2019 and ending on 02-07-2024 for the following sections:- **SECTIONS (03)** i. Tablet Section (General). ii. Capsule Section (General). iii. Oral Liquid Section (General).			
16.	M/s Lawari International, Valley Road, Gulkada, Saidu Sharif, **Swat.** **DML No 000658** **Period: 30-01-2019 to 29-01-2024** **Sections** 1. Tablet (General) 2. Capsule (General),	05-09-2020	**Good**	1. Prof. Dr. Muhammad Jamshaid, Member Central Licensing Board 2. Dr. Muhammad Abbas, Chief Inspector of Drugs, Khyber Pakhtunkwa, Peshawar 3. Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Peshawar"
	"Keeping in view the above, the Panel unanimously recommends the grant of renewal of DML NO. 000658 by way of formulation to M/s Lawari International, Valley Road, Gulkada, Saidu Sharif, Swat and resumption of production in the manufacturing facilities" **Decision of the Central Licensing Board in 277th meeting** The Board considered and approved the grant of renewal of (DML No. 000799) by way of formulation in the name of M/s Lawari International, Valley Road, Gulkada, Saidu Sharif, **Swat** on the recommendations of the panel of experts for the period commencing on **30-01-2019** and			

	ending on **29-01-2024** for the following sections:- **<u>SECTIONS (02)</u>** 1. Tablet (General) 2. Capsule (General),

ITEM – IV MISC CASES

CASE NO. 1 CHANGE OF MANAGEMENT OF M/S BIO-OXIME PHARMACEUTICALS FAISALABAD.

M/s Bio-Oxime Pharmaceuticals, Plot No. 31-32, Millat Garment City, Dry Port Road, Faisalabad under DML No. 000812 by way of Formulation has submitted request for change in management of the firm as per Partnership Deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as per form-1A	Current Management as per Partnership Deed
1. Mr. Abdul Razzak. 2. Mr. Muhammad Ajmal Jlvi.	1. Mr. Muhammad Ajmal Jlvi S/o Umer Din CNIC No. 38103-0666341-9. 2. Mr. Akhtar Ali S/o Nasir Khan CNIC No. 38201-9838280-3.

Decision of the Central Licensing Board in 277th meeting:

The Board considered and endorsed the change of management of M/s Bio-Oxime Pharmaceuticals, Plot No. 31-32, Millat Garment City, Dry Port Road, Faisalabad under DML No. 000812 by way of formulation as under:-

Previous Management	New Management as per Partnership Deed
3. Mr. Abdul Razzak. 4. Mr. Muhammad Ajmal Jlvi.	3. Mr. Muhammad Ajmal Jlvi S/o Umer Din CNIC No. 38103-0666341-9. 4. Mr. Akhtar Ali S/o Nasir Khan CNIC No. 38201-9838280-3.

CASE NO.2 CHANGE OF MANAGEMENT OF M/S MEDISEARCH PHARMACAL (PVT) LTD, LAHORE.

M/s Medisearch Pharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore under DML No. 000549 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-A	New Management as per Form-29
1. Mr. Uzair Nagra S/o Zafar Iqbal Nagra CNIC No. 35200-6402918-7. 2. Ms. Munzza Adeeb W/o Zafar Iqbal Nagra CNIC No. 35200-4345926-8.	1. Mr. Muhammad Haris Nagra S/o Zafar Iqbal Nagra CNIC No. 35200-3464301-9 2. Mr. Uzair Nagra S/o Zafar Iqbal Nagra CNIC No. 35200-6402918-7

Decision of the Central Licensing Board in 277th meeting:

The Board considered and endorsed the change of management of M/s Medisearch Pharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore under DML No. 000549 by way of formulation as under:-

Previous Management as per Form-A	New Management as per Form-29
1. Mr. Uzair Nagra S/o Zafar Iqbal Nagra CNIC No. 35200-6402918-7. 2. Ms. MunzzaAdeeb W/o Zafar Iqbal Nagra CNIC No. 35200-4345926-8.	1. Mr. Muhammad Haris Nagra S/o Zafar Iqbal Nagra CNIC No. 35200-3464301-9 2. Mr. Uzair Nagra S/o Zafar Iqbal Nagra CNIC No. 35200-6402918-7 .

CASE NO.3 CHANGE OF MANAGEMENT OF M/S HAMAZ PHARMACEUTICALS (PVT) LTD, MULTAN.

M/s Hamaz Pharmaceuticals (Pvt) Ltd, 13-Km, Bosan Road, Lutafabad Multan under DML No. 000427 by way of Formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	Current Management as per Form-29
1. Mr. Muhammad zafar Iqbal. 2. Mr. Shakeel Azhar. 3. Mr. Adnan Zafar. 4. Mr. Saleem Abu Bakar.	1. Mr. Muhammad Zafar Iqbal S/o Sardar Imam Bukhsh Khan CNIC No.36302-6724337-1. 2. Mr. Imran Manzoor S/o Manzoor Afshar CNIC No. 36302-3539145-3.

Decision of the Central Licensing Board in 277th meeting:

The Board considered and endorsed the change of management of M/s Hamaz Pharmaceuticals (Pvt) Ltd, 13-Km,Bosan Road, Lutafabad Multan under DML No. 000427 by way of formulation as under:-

Previous Management	New Management as per Form-29
5. Mr. Muhammad zafar Iqbal. 6. Mr. Shakeel Azhar. 7. Mr. Adnan Zafar. 8. Mr. Saleem Abu Bakar.	1. Mr. Muhammad zafar Iqbal S/o Sardar Imam Bukhsh Khan CNIC No.36302-6724337-1. 2. Mr. Imran Manzoor S/o Manzoor Afshar CNIC No. 36302-3539145-3.

CaseNo.4 **CHANGE OF NAME / TITLE AND MANAGEMENT OF M/S BAYER PAKISTAN (PVT) LTD, PLOT NO. C-21, S.I.T.E. KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000003(FORMULATION).**

M/s Bayer Pakistan (Pvt) Ltd, Plot No. C-21, S.I.T.E. Karachi, has submitted request for Change of Name / Title with fee of Rs.1,00,000/-. The pre-requisite documents of the change of name / title and management are as under: -

i. Change of Name/Title.

Current Title as per Form-29 & Form-A Year 2020	New Title as per Form-29 Year 2020
M/s Bayer Pakistan (Pvt) Ltd, Plot No. C-21, S.I.T.E. Karachi	M/s Novartis Pharma Pakistan Limited, Plot No. C-21, S.I.T.E. Karachi.

ii. Change of Management.

Current Management as per Form-29 & Form-A	New Management as per Form-29 Year 2020
1. Mr. Imran Ahmed Khan S/o Anwar Ahmad Khan CNIC No. 35202-0840996-1. 2. Mr. Muhammad Shafiq S/o Muhammad Rafiq Moti CNIC No. 42301-5878799-9	1. Mr. Imran Rasheed S/o Abdul Rasheed CNIC No. 37405-9936790-1. 2. Mr. Ziad bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhrey CNIC No. 42000-0519991-5. 3. Mr. Badaruddin fatehali vellani S/o fatehali Wali

	Muhammad vellani CNIC No. 42301-0918221-7. 4. Mr. Syed Khalid Noor S/o Syed Muhammad Noor ul huda CNIC No.42201-0506204-1. 5. Mr. Christopher Snook S/o David Patrick Snook Passport No. 507622357.

Decision of the Central Licensing Board in 277th meeting:

The Board considered, approved that change of title and endorsed the change of management of M/s Bayer Pakistan (Pvt) Ltd, Plot No. C-21, S.I.T.E. Karachi under DML No. 000003 by way of formulation as under:-

i. Change of Name/Title.

Current Title as per Form-29 & Form-A Year 2020	New Title as per Form-29 Year 2020
M/s Bayer Pakistan (Pvt) Ltd, Plot No. C-21, S.I.T.E. Karachi	M/s Novartis Pharma Pakistan Limited, Plot No. C-21, S.I.T.E. Karachi.

ii. Change of Management.

Current Management as per Form-29 & Form-A	New Management as per Form-29 Year 2020
1. Mr. Imran Ahmed Khan S/o Anwar Ahmad Khan CNIC No. 35202-0840996-1. 2. Mr. Muhammad Shafiq S/o Muhammad Rafiq Moti CNIC No. 42301-5878799-9	1. Mr. Imran Rasheed S/o Abdul Rasheed CNIC No. 37405-9936790-1. 2. Mr. Ziad bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhrey CNIC No. 42000-0519991-5. 3. Mr. Badaruddin fatehali vellani S/o fatehali Wali Muhammad vellani CNIC No. 42301-0918221-7. 4. Mr. Syed Khalid Noor S/o Syed Muhammad Noor ul huda CNIC No.42201-0506204-1. 5. Mr. Christopher Snook S/o David Patrick Snook Passport No. 507622357.

Case No.5. CHANGE OF MANAGEMENT OF M/S CARAWAY PHARMACEUTICALS,RAWAT.

M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone (RCCI) Rawat under DML No. 000629 by way of Formulation has submitted request for change in management of the firm as per Partnership Deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as per Partnership Deed	Current Management as per Partnership Deed
1. Mr. Muhammad Farooq Malik S/o Muhammad Anwar Malik CNIC No. 37405-6135233-7. 2. Mrs. Nighat Shaheen W/o Muhammad Farooq Malik CNIC No. 37405-5248041-2.	3. Mr. Muhammad Farooq Malik S/o Muhammad Anwar Malik CNIC No. 37405-6135233-7. 4. Mr. Sharjeel Farooq S/o Muhammad Farooq Malik CNIC No. 37405-5262860-7. 5. Mrs. Nighat Shaheen W/o Muhammad Farooq Malik CNIC No. 37405-5248041-2.

Decision of the Central Licensing Board in 277th meeting:

The Board considered and endorsed the change of management of M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone (RCCI) Rawat under DML No. 000629 by way of formulation as under:-

Previous Management as per Partnership Deed	New Management as per Partnership Deed
1. Mr. Muhammad Farooq Malik S/o Muhammad Anwar Malik CNIC No. 37405-6135233-7. 2. Mrs. Nighat Shaheen W/o Muhammad Farooq Malik CNIC No. 37405-5248041-2.	1. Mr. Muhammad Farooq Malik S/o Muhammad Anwar Malik CNIC No. 37405-6135233-7. 2. Mr. Sharjeel Farooq S/o Muhammad Farooq Malik CNIC No. 37405-5262860-7. 3. Mrs. Nighat Shaheen W/o Muhammad Farooq Malik CNIC No. 37405-5248041-2.

Case No.6. **WITHDRAWAL OF LICENSED SECTION BY M/S BIO FINE PHARMACEUTICALS (PVT) LTD MULTAN UNDER DRUG MANUFACTURING LICENSE NO. 000334 (FORMULATION).**

M/s. Bio Fine Pharmaceuticals (Pvt) Ltd, 74- Industrial Estate,Multan under DML No. 000334 by way of Formulation has submitted request for withdrawal of license of External Preparation Section.

Decision of the Central Licensing Board in 277th meeting:

The Board considered and acceded the request of M/s. Bio Fine Pharmaceuticals (Pvt) Ltd, 74-Industrial Estate, Multan under DML No. 000334 by way of Formulation for withdrawl of External Preparation Section. The External Preparation Section is cancelled being withdrawn with immediate effect. Manufacturing of drugs in the said section at said premised is prohibited and punishable offence under Section 23 and 27 of the Drugs Act, 1976 and rules framed thereunder.

Case No. 7. **REGULARIZATION OF LAYOUT PLAN OF M/S SYMANS PHARMACEUTICALS (PVT) LTD, 10-KM, SHEIKHUPURA ROAD, LAHORE**

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
	M/s Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhupura Road, Lahore DML No. 000323 by way (Formulation) **Regularization of Sections (06)** i. Liquid Injectable Section (Vial) (Veterinary) (General). ii. Liquid Injectable (Steroidal) Vials (Veterinary). iii. Oral Liquid Section (Veterinary).	28-10-2019 and 02-10-2020	**Good**	1. Dr. Ikram-ul-Haq, Member, CLB, Islamabad. 2. Dr. Mehmood Ahmed, Expert Member. 3. Abdul Rashid Sheikh, FID, DRAP, Lahore.

	iv. Oral Powder Section (General) (Veterinary). v. Bolus Section (Veterinary). vi. Repacking Liquid / Powder Section (Veterinary).			
	"Keeping in view the manufacturing facility like, building, HVAC System, sanitation, production machinery, equipment in Quality Control and microbiology laboratory, testing facilities, technical personnel met and documentation reviewed, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation and regularization for the following sections as per approved layout plan to M/s Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhupura Road, Lahore:- i. Liquid Injectable Section (Vial) (Veterinary) (General). ii. Liquid Injectable (Steroidal) Vials (Veterinary). iii. Oral Liquid Section (Veterinary). iv. Oral Powder Section (General) (Veterinary). v. Bolus Section (Veterinary). vi. Repacking Liquid / Powder Section (Veterinary). The panel of inspectors also recommend the grant of following additional sections: i. Oral Dry Powder (Penicillin) Section (Veterinary).			

Decision of the Central Licensing Board in 277th meeting:

The Board considered and approved the regularization of M/s Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhupura Road, Lahore DML No. 000323 by way (Formulation) on the recommendation of panel of experts for the following sections:-

Sections (06)

1. Liquid Injectable Section (Vial) (Veterinary) (General).
2. Liquid Injectable (Steroidal) Vials (Veterinary).
3. Oral Liquid Section (Veterinary).
4. Oral Powder Section (General) (Veterinary).
5. Bolus Section (Veterinary).
6. Repacking Liquid / Powder Section (Veterinary).

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

M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore had applied for renewal of DML No. 000555 by way of Formulation for the period of 01-11-2019 to 31-10-2024 on 28-10-2019.

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 19thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Detail of management, if any change, apply for change of management.
iii. Latest certified true copy of Form-29 (duly attested by SECP).
iv. Duly attested CNIC copies of all Directors.
v. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.
vi. Nothing due certificate regarding CRF from STO (Updated).

The firm replied to this letter on 21st April, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 19thMay, 2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 duly attested by SECP (original)
iii. Section approval letters, if not available, apply for regularization of Layout Plan of Cream / Ointment, Sachet & Dry Powder Syrup Sections.
iv. Nothing due certificate regarding CRF from STO (Updated).
v. Prescribed fee of 50,000/- for change in management, as there is change in management of the firm.

The firm did not reply to reminder and application for renewal of DML is still incomplete with following documents being deficient.

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 duly attested by SECP (original)
iii. Section approval letters, if not available, apply for regularization of Layout Plan of Cream / Ointment, Sachet & Dry Powder Syrup Sections.
iv. Nothing due certificate regarding CRF from STO (Updated).
v. Prescribed fee of 50,000/- for change in management, as there is change in management of the firm.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000555 by way of formulation of M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore, may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

Case No. 9 SITE APPROVAL OF M/S BIOSKILLS PHARMACEUTICALS, GUJRANWALA.

M/s Bioskills Pharmaceuticals, Gujranwala has filed application that the firm intends to convert their already approved site for establishment of Nutraceutical (Veterinary) unit into Pharmaceutical (Veterinary) unit at site located at Khewat No. 18, Khatooni No. 33-37, 4-Km, Tamboly, GT Road, Sadhoke, District Gujranwala. Site inspection was conduction by FID on 24-09-2019 for establishment of Nutraceutical Unit and as per inspection report, the proposed site is an agricultural area and plot is not located in commercial or residential area. Total size of the plot is 7-Kanals and 8 marlas approx. out which the firm allocated 3 kanals for Nutraceutical unit.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and observed that site verifications are carried through federal Inspector of Drugs by the Division of Licensing, Division of Health and OTC Products and even Division of Medical Devices and Medicated Cosmetics. The Board therefore, decided that once site is verified by Federal Inspector of Drugs shall be considered for establishment of pharmaceutical unit subject fulfillment of other codal fornalities.

Case No. 10 <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ALI INDUSTRIES, LAHORE.</u>

M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000222 by way of Formulation for the period of 24-10-2018 to 23-10-2023 on 16-10-2018.

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 7th November, 2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A as per format.
ii. Detail of management at the time of previous renewal and at present if any change, prescribed fee of Rs. 50,000/ alongwith proper application for change of management.
iii. CNIC Copies of all Partners.
iv. Copy of partnership deed issued by the Registrar of firm.
v. Proof of Sections approved by CLB, If not available, apply for regularization of layout plan.
vi. Approval letters of technical staff.
vii. All documents should be duly attested.

The firm replied to this letter on 24th February, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 18th August, 2020 to the firm for completion of application:

i. Copy of partnership deed.
ii. Copy of final sale deed.
iii. Copy of CNIC Copies of all participants mentioned in provisional sale deed.
iv. Copy of succession certificate as mentioned in provisional sale deed
v. **All documents should be notarized.**

The firm replied to reminder on 4th September, 2020 and application for renewal of DML is still incomplete with following documents being deficient.

i. Copy of final sale deed.
ii. Copy of succession certificate as mentioned in provisional sale deed

iii. **All documents should be notarized.**

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000222 by way of formulation of M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 11 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ENVOY PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Envoy Pharmaceuticals (Pvt) Ltd, 27-Km, Multan Road, Maraka Lahore had applied for renewal of DML No. 000607 by way of Formulation for the period of 21-03-2017 to 20-03-2022 on 14-03-2017 and approval of production Incharge.

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 21st April, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form-29 from SECP.
ii. Fee for change of management.
iii. Detail of previous and new management contents & their attested CNIC copies and concerns.
iv. Experience certificates as under Drugs (Licensing, Registering, Advertising) Rules, 1976 (Not less than 10 years).
v. Resignation or termination letter of appointee from previous firm/promotion letter/transfer letter from same firm.
vi. All documents should be duly attested.

The firm did not reply to this letter and final reminder letter was issued on 26th February, 2020 to the firm for submission of following documents:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Duly attested CNIC copies of all Directors.
iv. Prescribed fee of Rs. 50,000/- for change in management of the firm as there has been change in management of the firm.
v. Complete set of duly attested documents of proposed Production Incharge (as per checklist)
vi. Updated Nothing Due Certificate regarding CRF from STO (R&D),DRAP.
vii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm did not reply and application for renewal of DML is still incomplete with following documents being deficient.

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Duly attested CNIC copies of all Directors.
iv. Prescribed fee of Rs. 50,000/- for change in management of the firm as there has been change in management of the firm.
v. Complete set of duly attested documents of proposed Production Incharge (as per checklist)
vi. Updated Nothing Due Certificate regarding CRF from STO (R&D),DRAP.
vii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000607 by way of formulation of M/s Envoy Pharmaceuticals (Pvt) Ltd, 27-Km, Multan Road, Maraka Lahore may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

CASE NO.12. REGULARIZATION OF LAYOUT PLAN OF M/S STANDARD DRUG COMPANY., PLOT NO. E-6-A, S.I.T.E. HYDERABAD

M/s Standard Drug Company Hyderabad., Plot No. E-6-A, S.I.T.E, Hyderabad DML No. 000118 (Formulation), has applied for regularization of layout plan of running facility for their existing following sections;

1. Tablet (General)
2. Capsule (General)
3. Syrup (General)
4. Dry Suspension (General)
5. Ointment/External Preparation (General)
6. Warehouse
7. QC laboratory

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Additional Director (E&M), DRAP, Karachi.
3. Area FID, DRAP, Karachi

Accordingly, Panel has inspected the premises and verified the below mentioned section.

Recommendations of the panel: -

Based on the stated observations, the panel recommends the renewal of DML No. 000118 and regularization of manufacturing facility for following sections.

1. Tablet (General)
2. Capsule (General)
3. Syrup (General)
4. Dry Suspension (General)
5. Ointment/External Preparation (General)
6. Warehouse
7. QC laboratory.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s Standard Drug Company Hyderabad., Plot No.E-6-A, S.I.T.E, Hyderabad DML No. 000118 (Formulation) on the recommendation of panel of experts for the following sections:-

SECTIONS / FACILITIES (7)

1. Tablet (General)
2. Capsule (General)
3. Syrup (General)
4. Dry Suspension (General)

5. Ointment/External Preparation (General)
6. Warehouse
7. QC laboratory.

CaseNo.13 **CHANGE OF NAME / TITLE OF M/S DOW UNIVERSITY OF HEALTH SCIENCES, OJHA CAMPUS, SUPARCO ROAD, OFF MAIN UNIVERSITY ROAD, KARACHI.**

M/s Dow University of Health Sciences, Ojha Campus Road, Off Main University Road, Karachi, has submitted request for Change of Name / Title with fee of Rs.50,000/-. The pre-requisite documents of the change of name / title and management are as under: -

i. Change of Name/Title.

Previous Name	**New Name**
M/s Dow University of Health Sciences, Karachi.	M/s Dow Institute of Life Sciences, Karachi.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considered the case and approved change of title M/s Dow University of Health Sciences, Ojha Campus Road, Off Main University Road, Karachi as under:

Previous Name	**New Name**
M/s Dow University of Health Sciences, Karachi.	M/s Dow Institute of Life Sciences, Karachi.

Case No. 14. **APPROVAL OF LAYOUT PLAN FOR REGULARIZATION OF PENDING DRY POWDER INHALER (GENERAL) SECTION UNDER DRUG MANUFACTURING LICENSE NO.000141 (FORMULATION) OF M/S MACTER INTERNATIONAL LTD, PLOT NO. F-216, S.I.T.E, KARACHI.**

The Central Licensing Board in its 272nd meeting approved the regularization of master layout plan of M/s Macter International Ltd, Plot No. F-216, S.I.T.E, Karachi, under DML No. 000141 (Formulation), and decided as under :

The Board considered and approved regularization of Lay out plan in the name of M/s. Macter International Ltd, Situated at Plot No.. F-216, S.I.T.E, Karachi on the recommendation of the panel of experts for the following secons:-

Ground floor:

1. Tablet (General),
2. Tablet (Psychotropic),
3. Oral Liquid, (syrup/suspension/ solutions),
4. Warehouse (RMS/PMS/FGS).

First Floor:

1. Ointment/Cream/Gel-I (General),
2. Ointment/Cream/Gel-II (General,
3. Aerosol Section,
4. Liquid Parental (SVP),
5. Liquid Parental (LVP),
6. Dry Powder Suspension (general),
7. Encapsulation (General) Including DPI Capsule,
8. Biotech (Lyophilization/Liquid Section),

Second floor (A and B):

1. Dry Powder Suspension (Ceph),
2. Capsule (Ceph),
3. Injectable Section (Ceph),
4. Raw Material Store (Ceph),
5. Encapsulation (Steroid) Including DPI Capsule,
6. Raw Material Store (Steroid),
7. Quality Control Laboratory

The Board also decided to confirm availability of required equipments and machinery for General Dry Powder Inhaler manufacturing by the area Federal Inspector of Drugs in the light of

the decision of the Drug Registration Board as the same is confirmed by the panel in respect of DPI steroidal section and mentioned in the report.

The decision of the CLB was communicated to the firm.

Now the area FID Mr. Hakim Masood has submitted report regarding availability of required equipments and machinery for General Dry Powder Inhaler. The recommendations of the area FID are mentioned below:

Recommendations:-

In conclusion it is confirmed that the firm has requisite facilities for the manufacturing & testing of the DPI Capsule (General) & accordingly recommended for the grant of additional section namely Encapsulation (General) including Dry Powder Inhaler as per recommendations of renewal of DML panel inspection dated 10-10-2019.

Decision of the Central Licensing Board in 275th meeting:

The Board considered the case and decided to call the company in the next meeting of the Board regarding seeking clarification for manufacturing of General as well as DPI in one and same Section.

Firm is also called for personal hearing vide letter Dated : 27-08-2020.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

Dr. Salman Ahmed Technical Director of the firm and Mr. Fakhruddin Ahmad Director Regulatory affairs appeared before the Board. They contended that they are ready to abide by law and would address the matter. The Board decided to advise the firm to regularize the layout plan and establish separate sections for Capsule (General) and Capsule (DPI). Meanwhile, till regularization, manufacturing shall remain stopped in the section which needs regularization.

The decision of the CLB was communicated to the firm. Later on firm submitted layout plan for regularization of Capsule (General) and Capsule DPI(General) Section which was evaluated & approved by the LOP committee and approval letter of layout plan was issued.

Firm then submitted request for inspection of Capsule (General) and Capsule DPI(General) Section for which area FID Karachi was advised to inspect the same and submit report .

The area FID Mr. Sajjad Abbasi has forwarded the inspection report the conclusion of which is as follows :

This is verified that the area is well established & properly labeled according to the approved layout plan. Also the firm has requisite facilities for the manufacturing & testing of the Capsules (General) & DPI Capsule (General). Therefore recommended for regularization of the Sections as:

i. Capsule (General) Section – Regularization.

ii. Capsule DPI (General) Section – Regularization

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s Macter International Ltd, Plot No. F-216, S.I.T.E, Karachi, under DML No. 000141 (Formulation) on the recommendation of panel of experts for the following sections:-

SECTIONS (2)

i. Capsule (General) Section – Regularization.

ii. Capsule DPI (General) Section – Regularization

Case No. 15 **RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S OBSONS PHARMACEUTICALS , LAHORE AND SITE APPROVAL AT NEW PREMISES.**

Case background. The Central Licensing Board in its 269th meeting considered the case of M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore under Drug Manufacturing License No. 000416 (Formulation) and decided as under:-

> "Mr Noor Hussain Gondal, Partner of the firm appeared before the Board and contended that he has recently taken over management of the firm and submitted an undertaking on Affidavit that he would shift to new premises for which he has already submitted an application for site verification. The Secretariat of the Licensing Division also confirmed that application for site verification is received and being processed. The Board after hearing the representative of the firm and perusal of orders of the Honourable High Court observed that SRO. 470 (I)/98 which specify the minimum area requirement for a pharmaceutical firm is applicable as renewal of a Drug Manufacturing Licencee is always subject to updated law and rules. The Board considering the commitment of new management decided to give period till August, 2020 to the firm to shift to new premises and for that purpose the applicant shall get its site verified and Lay out plan approved by 30th April, 2019 and shall file application for grant of Licencee before 31st August, 2020".

The decision of Central Licensing Board conveyed to M/s Obsons Pharmaceuticals, Lahore on 7th March, 2019 with direction to get site verified and layout plan approved by 30th April, 2019 and apply for grant of license before 31st August, 2020.

In the light of decision of Central Licensing Board M/s Obsons Pharmaceuticals (Pvt) Ltd submitted an application for site approval located at Khewat No. 14, Khatooni No. 69-71, Sangrai Tehsil Ferozewala, District Sheikhupura. Upon evaluation of submitted documents following shortcoming has been observed in the site approval application and shortcoming letters issued to the firm on 20th February, 2019, 4th May, 2020 and 17th August, 2020 :-

i. Plot allotment and possession letter in the name of firm.

The firm M/s Obsons Pharmaceuticals has submitted an application in response to this Division's letter dated 7th March, 2019 wherein the firm has requested for extension of validity time. Firm also requested to allow continuing their production activities and purchase of active materials through L.Cs. Firm has also informed that they have purchased 8 kanal land in Quaid-e-Azam Business Park Sheikhupura for shifting of their manufacturing plant.

The Firm M/s Obsons Pharmaceuticals has also requested for renewal of Drug Manufacturing License under DML No. 000416 for next tenure of five years M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, wherein the firm has submitted the documents for renewal of Drug Manufacturing Licencee No. 000416 (by way of Formulation) for the period 07-08-2020 to 06-08-2025. The application was received on 20-07-2020 and due date of renewal of DML 07-08-2020. The firm has submitted a fee of Rs. 50,000/- (Pages 275/Corr) for renewal of DML.
On scrutiny of grant of renewal of Drug Manufacturing License and site approval applications the following observations have been observed:-

For Site approval.

i. Plot allotment and possession letter in the name of firm.

For Renewal of DML.

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

Firm M/s Obsons Pharmaceuticals, Lahore, has submitted a response to this Division's letter dated 17th August, 2020 wherein the firm has informed that allotment letter is in the process which will be completed soon and will submit the allotment letter when it will be issued by Punjab Industrial Estate Development & Management Company.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000416 by way of formulation of M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 16 M/S TAS PHARMACEUTICALS, ISLAMABAD (DML NO. 000375)

Following panel of members conducted inspection of the firm M/s Tas Pharmaceuticals, Plot No. 209, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000375) on 06.02.2020 to verify GMP compliance and verification of consumption of narcotics.

i. Mr. Babar Khan, area FID, DRAP, Islamabad.
ii. Dr. QurratulAin Jamil Rana, Assistant Director I&E, DRAP Islamabad.

2. The panel during inspection noticed following critical observations:-

Observations

i. There was no approval of section by the licensing Board.

Change Rooms (Premises)

ii. In general the room was very dusty.
iii. Air Curtains provided at entrance were in very poor condition.
iv. The cross-over bench was not of appropriate dimensions.
v. The Rack for holding shoes was present bit full of dust.
vi. Mirror is in the change room but in very dirty condition.
vii. Light was inadequate in the room even SOP hanged in the room couldn't be read.
viii. There was dust on the cupboard, wall and doors.
ix. There were no hand wash and dryer in the change room.
x. Many cobwebs were noticed in the change room.
xi. There was no water supply in the sink.
xii. There were gaps in the door.
xiii. The paint was shedding at some places.
xiv. Pipe work, light fittings, ventilation points and other services have not been designed to avoid the creation of recesses. There were cracks seen at some points.
xv. Though insect killer were present but it was not maintained for cleanliness.

xvi. There were male clothes seen in the cupboard in the female change room.
xvii. The exhaust was installed but not working
xviii. There was a room adjacent to change room in which electric panel was installed. The room was in very poor condition due to non-maintenance.
xix. The changeover facilities were inadequate as not complying with GMP requirements.
xx. There was a space/room between change room and manufacturing/production area which was according to the GM a buffer room while one the door of this room opens to the roof through stairs. Hence, the purpose of the buffer couldn't be achieved.

Storage area/ Ware houses (Premises)

i. There was not a single material present in all stores.
ii. No pharmacist was hired to look after the activities of the stores as recommended in GMP (Schedule B-II of the Drugs (Licensing, Registering and Advertising) Rules, 1976.
iii. There was no evidence of clearance of import of any raw material by DRAP as required under the rules for last three years.

Production Area (Premises)

i. There was no pharmacist under supervision of Production Manager
ii. Walls and floors were not in good condition. The surfaces were in rough condition.
iii. There were gaps in doors.
iv. The alignments of doors were also not in good condition. Many surfaces were in rough condition.
v. There was no pressure maintenance/ balancing in the rooms.
vi. The temperature and humidity conditions were not proper as in some areas like Psychotropic Tablet it was 18°C and 37% RH.
vii. The grills in the return were very dusty. The GM, PM and QCM could not tell about the filters present in return.
viii. There was fresh paint giving nauseous/ pungent smell.
ix. In the mixer, sticky material was seen while cleaned label was mentioned on the mixer.
x. The white sticky material present on granulator in the Psychotropic section was referred as Paracetamol by GM and PM. It means that firm has not followed concept of segregation as per GMP requirement during manufacturing.
xi. Some expired calibration stickers were seen on equipment mentioning the date of 20-09-2019
xii. Labels about cleaning status mentioned date 02-01-2018.
xiii. There was no temperature measuring equipment in the mixing area.
xiv. There were steel nails fixed on the walls.
xv. In compression area, the placement of compression machine ZP-19 was questionable since it was causing hindrance in flow air thus producing the dead ends. The floor was very dirty, full of powder, paint and rust.
xvi. Hopper of ZP-19 compression machine was found stick with powder.
xvii. Though the tablet machine was labeled as "Clean" but there was sticky powder in lumps seen in the machine. The temperature in the tablet (General) area where ZP-25 was present was 14.1°C while relative humidity was 54%. The pieces of papers were found on the floor.
xviii. There was no operator/technician seen.

xix. There was no log book available in the compression machine area.
xx. The electrical balance in the IPQC was not operative. The calibration sticker mentions the date 29-08-2018. There was no other equipment in IPQC lab.
xxi. In coating area, the door could not be closed properly.
xxii. The pressure differential measurement devices were not in working condition.
xxiii. The surface of the coating pan was not smooth.
xxiv. In packaging area, the blistering machine was in very rusty condition.
xxv. There was no pest and rodent control system noticed to be existed in the firm.
xxvi. The drainage system does not seem proper for cleaning of area.
xxvii. Some primary packaging rolls found uncovered
xxviii. In packaging area, the glass of the door found in broken condition.
xxix. The cleanliness in the cream/ointment semisolid area was also very poor. Floor was not clean. Water was leaking and sticky material was present on floor.
xxx. Cleaning tag mentioned date 02-01-2018
xxxi. In packing hall, smell of fresh paint was present.
xxxii. There were cobwebs in Finished goods store.
xxxiii. There was no product in the Finished Goods Store. No temperature and humidity control device was present as well.
xxxiv. No proper proper dispensing booth present in RMS, hence dispensing practices were questionable with regard to GMP code. The dispensing tools were also not in accordance with GMP hence may cause source of contamination.
xxxv. There were gaps in the duct of A/C installed in the store.
xxxvi. Broken balance was present in RMS
xxxvii. In capsule section, log boojk of period of May 2019- may 2019 shows no manufacturing of any product. Dust was present on the mixer.
xxxviii. There was no temperature/ humidity control and differential pressure monitoring in capsule section.
xxxix. There was no temperature/humidity control or monitoring in the retained samples area.

Quality Control (Premises)

i. Condition of QC lab was very poor and it seemed that it was not functional since long.
ii. The sink was full of dust.
iii. The equipment like Friabilator, Disintegration Apparatus, Dissolution Apparatus, Moisture Analyzer were checked and found out of order or not in operative condition.
iv. Some reagent (Tryptone Lot No. 10P010 expiry date 19.02.20) were checked and found expired.
v. No primary reference standard was available.
vi. The firm has no operational microbiology laboratory.
vii. Calibration of Oven mentioned date 29-08-2018. (Calibration expired)
viii. No FTIR/IR for identification of API or by any other method.
ix. There was no Validation Master Plan (VMP) and Stability Programme.
x. There was one stability chamber that was not operational. No product was present in the chamber.
xi. An isocratic HPLC was present but not in a functional state hence analysis of products became under question.

HVAC System (Utilities)

i. There was no person who could demonstrate HVAC System. The filters like pre-filter (Like G-4), Bag filters (Like F-6, F-9) and HEPA couldn't be ascertained at their respective. The preventive and maintenance system for HVAC is not in place.
ii. Since there is no microbiology laboratory, hence microbiological standards of water remains questionable.

Water Treatment System (Utilities)

There is no water system shown by GM and since there is no microbiology lab, hence microbiological standards of water remains questionable.

Quality Assurance

There is no QA Manager appointed in the firm. The firm has very poor QA system and hence has no Pharmaceutical Quality System.

Sanitation and Hygiene

i. Overall, sanitation and hygiene was observed to be maintained at highly unsatisfactory level.
ii. There was no Sanitization and Hygiene System and Record.

Medical Checkups

There is no record of routine medical checkups available.

Qualification and Validation

Calibration of all equipment is not upto date, hence remains questionable. No validation master plan was available. No validation of process and analytic methods were performed.

Complaints

No SOP exists to deal with complaints.

Product Recalls

There is no SOP for recall.

Contract Production and Analysis

According to GM, there is no contract manufacturing and analysis by the firm and for the firm.

Self-Inspection and Quality Audit

There is no SOP for self-inspection.

Training

There is no SOP for training of personnel.

Equipment & Machinery

The firm does not have sufficient machinery/equipment in every section and their qualification and calibration status is questionable.

Documentation

i. There was no concept of documentation as SOPs seen during the visit were without any date, approval, authorization and date of revision.
ii. Overall the pharmaceutical Quality Management System is very poor.

3. The Panel concluded and recommended as under:-

Conclusion:

Based on the areas inspected, the people met, the documents reviewed, and assessment made on-site, the panel of inspectors concluded that the firm is operating at a very poor level of GMP compliance. The firm hence is working at a very high risk since violations of GMP (which is also the violation of condition of license) have been assessed/noticed are of critical nature like no Pharmaceutical Quality System, validated HVAC system, water treatment system and microbiology laboratory exists and further poor Production and Quality control practices were being undertaken as indicated above in the production from the date of inspection till compliance of GMP duly verified by a panel approved by competent authority.

Recommendations:

Considering the risk-based approach, it is therefore recommended that the DML of firm should be suspended, as the firm has violated the condition of license by which they were required to comply with requirements of GMP, till compliance of GMP since public health is endangered due to high risk quality issues.

Action Taken by DRAP: -

4. Accordingly show cause notice and suspension of production order was issued to the firm on 04.05.2020 with immediate effect.

5. In response to Show Cause Notice the firm M/s TAS Pharmaceuticals, Plot No. 209, Industrial Triangle Kahuta Road Islamabad (DML No. 000375) submitted two (2) replies. One was submitted on 18.05.2020 and other on 28.05.2020.

6. The Response submitted on 18.05.2020 was presented before the board and is reproduced below;

> *"1. That the show cause notice dated 04.05.2020 is based on the chain if malafides and ulterior motives because the enmity of three officers of the department is instrumental in the issuance of notice under reply. The said officers have been carrying serious grudge for submission of a complaint to the Chief Executive Officer of Drug Regulatory Authority of Pakistan (DRAP). Before that complaint the matter was also*

verbally referred that the said officers have been extending threats blackmailing and maligning the respondent. The company reserves its right to initiate civil, criminal and other proceeding against the said officers before all the competent forums

2. That brief facts of the matter are that the respondent's company applied for issuance of Consumption Certificate on 2nd day of September 2019 upon which Dr. Qurat ul Ain visited the company to check the records and everything was satisfactory and the company was directed to collect the Consumption Certificate, where after the company representative visited the office almost on daily basis, but all in vain. Thereafter having no other option the CEO of the company met Dr. Qurat ul Ain and complaint that despite lapse of 3-4 months, the Consumption certificate was not issued to the company due to whioch the company is suffering financial losses as well as mental torture, whereas on the other hand this complaint displeased the Dr. Qurat ul Ain upon which she was

showed that certificate was required out of quota, otherwise the company will suffer great loss. The quota control was required for drug titled as "Alprazolam, the fee whereof Rs. 20,000/- was already paid. Its meeting was about to take place but even then the company was not issued Consumption Certificate even after the meeting due to which quota was not allocated to the company. The entire responsibility of non-issuance of Consumption Certificate lies on Dr. Qurat ul Ain, Madam Hafsa and Federal inspector of Drugs Babar. All these persons inordinately delayed the matter without any lawful justification. The complaint the above referred officials was submitted to the CEO of DRAP, who took cognizance of the matter and directed all the concerned officials for issuance of Consumption Certificate, which further annoyed the said officers and extended serious threats to the ready to see consequences of complaining to CEO. It is very important to mention here that above said officers were called by the CEO and verbal orders were passed and further asked FID Babar that he has no concern with the Consumption Certificate to be issued to the respondent's company. Issuance of Consumption certificate and inspection are separate subjects, Madam Hafsa was ordered to issue Consumption Certificate, but she failed to comply with despite clearly express orders/direction. The Consumption Certificate was issued on 16.03.2020 after 4 to 5 times visits to the office of CEO DRAP and long struggle of seven months. During that period three meetings of control drugs were held and the respondent factory's case file couldn't be included in those meetings due to which the company suffered huge financial losses for which the company reserves its rights to take up the matter before all the legal competent forums

3. That the company is in operation since the year 1994 carrying good report regarding its premises. The last report was issued on 27th day of April 2018 that too carries good remarks. For the facts, attitude of the said officers and circumstances stated above the respondent's company was not informed in any manner and FID Babar along with Dr. Qurat ul Ain Inspected the site and malafidely raised 27 observaions. Actually

all these officials were adamant to take revenge of their insult at the hands of CEO on the complaint of respondent's company.

4. That initially only 27 observations was raised but subsequently the observation was increased to 89 on the basis of malafides, whereas on the day of inspection the factory was not producing anything, rather the work of cleanliness was being carried out which was notified to FID Babar, therefore despite these aspects of the matter carrying inspection of the company was totally against the rules.

PARAWISE COMMENTs (Observations)

i. That the observation No. 1 is scribed that "There was no approval by licensing board" this observation is made without perusal of record because through the letters dated 17.01.2019 and 04.07.2018 the approval of licensing board was given. Copy of the letter is attached herewith.

ii. The observation clearly shows that both the above mentioned persons violated all the rules and regulations despite having perusal of both the above mentioned letters.

5. Most of the objections listed (e.g. Sr. No. 5, Sr. No. 6, SrNo. 8, sr. No. 16, sr. No. 20, sr. No. 35, sr. No. 30, Sr. No. 32, Sr. No. 38, Sr. No. 52, Sr. No. 60) are pointing towards presence of dust, rough surfaces, and mess in the unit.

In response to these objections, the unit was undergoing minor renovations due to which there was dust. In addition to that, there was no production going on at the time of renovation. As there was no production so raw material was not present in the unit (ref: Sr. No. 21).During renovation we placed the temperature balance aside (ref: Sr. No. 28) and S.S. nails was present as SOPs are hanged on them, but due to cleaning purposes they put the SOPs board aside (ref: Sr. No. 37). This is the reason SOPs were not present (ref: Sr. No. 81; Sr. No. 82).Also the books and documents were placed in the cupboard (ref: Sr. No. 41; Sr. No. 87). Furthermore Sr. No. 30 shows that FID was well-aware that renovation in the unit was taking place; still such objections were raised by him.

6. Referring to Sr. No. 1 which states no approval of section, even though there are four sections i.e. Psychotropic Tablet section, General tablet section, Capsule Section, and Cream ointment section including complete Quality

Control (QC) Lab consisting of Microbiology lab.

7. The objections rose in the recent inspection(ref: Sr. No. 3, Sr. No. 4, Sr. No. 11, and Sr. No. 57) were not raised in inspection that took place in 2018. FID checked and appreciated the presence of air curtain, the cross over bench, and dispensing booth at the time of 2018 inspection. The same FID rose objections over air curtain, cross over bench, and dispensing booth in the recent inspection, even though these were not changed and were the same from that time till date. Same goes with the presence of water supply.

8. There is a great contradiction in Sr. No. 9 and Sr. No. 10, as Sr. No. 9 says no hand wash was present and in Sr. No. 10 it states no water supply in 'sink'. This shows that the water system is present, negating the objection raised in Sr. No. 9. Though, we accept that dryer was not present, so will install it.

9. In last inspection that took place in 2018, all the requirements were fulfilled as stated. No objection or suggestion was given (ref: Sr. No. 19). New labels have to be mentioned after the cleaning process (ref: Sr. No. 35).

10. During the process of making of granule by granulator in the General Tablet Section, meanwhile the belt was broken, therefore, it was granule with the other granulator, so that the batch may not rot.

11. In response to Sr. No. 48, the entire area gets cleaned with disinfectant. After every four months, fumigation in the unit also takes place. As summers are approaching, so Air-Conditioner was being cleaned/ serviced, so gaps were present (ref: Sr. No. 58). In reference to Sr. No. 59, the balance broke the day before the inspection. Though, temperature/ humidity control was present in samples area (ref: Sr. No. 62).

12. Referring to Sr. No. 63 and Sr. No. 64, after every four months thorough cleaning takes place in QC and production area, but no record is kept as it is a routine matter not solely for inspection purposes. Likewise sanitization and hygiene standards are strictly followed by GM but not recorded (ref: Sr. No. 78). The sink was found dirty as cleaning was being done.

13. In response to Sr. No. 65, the equipment was partially operative but still given for repair. Moreover, reagents were yet to be removed as cleaning was taking place (ref:Sr. No. 66). Unfortunately, primary reference standard was misplaced, but as an alternative USP/B.P was used as reference point. Reference standard would be bought (ref: Sr. No. 67).

14. In response to Sr. No. 68, the lab is well-equipped and operational but microbiology lab is not present as none of the products require this lab. Same for HPLC, as it is in working condition. However, we use spectrometer for testing purposes (ref: Sr. No. 73). Calibration is being done (ref: Sr. No. 69).

15. There is again a condition in Sr. No. 68 and Sr. No. 74. In Sr. No. 68 it mentioned that microbiology lab was not 'operational', but in Sr. No. 74 it says 'no' microbiology lab. This shows that the inspector is accepting that microbiology lab is present but not functional. Thus, it shows ambiguous statements.

16. Referring to Sr. No. 22, to Sr. No. 23, and to Sr. No. 77, as there is limited production so QC looks after QA matter and there is no pharmacist. But we assure you that we will hire them. Also due to limited product, we borrow raw material from other companies.

17. It would be assured that next time routine medical checkups would be available (ref: Sr. No. 79). Contract manufacturing is not done by the firm (ref: Sr. No. 83). According to the self-inspection SOPs, the unit was undergoing maintenance (ref. Sr. No. 84). In response to Sr. No. 86, more than sufficient equipment are present and are in proper working condition. FID checked all the machinery in the presence of GM and other staff members.

18. Fire extinguishers have been given for refill (ref: Sr. NO. 88). In response to Sr. No. 89, the location of emergency exits are exactly according to what is mentioned and approved in the map (the map is attached and the exits are highlighted).

19. That it is the historical aspect of the matter are that 89 observations are raised against any company with clearly show the ill-will of the above named officers whereas the CEO of DRAP was already informed of the prejudicial attitude of these officers.

20. That the allegation mentioned in the above captioned show cause notice are without explanation.

21. That all the allegations leveled against me in above referred show cause notice are baseless, frivolous and without any evidence

22. That above captioned show cause notice is illegal against the facts and circumstances, hence the same is liable to be withdrawn forthwith. In these circumstances, it is therefore most humbly prayed that the show cause notice may kindly be withdrawn and a honest, intelligent and impartial officers may be appointed to inquire the matter through a transparent, fair and just inquiry in order to reach at the truth.

The respondent's company is ready to remove their observation, so that the company can restart its The company is ready to given an undertaking in this regard. It is therefore respectfully submitted that the company's bore huge costs and has already removed almost all the so-called objections/observations which can be anytime.

It is further submitted that CEO of the respondent may kindly be granted an opportunity of personal order to explain each and everything in deal in accordance law."

7. The response of firm dated 28.05.2020 was also presented before the board. It is reproduced below;

S. No.	Observations	Rectification Status
1.	There was no approval of section by the licensing Board.	We have the Approval of Sections by Licensing Board issued on 4th July, 2018 & 17th January 2019

		(Copy Attached)
Change Rooms (Premises)		
2.	In general the room was very dusty.	The room has been cleaned as per set standards.
3.	Air Curtains provided at entrance were in very pathetic condition.	Air Curtains have been repaired and are in good condition now.
4.	The cross-over bench was not of appropriate dimensions.	Cross over bench is now fixed, cleaned and is in appropriate dimension.
5.	The Rack for holding shoes was present bit full of dust.	We have cleaned the Racks of male and female change room.
6.	Mirror is in the change room but in very dirty condition.	We have cleaned the mirror of male and female change room.
7.	Light was inadequate in the room even SOP hanged in the room couldn't be read.	Proper light has been placed, so SOP can easily be read.
8.	There was dust on the cupboard, wall and doors.	Cupboard, walls and doors have been cleaned.
9.	There were no hand wash and dryer in the change room.	There was already hand wash but now new dryer has been bought and placed.
10.	Many cobwebs were noticed in the change room.	Cobwebs have been cleaned.
11.	There was no water supply in the sink.	Water supply was already there but now new dryer has been bought and placed.
12.	There were gaps in the door.	Gaps in the doors have been properly filled.
13.	The paint was shedding at some places.	Where ever the paint was shedding, it has been fixed.
14.	Pipe work, light fittings, ventilation points and other services have not been designed to avoid the creation of recesses. There were cracks seen at some points.	The cracks and gaps have been filled and now cracks can be seen now.

15.	Though insect killer were present but it was not maintained for cleanliness.	The insect killer has been maintained.
16.	There were male clothes seen in the cupboard in the female change room.	Now male clothes have been removed from the female cupboard.
17.	The exhaust was installed but not working	Exhaust is now repaired and in working condition.
18.	There was a room adjacent to change room in which electric panel was installed. The room was in very pathetic condition due to non-maintenance's	Electric Panel room has been cleaned and maintained.
19.	The changeover facilities were inadequate as not complying with GMP requirements.	All the changeover facilities provided according to the GMP requirements.
20.	There was a space/room between change room and manufacturing/production area which was according to the GM a buffer room while one the door of this room opens to the roof through stairs. Hence, the purpose of the buffer couldn't be achieved.	The door is permanently closed.
Storage area/ Ware houses (Premises)		
21.	There was not a single material present in all stores.	There were no production going on at the time of renovation, as there was no production so Raw Material was not present in the unit.
22.	No pharmacist was hired to look after the activities of the stores as recommended in GMP (Schedule B-II of the Drugs (Licensing, Registering and Advertising) Rules, 1976.	Pharmacist is now appointed to look after the stores.
23.	There was no evidence of clearance of import of any raw material by DRAP as required under the rules for last three years.	Due to limited production we borrow the Raw Material from other companies. Next time, we will import all the Raw Material.
Production Area (Premises)		

24.	There was no pharmacist under supervision of Production Manager	Pharmacist is appointed for supervision of Production Manager.
25.	Walls and floors were not in good condition. The surfaces were in rough condition.	Walls and floor has been cleaned.
26.	There were gaps in doors.	Gaps in the door were removed.
27.	The alignments of doors were also not in good condition. Many surfaces were in rough condition.	The alignment of doors is in good condition, many surfaces have been smoothened.
28.	There was no pressure maintenance/ balancing in the rooms.	Now pressure has been maintained and balanced.
29.	The temperature and humidity conditions were not proper as in some areas like Psychotropic Tablet it was 18°C and 37% RH.	It has been maintained.
30.	The grills in the return were very dusty. The GM, PM and QCM could not tell about the filters present in return.	New filters have been installed in return.
31.	There was fresh paint giving nauseous/ pungent smell.	The renovation work was going due to which pungent smell of fresh paint was there.
32.	In the mixer, sticky material was seen while cleaned label was mentioned on the mixer.	Sticky material has been washed
33.	The white sticky material present on granulator in the Psychotropic section was referred as Paracetamol by GM and PM. It means that firm has not followed concept of segregation as per GMP requirement during manufacturing.	Sticky material has been washed.
34.	Some expired calibration stickers were seen on equipment mentioning the date of 20-09-2019	All machinery has been caliberated abd stickers have been placed.
35.	Labels about cleaning status mentioned date	New label has been placed.

	02-01-2018.	
36.	There was no temperature measuring equipment in the mixing area.	It has been placed.
37.	There were steel nails fixed on the walls.	SOP's were removed form cleanliness purpose now it has been hanged on the same steel nails.
38.	In compression area, the placement of compression machine ZP-19 was questionable since it was causing hindrance in flow air thus producing the dead ends. The floor was very dirty, full of powder, paint and rust.	All deficiencies have been removed.
39.	Hopper of ZP-19 compression machine was found stick with powder.	It has been cleaned.
40.	Though the tablet machine was labeled as "Clean" but there was sticky powder in lumps seen in the machine. The temperature in the tablet (General) area where ZP-25 was present was 14.1°C while relative humidity was 54%. The pieces of papers were found on the floor.	During cleanliness it has been cleaned properly.
41.	There was no operator/technician seen.	Due to renovation process the operators were on leave. Now they are back.
42.	There was no log book available in the compression machine area.	Was available, but –placed aside for cleanliness now placed there.
43.	The electrical balance in the IPQC was not operative. The calibration sticker mentions the date 29-08-2018. There was no other equipment in IPQC lab.	Electric balance has been repaired and calibrated.
44.	In coating area, the door could not be closed properly.	The door is properly closed.
45.	The pressure differential measurement devices were not in working condition.	All the devices are in working conditions,

46.	The surface of the coating pan was not smooth.	It is now smoothened.
47.	In packaging area, the blistering machine was in very rusty condition.	Blistering machine has been cleaned as per the requirement.
48.	There was no pest and rodent control system noticed to be existed in the firm.	The entire area gets cleaned through fumigation after every four months. The fumigation team comes to do so. Furthermore the area gets cleaned twice a day.
49.	The drainage system does not seem proper for cleaning of area.	Drainage system maintained properly.
50.	Some primary packaging rolls found uncovered	Machine testing rolls was present but removed now.
51.	In packaging area, the glass of the door found in broken condition.	The broken glass pieces was removed and placed with expensive glass.
52.	The cleanliness in the cream/ointment semisolid area was also very pathetic. Floor was not clean. Water was leaking and sticky material was present on floor.	Everything has been cleaned,
53.	Cleaning tag mentioned date 02-01-2018	New cleaning tag has been placed.
54.	In packing hall, smell of fresh paint was present.	Due to renovation process the packing hall was newly painted so the fresh paint smell was there.
55.	There were cobwebs in Finished goods store.	It has been cleaned.
56.	There was no product in the Finished Goods Store. No temperature and humidity control device was present as well.	Due to renovation there was no product in the finished Goods Store.
57.	No proper dispensing booth present in RMS, hence dispensing practices were questionable with regard to GMP code. The dispensing tools were also not in accordance with GMP hence may cause source of contamination.	HEPA filter is installed there; the dispensing tools were purchased with accordance of GMP.

58.	There were gaps in the duct of A/C installed in the store.	Gap has been removed.
59.	Broken balance was present in RMS	Balance has been repaired and is now in working condition.
60.	In capsule section, log boojk of period of May 2019- may 2019 shows no manufacturing of any product. Dust was present on the mixer.	No manufacturing was taking place of any product due to no order, and mixer is cleaned.
61.	There was no temperature/ humidity control and differential pressure monitoring in capsule section.	Pressure maintenance equipment has been placed now.
62.	There was no temperature/humidity control or monitoring in the retained samples area.	Pressure maintenance equipment has been placed now.
Quality Control (Premises)		
63.	Condition of QC lab was very pathetic and it seemed that it was not functional since long.	QC lab was functional but due to dust it seemed that it was not in working condition.
64.	The sink was full of dust.	It has been cleaned.
65.	The equipment like Friabilator, Disintegration Apparatus, Dissolution Apparatus, Moisture Analyzer were checked and found out of order or not in operative condition.	The equipment like friabilator, disintegration apparatus, dissolution apparatus, moisture analyzer are operative and calibrated.
66.	Some reagent (Tryptone Lot No. 10P010 expiry date 19.02.20) were checked and found expired.	Reagents with near expiry dates were removed.
67.	No primary reference standard was available.	We follow the books to make the assay and identify the Raw material.
68.	The firm has no operational microbiology laboratory.	The firm has Operational Microbiology Laboratory, in 2018 it was seen too (copy of last inspection report is attached)

69.	Calibration of Oven mentioned date 29-08-2018. (Calibration expired)	It has been caliberated.
70.	**No FTIR/IR for identification of API or by any other method.**	**Other methods of API identification are available.**
71.	There was no Validation Master Plan (VMP) and Stability Programme.	Validation master plan is available and in future we have the plan of stability.
72.	There was one stability chamber that was not operational. No product was present in the chamber.	Electric Switch of Stability Chamber was replaced and is in working condition now.
73.	An isocratic HPLC was present but not in a functional state hence analysis of products became under question.	HPLC is in working condition and calibrated.
HVAC System (Utilities)		
74.	There was no person who could demonstrate HVAC System. The filters like pre filter (Like G-4), Bag filters (Like F-6, F-9) and HEPA couldn't be ascertained at their respective. The preventive and maintenance system for HVAC is not in place.	We hire on call person for demonstration and maintenance of HVAC. At the time of inspection he will be available for demonstration. The filters are present in HVAC unit.
75.	Since there is no microbiology laboratory, hence microbiological standards of water remains questionable.	Microbiology Laboratory is well-equipped.
Water Treatment System (Utilities)		
76.	There is no water system shown by GM and since there is no microbiology lab, hence microbiological standards of water remains questionable.	Water system is available and calibrated. It is also in working condition.
Quality Assurance		
77.	There is no QA Manager appointed in the firm. The firm has very poor QA system and hence has no Pharmaceutical Quality System.	QA Manager has been appointed.

Sanitation and Hygiene		
78.	Overall, sanitation and hygiene was observed to be maintained at highly unsatisfactory level. There was no Sanitization and Hygiene System and Record.	Sanitation and hygiene has been maintained.
Medical Checkups		
79.	There is no record of routine medical checkups available.	Record will be maintained from now.
Qualification and Validation		
80.	Calibration of all equipment is not upto date, hence remains questionable. No validation master plan was available. No validation of process and analytic methods were performed.	All the issues raised have been rectified.
Complaints		
81.	No SOP exists to deal with complaints.	SOPs are available to deal with complaints.
Product Recalls		
82.	There is no SOP for recall.	SOPs are available to deal with complaints.
Contract Production and Analysis		
83.	According to GM, there is no contract manufacturing and analysis by the firm and for the firm.	We do not do any kind of contract manufacturing for any firm.
Self-Inspection and Quality Audit		
84.	There is no SOP for self-inspection.	SOPs are available to deal with self inspection.
Training		

85.	There is no SOP for training of personnels	SOPs are available to deal with training of personnel.
Equipment & Machinery		
86.	The firm does not have sufficient machinery/equipment in every section and their qualification and calibration status is questionable.	Sufficient machinery is available in every section. Qualification and calibration has been updated.
Documentation		
87.	There was no concept of documentation as SOPs seen during the visit were without any date, approval, authorization and date of revision. Overall the pharmaceutical Quality Management System is very poor.	Now all the SOPs are there with date, approval, authorization, and date of revision are available. Pharmaceutical quality management system has been improved.
Fire Fighting System		
88.	All fire extinguishers were expired with date 18-09-2018	Fire extinguisher has been filled and new expiry has been mentioned.
89.	There were no proper emergency exists.	As per layout plan the emergency exits are available. The copy of layout plan is attached.

Proceedings of 276th meeting of CLB:

Division of QA&LT presented the case before the Board. Syed Muhammad Tayyab (Son of CEO M/s TAS Pharma/Representative) and Mr. M. Saleem Shahzad (General Manager) appeared before the board with authority letter from Syed Tariq Ahmed CEO M/s TAS Pharmaceuticals (Pvt.) Ltd. Islamabad. Mr. Saleem Shahzad submit that they have rectify all the observations noted in the inspection dated 06.02.2020. The Board enquire about the two letters dated 18.05.2020 & 28.05.2020. submitted by the firm. Mr. Saleem Shahzad stated that their letter dated 18.05.2020 may please be considered as withdrawn and their detailed reply dated 28.05.2020 mentioned at para 7 of the case, may please be considered as reply of show cause notice.

Decision of 276th meeting of CLB:

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to: -

i. Constitute following panel of experts for verification of rectification status of the observations noted by the panel in their report dated 06.02.2020: -

   a) The Deputy Director (QA-III), DRAP Islamabad.
   b) Area FID, DRAP, Islamabad
   c) Mr. Rao Abdul Hameed, Drug Controller, Rawalpindi

ii. The panel shall submit detailed inspection report including rectification status of the observations noted by the panel in their report dated 06.02.2020, with clear and candid recommendations.

iii. Production of the firm M/s TAS Pharmaceuticals (Pvt.) Ltd. Plot No. 209-Sihala Triangle, Kahuta Road Islamabad (DML No. 000375) shall remain suspended till recommendation by panel and subsequent approval by the CLB.

Accordingly, a letter was issued on 28th September, 2020

M/s Tas Pharmaceuticals (Pvt) Ltd, Plot No. 209, Industrial Triangle, Kahuta Road, Islamabad wherein the firm has submitted vide letter NO. TAS/Lic/20 Dated 14-9-2020 that they are surrendering the DML No. 000375 (Formulation) under protest. The contents of the letter are reproduced as under;

1. *"That the applicant is Chief Executive Officer of M/s TAS Pharmaceuticals Pvt. Ltd. 209, Sihala Triangle, Kahuta Road Islamabad and produce different products in the same building. It is a duly licensed company since the year 1994 and there has been no occasion of any complaint against it in any manner throughout this period.*
2. *That the production of the applicant's factory was forcibly stopped due to blackmailing of staff of DRAP i.e. Drug Inspector Babar Khan, Ms. Hafsa Additional Director and Additional Director I&E, QALAT Dr. Qurat-ul-Ain Jamil Rana.*
3. *That the applicant earlier submitted an application for setting aside of order dated 09.03.2020 before the CEO DRAP but no action has been taken as yet.*
4. *That due to illegal acts and malafide intentions of the officials of the DRAP, the applicant has already suffered the financial losses worth hundreds of millions of rupees because the production is stopped since 06.02.2020 without any cogent reason or lawful justification.*
5. *That the applicant is a law abiding citizen of Pakistan, he cannot bribe and keep happy the officials of DRAP, he is left with no other option but to surrender his License bearing No.000375 under protest. Now it has become impossible for the applicant to suffer anymore blackmailing or fulfill their unlawful demands. In this regard, the applicant earlier submitted an application on 19.03.2020 that has not*

yet been disposed of by the authorities. The submission of the earlier application are as under;

a . *The applicant filed an application for grant of consumption certificate on 02nd September 20 19 Dr. Qurat-ul-Ain Jamil Rana weighed the unit who come to carry the verification of consumption Alprazolam.*

b . *Dr. Qurat-ul-Ain Jamil Rana declared the record as satisfactory and told the applicant to collect the Consumption Certificate in the next week.*

c . *That the applicant made several visits of I&E Department of DRAP for about 04 months but all in vain, he was frequently called and was told to come in the next week.*

d . *That on 02.09.2019, the applicant filed an application for grant of quota control of the drug titled Alprazolam and deposited the dues of the same to the tune of Rs.20,000/-. Prior to the meeting of Drug control Department, the applicant was asked to give Consumption Certificate, the applicant again approached I&E Section that the control drug department was demanding consumption certificate which may be issued because all the formalities had been completed after inspection.*

e . *That despite of all this, the consumption certificate was not issued to the applicant even after the meeting control drug. The allocation was also not given to the applicant in time due to which the applicant suffered financial losses and mental torture for which the above named officials Drug Inspector Babar Khan, Ms. Hafsa Additional Director and Additional Director I&E, QALAT Dr. Qurat-ul-Ain Jamil Rana are responsible. In this manner, the Control Drug closed the file at the end of year 2019 and directed the applicant to submit a fresh file for the year 2020.*

f . *That on 06.01.2020 the applicant submitted fresh application for allocation of quota of Alprazolam, again deposited the fee Rs.20,000/-, again contacted I&E Section and requested that due non-issuance of certificate in time, the applicant suffered financial losses and mental torture, hence they should formally issue the letter because the inspection was already completed and the consumption was also declared satisfactory. The applicant complained the attitude of Dr. Qurat-ul-Ain to Madam Hafsa which annoyed them as a result of which, they turned foe of the applicant. The above named officials extended serious threats that they will carry re-inspection of the applicant's factory.*

g . *That on 06.02.2020, the above named officials Drug Inspector Babar Khan Dr. Qurat-ul-Ain Jamil Rana again came in the factory of applicant and said that they had come on the instructions of , Ms. Hafsa Additional Director and Additional Director I&E, QALAT. Babar Khan was facilitated to carry the inspection of the entire factory thereby raising several objections those were accepted with open mind and accordingly rectified. It is pertinent to mention here that both the officials had come on the basis of chain of malafides just in order to harm the applicant.*

h . That having no other option, the applicant complained to CEO whereby the above named officials got infuriated whereas they were ordered to immediately issue the Consumption Certificate.

i . That the above named officials have continuously been extending serious threats that they will destroy the applicant's business, how the applicant dared to raise a complaint before the CEO.

j . That all the objections raised dated 09.03.2020 are based on ulterior motives because the applicant approached the CEO for his lawful demands.

k . That the above named officials threatened that if the applicant dared to raise any complaint before CEO or Minister, his factory will be sealed/locked and the license will be cancelled.

l . That the applicant visited CEO office for five times that the above named officials have turned personal towards the applicant.

m . That all the objections are based on the basis of a chain of malafides which have no connection with the reality. On repeated orders of CEO, the consumption certificate was issued on 16.03.2020, the inspector reported Good during the inspection on 27.04.2018 in the same building with the same machinery which are duly recorded in the register.

n . That the applicant reserves his right to initiate legal, civil, criminal and other proceedings at the appropriate time and forums.

o . That on 03.09.2020, the board decided in the meeting of Licensing, that the re-inspection of the applicant's factory will be carried, after two or three days, the Drug Inspector Babar Khan said that he is in doubt that will clear the inspection of the factory of the applicant.

In these circumstances, it is therefore humbly requested that no decision has been made on the applications of the applicant, the objections have been raised just in order to tease, blackmail and inflict losses to the applicant.

As long as the above named officials are running the DRAP, the applicant cannot run his factory, hence the applicant do hereby surrender his License No.000375 under protest as he is left with no other option.

The original license bearing No.000375 is attached with this application. Please acknowledge."

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The case has been considered at length by the Board and as per previous practice the licensee has failed to produce any evidence in support of his allegations made against the panel officers who made inspection on 06.02.2020 and he has now come up with request to surrender his license. It has also been observed during personal hearing before the Board in 276th meeting held on 3rd September, 2020 that the licensee had withdrawn all his allegations before the Board whereupon a fresh panel of experts was constituted but before the inspection, the licensee has come up to

surrender his licence reiterating his previous allegations without any corroborative evidence. In these circumstances, the Board acceded to his request for withdrawl of the licence which is cancelled as withdrawn with immediate effect under Section 41 of the Drugs Act, 1976.

Case No. 17 <u>SITE VERIFICATION OF M/S STEFANIE PHARMACEUICALS PLOT/BLOCK NO.69-B, LARGE INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR .</u>

M/s Stefanie Pharmaceuticals, Peshawar vide their application dated Nil has forwarded a request for approval of site to establish a pharmaceutical unit located at Plot/Block No.69-B, Large Industrial Estate, Hayatabad, Peshawar. Accordingly Area FID, DRAP, Peshawar was directed vide letter dated 19th April, 2018 for verification of site. Area FID, DRAP, Peshawar, after visiting the site has forwarded site verification report of the said firm. The recommendation of the Area FID, DRAP, Peshawar is as under;

Size of the plot:

The management has already submitted "Transfer Lease" for the proposed site which shows it is 1.0 (one) Acres plot and dimensions are (370' 0 ½" X 115' 3") which measures about 44464.0 sq. Ft. However, the management has spared 150627.73 Sq. Ft for M/s Stefanie Health Care" and rest for "M/s Stefanie Pharmaceutical" i.e 28457.27 Sq. Ft. the rest for the offices i.e 944.00.

Location:

The proposed site is located at Hayatabad Industrial Estate, Peshawar, the boundaries are as under;

Surroundings:

On North side is Plot No.69B (M/s Oriental Enterprises).

On South side is Plot No.69C. (M/s Shanghai UPVC)

On East side is Plot No.70 and 70A (M/s United Rubber (Pvt) Ltd.)

On West side is Road S/3

Environment:

Smoke pollution is seen from in its surrounding (east side) as the Rubber factory is emitting dense black fumes at the time of visit.

Conclusion:

As per requirement laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(I)/98 dated 15.05.1998) under rule 16(a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976, the proposed premises is **not suitable** to construct a pharmaceutical unit as of today.

Sketch of plot and its adjoining area is attached as desired.

2. Meanwhile, another application is received from M/s Stefanie Pharmaceutical, Peshawar for re-inspection of the site alongwith prescribed fee of Rs.5,000/- and he has also submitted an affidavit wherein he has stated that he will install HVAC system in the building.

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and decided to call the representative of the firm for personal hearing before taking final decision.

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

Accordingly, a letter for personal hearing was issued on 7th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Ehsan Ullah, CEO of the firm appeared before the Board and contended that Rubber factory which was emitting smoke has taken precautionary measures to avoid smoke contamination & he also presented provisional NOC from EPA. The Board after hearing the representative of the firm decided to re-inspect the firm for site verification after submission of NOC from EPA.

Accordingly, a letter for re-inspect the firm for site verification was issued on 20-02-2020.

In response to this office letter No. F. 3-1/2018-Lic dated 20/02/2020 issued in light of Decision of CLB in its 273rd meeting held on 15th January, 2020, the Area FID, Peshawar has submitted Inspection report for site verification of M/s Stefanie Pharmaceutical, Large Industrial Estate, Hayatabad Peshawar.

In the above inspection report it is stated that;

i. The Area FID and Additional Director (E&M), DRAP Peshawar inspected the proposed site for M/s Stefanie Pharmaceutical, Large Industrial Estate, Hayatabad Peshawar.

ii. The owner of the firm Mr.Ahsan Ullah briefed that they have taken following measures/changes after rejection of the site by the Panel earlier in February, 2019.

   a. They have obtained an Environmental Approval/Decision Note on Environmental Impact Assessment (EIA) from Environmental Protection Agency Khyber Pakhtunkhwa vide their letter No. EPA/EIA/Pharma/Stefanie/Pesh/20/819-20 dated 02/07/2020 wherein it has been stated that "After careful review and upon feasibility of external and internal environmental conditions, the Environmental protection Agency, Govt. of Khyber Pakhtunkhwa has decided to accord approval of the Environmental Impact Assessment of the firm in line with the Khyber Pakhtunkhwa Environmental Protection Act, 2014 and IEE/EIA Regulations, 2000 subject to some terms & conditions" (Copies letter from EPA and Decision on EIA attached as Annexure-I)

   b. The firm had two separate plots i.e Plot No. 69-B/2 measuring 2.5 Kanals and Plot No. 69-B/1 measuring 5.50 Kanals. Initially the firm intended to establish a neutraceutical unit on Plot No. 69-B/2 measuring 2.5 Kanals and an allopathic Pharmaceutical unit on Plot No. 69-B/1 measuring 5.50 Kanals. Later on the investor in their neutraceutical project (M/s Stefanie Healthcare) left the project and they withdrew their project with written application to Director H & OTC Division DRAP (copy of letter attached as annexure-II). Now they have merged the two plots together and changed the name of the unit as Stefanie Pharmaceuticals. (Copy of merger of Plots attached as annexure-III),

   c. They requested the neighboring rubber industry M/s United Rubber (Pvt) Ltd. to amend in their plant to reduce the amount of smoke particles emitted in the chimney of their plant. Now they have done certain changes in their plant due to which the amount of smoke particles emitted in the chimney have been reduced significantly. (Copy of letter from the rubber factory attached as annexure-IV, copy of undertaking on stamp paper attached as annexure-V),

   d. They will install HEPA filters in the premises of their Pharmaceutical unit to avoid contamination of end products. They will comply all the guidelines of DRAP and WHO etc of clean rooms required for relevant sections of a Pharmaceutical Unit. They will also do design qualification of HVAC system keeping in view the surrounding environment and user requirement specification (URS). (copy of undertaking on stamp paper attached as annexure-V)

iii. Now the specifications/dimensions of the plot are as under:

Total Area: 2.5 Kanals (Plot No. 69-B/2) and 5.50 Kanals (Plot No. 69-B/1 measuring) = 8 Kanals **{Plot No. 69-B/2 has already a three floors building each floor has a covered area of 8427.583 Sq. Ft.}**

Location:-
The proposed plot is located in the industrial Estate of Hayatabad Peshawar. The boundaries are as under:
Surroundings:

East:	Plot No. 70 and 70A (M/s United Rubber (Pvt) Ltd.)
West:	Road S-3
North:	Plot No. 69B (M/s Marks Razmak)
South:	Plot No. 69C (M/s Shanghai UPVC & Pumps (Pvt) Ltd)

Environment: The plot is situated in the industrial Estate of Hayatabad Peshawar. The rubber factory on the east side **now emits less dense black fumes**.

iv. Based on above mentioned description, and submission of the firm as mentioned in para 03 above the case for approval of proposed plot may be placed before Central Licensing Board for consideration of a Pharmaceutical unit as per requirement laid down under paragraph 1 of section 1 of Schedule "B" (SRO. 470(I)/98 dated 15.05.1998) under rule 16(a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Sketch of plot and its adjoining area is attached as desired.

Paragraph 1 of Section 1of Schedule B

1.2. **Surroundings:** Premises shall be situated in an environment that, when considered together with measures to protect the manufacturing processes, presents minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odour or fumes or large quantities of soot, dust or smoke which may contaminate the drugs being manufactured or adversely affect their quality. Existing units shall keep the surroundings under their control to be clean.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the case and decided to provide last opportunity to applicant before taking any final decision.

Case No. 18. GMP INSPECTION OF M/S NOA HEMIS PHARMACEUTICALS, KARACHI

GMP inspection of M/s Noa Hemis Pharmaceuticals, Karachi was conducted by area FID Mr. Najam-us-saqib on 12-08-2020 by him . During inspection it was observed that all production doors were locked and no production was underway. The reasons for stoppage of

production/manufacturing operations without any information to DRAP was enquired from the firm . The management of the firm submitted reply which is reproduced as below :

‘ The production facility ‘ Noa Hemis Pharmaceuticals’ is a partnership firm owned by Mr. Aziz Pervez and Mr. Saeed Jawaid. This is to inform you that Mr. Saeed Jawaid has filed a **suit bearing No. 163 of 2020 before the High court of Sindh at Karachi** . Furthermore, Mr. Saeed Jawaid was managing Human Division and he has stopped all production processed in its enterety on 3rd March 2020 due to the nonpayment of utility bills. Veterinary Divison operated by Mr. Aziz Pervez had sold all the veterinary finished goods by June 2020. And upon stoppage of production veterinary Division immediately ceased its production activities (including packaging) and has been at halt since then. Any claims otherwise are baseless and not provable.

Any letter submitted on behalf of Mr. Saeed Jawaid is not condoned by Mr. Aziz Pervez as a partner in the partnership firm M/s Noa Hemis Pharmaceuticals.

Mr. Jawaid commenced aforementioned as a response to Mr. Aziz’s request for joint-signature implementation of all the firm’s bank accounts. The reasons for the joint-signature by Mr. Aziz include :

1). Non-compliance to access the books of accounts and refusal for an external audit of the Human Division by Mr. Saeed Jawaid.

2) Surreptitious behavior fraudulent activity and disregard of GMP SOPs by Mr. Saeed Jawaid.

The reasons for suspension application by Mr. Aziz :

1) Mr. Aziz came on high alert when it came to his knowledge that the human division was relentiessly abstaining GMP standards and protocoals. And he wanted to investigate them prior to the law suit by Mr. Jawaid.
2) After the halting of the production on 3rd March 2020 Mr. Jawaid laid off all the technical staff including the QC Manager and Production manager. After which Mr. Jawaid commenced a few months spree of packaging of tablets, blisters and liquids by unqualified staff using solar panels(for electricity) at the premises non-qualified and non-equipped by any drug law standards for pharmaceutical packaging. Upon finding occurrence of such activities Mr. Aziz had to emphatically stop such operations and removed all the non- hired personnel immediately.

Appropriately, Mr. Aziz would like to make a 3-part request :

1. Considering the above and to stop jeopardizing pharmaceutical (drug) law of Pakistan, Mr. Aziz requests to suspend the license No. 000525(Formulation) granted to M/s Noa Hemis Pharmaceuticals.and all its products . Mr. Aziz is not liable for nay activities conducted by or on behalf of Mr. Jawaid and its consequences as the production and packaging of human drugs are non-compliant of GMP standards and can potentially be hazardous to the masses.

2. The brand name of the drugs(both local and export) already registered in the name of the Partnership firm may not be transferred in the name of any other person without the consent of both partners.
3. Proceedings and approvals of contracts related to drug manufacturing by third parties in the name of Partnership firm including but not limited to contract between M/s Seraph Pharma Islamabad and that the Noa Hemis Pharmaceutical (as mentioned in 295th meeting DRAP) may not be approved.

   Your attention and nimble execution are highly appreciated in this matter.

As per available record of Licensing Division, DRAP M/s Noa Hemis Pharmaceuticals is a licensed manufacturing facility at Plot No. 154, Sector 23, Korangi Industrial Area, Karachi having a valid DML NO. 000525(formulation).

The management of the firm as per available record of Licensing Division, DRAP is comprising of two partners Mr. Saeed Jawaid and Mr. Aziz Pervez.

Proceedings and Decision by the Central Licensing Board in 277th 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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing Licence No. 000525 by way of formulation of M/s Noa Hemis Pharmaceuticals, Karachi may not be suspended or cancelled by Central Licensing Board.
The Board also decided to seek information from the Drug Regulatory Authority of Pakistan, Kararchi office regarding import of raw material by M/s Noa Hemis Pharmaceuticals, Karachi since renewal of Drug Manufacturing License, if any.

CaseNo.19 CORRECTION IN ADDRESS ON DML NO. 000350 (FORMULATION) OF M/S BOSCH PHARMACEUTICALS (PVT) LTD, KARACHI.

The Central Licensing Board in its 275th Meeting held on 25-06-2020 approved the renewal of DML No. 000350 (Formulation). in agenda and subsequently in the minutes of 275th meeting of the CLB, the address of the firm under DML No. 000350 was mentioned as Plot No. 221-223, Sector 23, Korangi industrial Area, Karachi and same was mentioned on the DML issued to the firm. However the correct address is as under :-

Existing	Correction Required
Plot No. 221-223, Sector 23, Korangi industrial Area, Karachi	Bosch House 221, 222 &223, Sector 23, Korangi industrial Area, Karachi

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the case and approved the correction in address as per documents available on record as under:

M/s Bosch House 221, 222 &223, Sector 23, Korangi industrial Area, Karachi, Drug Manufacturing Licence NO.000350 (Formulation)

Case No. 20. REQUEST/APPLICATION FOR RETAINNG A SUBSTANTIAL PORTION OF CRF FOR THE YEAR 2017 BY M/S. GETZ PHARMA (PVT) LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000284 (FORMULATION)

M/s Getz Pharma (Pvt) Limited Karachi has submitted request for retaining substantial portion of CRF and has stated as under;

1. At the outset, we would like to state that Sub-Rule 14 of Rule 19 of the Licensing, Registering and Advertising Rules, 1976 (LR&A Rule), requires a pharmaceutical company to contribute one percent of its gross profit before deduction of income tax towards the Central Research Fund to be maintained by the Federal Government.
2. However; under the proviso to this Sub-Rule 14 of Rule 19, the Central Licensing Board may allow a portion of such contribution to be spent by the Firm/Pharmaceutical Company itself for research and development of new drugs or for establishing research laboratories, when it is satisfied that such expenditure is being utilized for the said purpose effectively and properly.
3. To keep the record straight, we would like to submit that Getz Pharma has been paying CRF to DRAP since 1995. The total amount of CRF paid as of today in the last 21 years is Rs. 295.73 million [from 1995-2016].
4. We note with great regret that billions of rupees are lying unutilized in the Central Research Fund for which the pharma companies including Getz Pharma has contributed one percent profit to the CRF under the Rule LR&A Rules.
5. It is submitted that the total one percent CRF contribution of Getz Pharma for the year, 2017, comes to Rs. 86.49 million. However, the sums of investments made towards research and development of new drugs and/or for establishing

research laboratories in the year, 2017, are Rs. 232 million. As it is obvious, the amount of investments and expenditure incurred by Getz Pharma in the year, 2017, it almost three times more than the annual CRF contribution of Getz Pharma for the year, 2017.

6. Therefore, in view of the forgoing provisions and submissions, we would like to make our requests as follows:

    i. In accordance with Sub-Rule (14) of Rule 19 of the LR & A Rules, Getz Pharma may kindly be allowed to retain a substantial portion out of one percent CRF annual contribution on the grounds that it has already made substantial investment towards development of new drugs and establishing research laboratories/facilities, in the year, 2016, which investments exceed the prescribed limit of one percent. A summary of investments and audit reports are enclosed herewith (which can be substantiated with documentary proof as and when so required). We would also like to note that Getz Pharma is continuously making, and will be making, investments towards the development of new drugs and establishing research laboratories/facilities and we are willing to provide details of such continuous and future investments, as and when required (subject to requirements of business and trade confidentiality).

    ii. We should be informed as to the quantum of the CRF contribution which can be retained by Getz Pharma.

    iii. As you are already aware, and as is our legal right, the contribution to CRF is subject to intimation by DRAP regarding the quantum of the contribution which can retained by the company. Therefore, once you have informed us as to how much of the contribution can be retained by Gets Pharma and what the balance reminder amount is, the balance remainder amount will be deposited by Getz Pharma.

    iv. In the meantime, no adverse or coercive action, including but not limited to suspension of Getz Pharma's routine work concerning pending or new registration applications, should be taken by DRAP. Please note that in relation to CR amount, we have filed a Constitution Petition No. 3896 of 2016, which is pending before the Honorable High Court of Sindh, and through Order dated 01-07-2016, the Honorable High Court has been pleased to restrain DRAP from taking my adverse or coercive action against us. Therefore, if any adverse or coercive action, including but not limited to suspension of Getz Pharma's routine work concerning the pending new registration applications is taken against Getz Pharma by

DRAP, We reserve the right to institute contempt proceedings against you and other relevant officials. Similarly, another Const. Petition No. D-5820 of 2017 is also pending before the Honorable Sindh High Court in relation to CRF amounts for the year, 2016, and the Honorable Sindh High Court was pleased; vide Order dated 11-4-2018, to restrain, inter-alia, DRAP from taking any adverse/coercive action against Getz Pharma.

Budget & Accounts Division, DRAP, Islamabad has also forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit.

It is submitted that M/s. Getz Pharma (pvt) Ltd, Karachi having DML no. 000284 has submitted CRF till year 2014. However, firm has failed to submit nothing due certificate for the further period which is mandatory under Rule 12 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

Decision by the Central Licensing Board in 269th meeting:

The Board considered and deferred the case till decision by the Court on the matter since the matter is *sub judice*.

Now, request submitted by M/s Getz Pharma (Pvt) Ltd, Karachi for retaining a substantial portion of CRF for the year 2019 was considered by the DRAP Authority in its 91st meeting of the Authority wherein following decision has been made :

> ''The Authority endorsed the proposal of Legal Affairs Division to forward the case of utilization of portion of CRF by the firm to Secretary CLB for placing the same before the Central Licensing Board under proviso of rule

19(14) of the Drugs (L,R&A) Rules, 1976 along with legal interpretation made by Division of Legal Affairs.''

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board has been apprised that there are three petitions pending before High Court of Sindh and there is some injunction order of the said Court restraining the respondents to take adverse action against the petitioner firm/ company. The petitioner firm/ company has sought relief in accordance with Sub-rule (14) of the Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 having enabling provision under Section 12 of the Drug Regulatory Authority of Pakistan Act, 2012 for the purpose of utilizing certain portion of Central Research Fund (CRF) due ~~to~~ from him since long without approval of the authorities in respect of research and development of new drugs or for establishing research laboratories. Perusal of the record placed before the Board shows that the petitioner firm has not so far provided a plan in accordance with the aforesaid provisions of law on the basis of which it seeks approval of the Board for utilization of certain part of its outstanding CRF for the purpose of research and development of new drugs or for establishing research laboratories, if any, which new drugs or laboratories, it is responsibility of the firm, to identify. In these circumstances the Board unanimously decided that, without prejudice to any existing order of the said Court and any other court and also subject to ultimate decision of the said Court and any other court and judicial forums, in the first instance the three petitions should be vigorously pursued in the Court with due care and also for vacation of injunction order, if any. Simultaneously the petitioner firm may be advised to make application as per applicable law, statutory rules and procedure by submitting a plan for making research on a new drug to be identified in the said application or, as the case may be, for establishing research laboratories, similarly to be identified in the said application . Thereafter, his request will be considered in accordance with applicable provisions of law, statutory rules and procedures as well as in accordance of orders of the said Court and all other courts and judicial fora in this regard.

Case No. 21 REGULARIZATION OF MANUFACTRUING FACILITY- INSPECTION THEREOF

It is submitted that previously lay out plan were approved as submitted by the pharmaceutical Industry before notification of cGMP in 1998. There was transition period for implementation of cGMP. Resultantly, lay out plan were approved in compliance of cGMP after 2003.

It is also submitted that most of the industry established before 2003 do not have lay out plan as perc GMP or even approved lay out plan. Now, industry is approaching for regularization of Lay out plan and insisting for approval as such as per built building.

Decision of CLB in 251st meeting of the CLB :

The Board considered the above proposal and decided that Licensing Division may approve regularization of Lay out Plan keeping in view flow requirements. After initial scrutiny, Lay out Plan may be forwarded to Panel for verification before regularization by the Board.

Current Status :

In compliance, pharmaceutical industry is getting layout plan regularized regularly but club their regularization inspection with the renewal of Drug manufacturing License and there is no defined time line in which firm must get their manufacturing facility inspected in the light of approved layout of regularization.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board deliberated the matter of regularization of lay out plan in detail. The Board observed that regularization of existing facilities of the pharmaceutical unit was encouraged to make old unit GMP compliant in accordance with Schedule B under Rule, 16 of the Drug (Licensing, Registering and Advertising) Rules, 1976. However, company or firm come up for regularization of lay out plan at the time of renewal of Drug Manufacturing Licence or club the inspection for regularization of lay out plan with renewal of Drug Manufacturing Licence. The Board noted that compliance to GMP requirements is mandatory and pre-requisite for renewal of Drug manufacturing Licence. The Board, therefore, decided that in future inspection for regularization of lay out plan should be carried within 2 months after completion of improvements as envisaged in lay out plan and same should not be clubbed with inspection of renewal of licence.

Case No. 22 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S WAHABSONS PHARMA (PVT) LTD., 4-KM, BUNNER ROAD, BARIKOT, SWAT.**

M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat had applied for renewal of DML No. 000533 by way of formulation for the period of 27-01-2019 to 26-01-2024 on 30-10-2018.

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 17th December, 2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form-1A alongwith enclosure/Flags/Annexure.
2. Class (es) of Drugs.
3. Dosage(s) forms of drugs.
4. Name(s) of registered drug(s).
5. Detail of management at the time of previous renewal and present renewal.
6. Updated Form-29 from S.E.C.P. attested alongwith CNIC's of all Directors.
7. Approved layout plan.
8. Proof of licensed sections from Central Licensing Board.
9. Detail of section wise equipment and machinery for manufacture and QC Lab.
10. Approval letter of QC Incharge in case of change then submit required documents as per checklist (attached) alongwith prescribed fee.

The firm submitted their reply on 09th January, 2019. After evaluation of the submitted documents, a final reminder was issued on 29th May, 2019 to the firm with following shortcomings: -

1. Form-1A dully signed and attested by the management of firm alongwith all enclosures.
2. Names/detail of Directors of firm on firm's letter head alongwith attested CNIC copies of all directors (at this renewal and at previous renewal).
3. Form-29 and Form-A for year 2019 (certified true copy) issued by S.E.C.P. alongwith prescribed fee for change of management (if management is changed).
4. Proposed QC Incharge Ms. Seema Mughal does not fulfill the requirements of Rule-16 of Drugs (Licensing, Registering & Advertising) Rules, 1976 in terms of required experience, therefore, submit documents of new proposed QC Incharge.

5. Detail of all licensed sections on firms letter head alongwith approval letter(s) of all sections issued from CLB.

The firm submitted their reply to Final Reminder on 15th July, 2019 and following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Form-1A dully signed and attested by the management of firm alongwith all enclosures.
2. Form-29 and Form-A for year 2019 (certified true copy) issued by S.E.C.P. alongwith prescribed fee for change of management (if management is changed).
3. Approval letter(s) of all sections issued from CLB.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat Drug Manufacturing Licence No 000533 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Accordingly a show cause notice was served to the firm dated 25-09-2020. But no reply has been received from the firm till to date. Now a personnel hearing letter issued to the firm on 08-10-2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

No person appeared on behalf of the firm. The Board deliberated the case and decided to afford final opportunity for personal hearing to the firm in the next meeting of the Central Licensing Board before taking decision.

Case No. 23. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S UNI-TIECH PHARMACEUTICALS (PVT) LTD, KARACHI UNDER DRUG MNAUFACTURING LICENSE NO. 000356 (FORMULATION)

M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi, had applied for renewal of DML No. 000356 by way of formulation for the period of 04-10-2019 till 03-10-2024.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 20-12-2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Application on Prescribed Form 1A dully signed by current management of the firm along with dully attested enclosure/annexures.
(ii) Original Certified True Copy of Form-29 & Form-A for the year 2019 issued by SECP.
(iii) Detail/names of all directors on firm's letter head along with attested CNIC copies of all directors.
(iv) Detail of all licensed sections on firm's letter head along with approval letters of sections issued from the Central Licensing Board & if not available then submit layout plan for Regularization of facility.

The firm submitted their reply on 16th April 2020. After evaluation of the submitted documents, Final reminder was issued on 19h May 2020. to the firm to submit following shortcomings: -

1. Application on Prescribed Form 1A dully signed by current management of the firm along.
2. Original Certified True Copy of Form-29 & Form-A (Updated) issued by SECP.
3. Prescribed fee for change of management as the management is changed from last renewal.
4. Detail of all licensed sections on firm's letter head along with approval letters of sections issued from the Central Licensing Board & if not available then submit layout plan for Regularization of facility.
5. **All documents should be duly attested.**

Reply of the firm was received on 10-0-2020 which was evaluated and application for renewal of DML was still found deficient of following documents.

1. Application on Prescribed Form 1A dully signed by current management of the firm.
2. Original Certified True Copy of Form-29 & Form-A (Updated) issued by SECP.
3. Detail of all licensed sections on firm's letter head along with approval letters of sections issued from the Central Licensing Board & if not available then submit layout plan for Regularization of facility.

proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000356 by way of formulation of M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi , may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Accordingly, the show cause notice Dated : 30-09-2020 was issued to the firm.

Firm has submitted layout plan for regularization of manufacturing facility which was discussed in the LOP committee and observations were observed in the layout plan which are communicated to the firm vide letter Dated : 13-10-2020.

In the meanwhile approved Quality control Incharge of the firm Ms. Amir Zadi as forwarded her resignation stating that she has resigned from the post of Quality control Incharge of M/s Uni-Tiech Pharmaceutical (Pvt) Ltd, Karachi with effect from 15-08-2020.

The firm is called for personal hearing vide letter Dated : 08-10-2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

No person appeared on behalf of the firm. The Board deliberated the case and decided to afford final opportunity for personal hearing to the firm in the next meeting of the Central Licensing Board before taking decision.

Case No. 24 SUSPENSION OF LICENSES OF ABSCONDER ACCUSED PERSONS IN CASE NO. 42/2016, THE STATE VS M/S FRIENDS PHARMA (PVT) LTD & OTHERS.

Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta, directed the Licensing Division to provide information regarding accused persons namely Meheryab, Quality Control Manager and Ms. Shabana Malik, Production Manger of M/s Friends Pharma Pvt Ltd, 31-Km, Ferozepur Road, Lahore that whether they are registered/license-holder in any other company / firm by our office in case No. 42/2016 The State Vs M/s Friends Pharma Pvt Ltd, Lahore. Licensing Division informed the Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta via letter dated 22nd May, 2019 that as per available record of Licensing Division, M/s Friends Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore promoted Ms. Shabana Malik D/o Fazal Karim CNIC No. 35202-2380250-0 as Production Inchargew.e.f 18-04-2018 as per promotion letter and working on the same post till date. Mr. Meheryab S/o Muhammad Akram CNIC No. 35201-1676468-3 joined the firm as Quality Control Inchargew.e.f 07-07-2014 as per appointment letter and he resigned from his post w.e.f. 06-2015. Furthermore, Mr. Meheryab joined M/s Theramed Pharmaceutical (Pvt) Ltd, Lahore DML No. 00696 (formulation) as Quality Control Inchargew.e.f 06-02-2018 and working on the same post till date. Now, Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta ordered that the licenses of both the qualified persons i.e. Meheryab and Shabana Malik be suspended forthwith being the willful absconders of the Court as both are reluctant to appear the Court and concealing themselves in this connection, due to which Court has already declared them as proclaimed offenders.

Decision by the Central Licensing Board in 273rd meeting

The Board considering the orders of the Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta and after thread bare deliberation decided to serve Show Cause Notice

to the accused persons namely Meheryab, Quality Control Manager and Ms. Shabana Malik, Production Manger, who were working in M/s Friends Pharma Pvt Ltd, 31-Km, Ferozepur Road, Lahore and now working in M/s Theramed Pharmaceuticals (Pvt) Ltd, 45-Km Multan Road, Lahore and M/s Friends Pharma Pvt Ltd, 31-Km, Ferozepur Road, Lahore respectively under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976as to why their approval as technical staff may not be cancelled on the orders of the Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta.

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

The show cause notice dated 3rd March, 2020 was issued to Mr. Meheryab and Ms. Shabana Malik.

Mr. Meheryab replied to Show Cause Notice and submitted that he did not receive any official letter or any intimation regarding said case. He further stated thathe worked in Friends Pharma during July 2014 to June 2015. After receiving Show Cause Notice, he contacted M/s Friends Pharma, from where he came to know that Court has given order in the favor of M/s Friends Pharma (Pvt) Ltd, Lahore. He has requested to not cancel his approval as technical staff.

Ms. Shabana Malik replied to Show Cause Notice and requested to consider her application sympathetically and stated on the behalf of firmthat the above case has been decided in the favor of the firm and copy of decision will be provided.

A letter of Personal Hearing was issued toMr. Meheryab and Ms. Shabana Malikon 8thOctober, 2020.

Proceedings and Decision of the Central Licensing Board in 277th meeting:

Ms Shaban Malik appeared before the Board and contended that she had resigned from M/s M/s Friends Pharma Pvt Ltd, 31-Km, Ferozepur Road, Lahore in 2009 and left for abroad in 2013. She further stated that she returned to Pakistan in 2018 and rejoined M/s Friends Pharma Pvt Ltd, 31-Km, Ferozepur Road, Lahore again. She submitted an undertaking on stamp paper that she would appear before the Court when ever called. She, therefore, contented that Show cause Notice may be with drawn. The Board after hearing Ms Shaban Malik decided to provide an opportunity to her to appear before the Court. The Board also decided to afford last opportunity to Mr. Meheryab to in the next meeting of the Central Licensing Board.

CASE NO. 25. CORRECTION IN ADDRESS ON DRUG MANUFACTURING LICENSE M/S JENNER RESEARCH LABORATORIES, SHEIKHUPURA.

M/s Jenner Research Laboratories, Sheikhupura had applied for site verification at site located at M-2, Pharmazone, 26th Km Lahore Sharikpur Road, Dhamkey, District Sheikhupura then site was approved at 26th Km Lahore Sharikpur Road, Dhamkey, District Sheikhupura and layout plan of the firm was also approved at the same address. Late on, the firm filed application for grant of Drug Manufacturing License and in Form-1 address of the firm was Plot No. 2, M-2, Pharmazone, 28th Km Lahore Sharqpur Road, District Sheikhupura and Form-2 was issued to the firm with the address Plot No. 2, M-2, Pharmazone, 28th Km Lahore Sharqpur Road, District Sheikhupura.
Now the firm has requested to correct the address on Drug Manufacturing License as Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupura.

Decision of the Central Licensing Board in 275th meeting:

The Board considered the case and decided to call the firm in the next meeting of the Board to apprise the Board with all documentary evidence in support of the claim. Moreover, information may also be sought from Industrial Estate.

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

Decision of the Board was conveyed to the firm vide letter dated 23rd July, 2020.
The firm replied to this letter and submitted that M/sJenner Pharmaceuticals is not situated in any industrial zone, it is situated on private land dedicated for only pharmaceutical units. In this area provision of six pharmaceutical units is available, out which three unit are already licensed i.e. Jenner Pharma, McOlson RL, Variant Pharma and three more pharmaceutical unit are also in pipe line. Due to which this land is named as M2-pharmazone.
A letter of Personal Hearing was issued to the firm on 8thOctober, 2020.

Proceedings and Decision of the Central Licensing Board in 277th meeting:

Mr. Umer Jajja, Director of the firm appeared before the Board and contended that correct address of the firm is Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupura. He submitted lay out plan attested from TMA, Sheikhupura in his claim. He further submitted goofle imapges of the location wherein other two pharmaceutical licensed units namely McOlson RL, Variant Pharma are in adjacent vicinity. The Board after agreeing to the clarification decided to approve the correct address of the firm as under:

M/s Jenner Research Laboratories, Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupura.

Case No. 26 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDI-VET (PVT) LTD, LAHORE.

M/s Medi-Vet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore had applied for renewal of DML No. 000269 by way of Formulation for the period of 22-12-2019 to 21-12-2024 on 24-10-2019.

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 19th February, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Classes of drugs & dosage forms of drugs.
iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm replied to this letter on 11th March, 2020but application was incomplete with following shortcomings and reminder letter was issued on 8th May, 2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format) signed by management.
ii. Classes of drugs & dosage forms of drugs.
iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm submitted documents on 28th July, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Properly filled, signed & stamped Form-1A (as per format)filled by Mr. Saeed Iqbal and signed by Mr. Haris Saeed.
ii. Prescribed fee of Rs. 50,000/- as there is change in management of the firm.
iii. Latest certified true copy of Form-29 duly attested by SECP.
iv. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medi-Vet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore Drug Manufacturing Licence No. 000269 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The show Cause Notice dated 25th September, 2020 was issued to M/s Medi-Vet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore.
The firm replied to show cause Notice but following documents are still deficient in the application for renewal of Drug Manufacturing License.

i. Latest certified true copy of Form-29 duly attested by SECP.
ii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

A letter of Personal Hearing was issued to the firm on 8thOctober, 2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

No person appeared on behalf of the firm. The Board deliberated the case and decided to afford final opportunity for personal hearing to the firm in the next meeting of the Central Licensing Board before taking decision.

Case No. 27 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HIGHNOON LABORATORIES LTD, LAHORE.

M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore had applied for renewal of DML No. 000155 by way of Formulation for the period of 21-08-2020 to 20-08-2025 on 28-11-2019.

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 26thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Section approval letters of Tablet (General) section & Capsule (General) section approved by CLB.
ii. Duly attested CNIC copies of all Directors.
iii. Prescribed fee of Rs. 50,000/- for change in management of the firm as there has been change in management of the firm.

The firm replied to this letter on 18thMarch, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 19thMay, 2020 to the firm for completion of application:

i. Section approval letters of Tablet (General) section & Capsule (General) section approved by CLB.

The firm submitted documents on 08thJune, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Section approval letters of Tablet (General) section & Capsule (General) section approved by CLB.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore Drug Manufacturing Licence No. 000155 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The show cause notice dated 24th September, 2020 was issued to M/s Highnoon Laboratories Ltd, Lahore.
The firm replied to show cause notice and submitted layout plan for regularization of facility.
A letter of Personal Hearing was issued to the firm on 8thOctober, 2020.

Proceedings and Decision of the Central Licensing Board in 277th meeting:

Ms Iram Naila, Associate Director Regulatory affairs appeared before the Board and contended that since all codal formalities for renewal of licence has been completed therefore, show Cause Notice may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of show cause notice.

CASE NO. 28. M/S MEDIWAYS INTERNATIONAL, LAHORE

Background:-

M/s Mediways International, Multan Road, Lahore was inspected on 09.02.2015 by Mr. Ajmal Sohail Asif, FID Lahore to see/verify the GMP compliance. During inspection the FID pointed out a number of serious shortcomings and gross violations including the following:-

Change Rooms:

- Air curtains were installed but were not functional at the time of inspection.
- No Separate change room was provided for visitors or executives.
- Change rooms were very small and need to be reorganized in respect of outside doors.
- The firm was also advised to provide cabinets in the change rooms for keeping the workers belongings etc.
- It was also noticed that at the time of inspection the change rooms were not maintained and were not neat and clean.

Storage Areas:

- Quarantine area not properly demarcated and separated from the de-dusting area.
- The firm has provided a dispensing hood which was placed in the raw material store for recipients. But it seemed not to be in use, since there were no accessories like balance, scoops etc inside the dispensing booth.
- Balances and other accessories for dispensing were available on one of the racks of raw materials.
- No separate facility for sampling of the materials was available; the firm was advised to provide proper sampling facility.
- The firm was also advised to rearrange the placement of dispensing hood providing separate cabin and proper flow of pre and post dispensed materials
- However packing material store was congested the firm was advised to expand the storage area for packing materials.

Production Areas:

- HVAC was not functional at the time of inspection due to load shedding as informed by management of the firm.
- The firm was advised to partition this room for separation of de-cartooning and bottle blowing functions.
- It was also noticed that all the doors in production area were wooden and the firm was advised to replace all the wooden doors.

Quality Control Laboratory:

- It was noticed that QC lab was accessed through the de-dusting/ quarantine area of raw material store; the firm was advised to provide some other entrance to QC laboratory in order to avoid unnecessary movements QC of staff in stores.

Quality Assurance:

- During the last inspection the firm has presented a QA officer but at the time of this inspection no QA personnel was present.
- From ware houses to production and quality control no prevalence/involvement of quality assurance was observed.
- The management of the firm was also advised during previous inspection to strengthen the QA department but no improvement was seen in this department.
- Due to lack of QA system, deviations from SOPs, GMP, GSP etc, were observed in stores, manufacturing areas and quality control.
- Non existence of an independent check and balance system may result in compromises, by manufacturing and QC personnel, for routine deviations from practices and procedures. Such a situation may pose a great potential of compromises on overall quality of the products being manufactured.

Sanitation and Hygiene:

- The equipments in QA laboratory and different gauges, matters and equipment in manufacturing areas were not calibrated.
- There was no system for qualification and validation of machines, procedures and practices.
- The firm has no procedures for cleaning validation and was advised to develop.

Products Recalls:

- The firm was advised to assign a separate area for recall products and demark it well

Self Inspection and Quality Audit:

- No record was available for any audit.

Personnel:

- However, there was no technical person to look after the QA.
- The firm was advised to establish proper QA department and to hire appropriate personnel to strengthen the QA

Training:

- However, It was not being implemented as no record was available

Equipment & Machinery:

- However, the firm was advised to upgrade the syrup filling machine.
- The machines/equipments were not properly labeled regarding the status.
- However, the firm was advised to purchase the FTIR on priority basis.

Materials:

- The firm was advised to purchase the materials from manufacturers or authorized suppliers.
- The firm was also advised to conduct vendor qualification.
- The firm has not developed a proper material management system.
- The materials were not properly labeled.

- The firm was advised to affix the label on each and every container / bag of a lot of material.
- The firm was also advised to develop and implement the procedures for safety and security of the workers/personnel handling the materials in stores and also to mark the racks and allocate locations of the materials.
- In packing materials store the firm was advised for safe storage of printed materials and unit cartons under lock and key.

Documentation:

- It was found that some of the SOPs and BMRs needed review, improvement and updating regarding the actual practices.
- The log books for QC equipment were not maintained.
- The firm was advised to prepare procedure for OOS, cleaning validation etc.

Good Practices in Production:

- In general the practices were observed not to be in accordance with the prescribed procedures.
- The firm was asked to present the BMR for the last batch of a product namely "Antizile Syrup" but the management failed to produce any documentation.

Good Practices in Quality Control:

- There were procedures for QC analysis but they needed to be updated.
- The log books for instruments and equipments were not maintained.
- In general the practices were observed not to be in accordance with the prescribed procedures.

Utilities

Water Purification System:

- The firm was advised to install transfer pipes for supply of purified water to manufacturing area to minimize the exposure to external environment during manual transfer.

HVAC System:

- The firm was advised to repair the manometer so that the pressure gradients in buffer and manufacturing areas may be checked.

The FID further concluded that: The non compliant behavior of the firm towards advises made during previous panel inspection; the firm was considered to be operating at unsatisfactory level of the compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under.

Action Taken by DRAP: - Accordingly, a show cause notice and suspension of production order in all section was issued to the firm on 20.03.2015 with immediate effect.

Reply of the firm: - In response to show cause notice the firm vide letter No. Nil dated 15.06.2015 submitted their reply and requested to verify the shortcomings through area FID.

Proceedings of 245th meeting of CLB held on 30.12.2015

Mr. Jamil Ahmad, CEO of the firm appears before the Board. He informed that the observations given by the FID were given attention and most of the observations have been rectified and compliance report was also submitted. The firm is ready for inspection.

Decision of 245th meeting of CLB held on 30.12.2015

The case was placed before the Central Licensing Board for consideration. The Board after thorough discussion, keeping in view the available record, compliance report and request from CEO of the firm, decided to conduct panel cGMP inspection of the firm, on approved Schedule B-II cGMP format and panel will also submit report in tabulated form identifying the previous observations and the current status, by the following members:-

i. Dr. Ikram ul Haq, Member, CLB
ii. Dr. Zakaur Rehman, Member, CLB
iii. Mr. Ajmal Sohail Asif, Area FID.

Accordingly decision of 245th meeting of CLB was conveyed to the firm on 10.02.2016

Letter of Secretary PQCB, Lahore:-

Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that Deputy Drug Controller Allama Iqbal Town Lahore alongwith other members inspected the premises on 16.06.2016. The team observed that:-

i. Manufacturing of Drugs was being carried out under unhygienic conditions.
ii. Improper storage of drugs (at 40 degree Centigrade).
iii. Illegal or unauthorized import of raw materials without label (misbranded).

The case was placed in 249th meeting of CLB held on 29.08.2016.

Proceedings of the 249th meeting of CLB

The Board was informed that Mr. Ajmal Sohail Asif, FID conducted inspection of the firm on 09.02.2015. The firm was issued order for suspension of production activities and issued showcause notice / Suspension of production order No.F.4-4/2001-QA on 20.03.2015. Accordingly, the case was discussed in 245th Meeting of CLB, wherein the CLB had constituted following panel of experts to verify the improvements:-

a. Dr. Ikram ul Haq
b. Dr. Zakaur Rehman
c. Mr. Ajmal Sohail Asif

Inspection report of the firm is still awaited. The Board also discussed and evaluated the reports / cases forwarded by the Secretary, PQCB, Punjab, Lahore and Chief Drug Controller, Punjab for cancellation / suspension of DML of the firm M/s Mediways, Lahore. The Board also

consider sub Rule 3 of Rule 5 of Punjab Drugs Rules, 2007 which categorically stated that *"The provincial and district Board shall examine a case referred to it by an inspector and shall , if an action is proposed to be taken against a person under the Act or the rule, issue a showcause notice to the personal and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*

Decision of the 249th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board considered the recommendations of the Secretary, PQCB, Punjab and took a serious notice on illegal / unauthorized manufacturing and violation of the orders of the DRAP's letter No. No.F.4-4/2001-QA dated 20.03.2015. The Board decided to issue a showcause notice to the firm M/s Mediways, Lahore on illegal / unauthorized production activities and disobeying the orders of DRAP.

Accordingly showcause notice was issued to the firm on 03.10.2016.

Proceedings of the 250th Meeting of CLB

Mr. Jamil Ahmed, Chief Executive of the firm M/s Mediways International, Lahore appeared before the Board for personal hearing. He informed that the production is suspended since March, 2015, as per direction of the Division of QA&LT. The provincial government during the raid sealed the premises, which was later on de-sealed on the order of the Drug Court, Lahore. He also informed that inspection book is also in the custody of provincial drug inspector, which has not been handed over to him till date, despite number of requests. Dr. Ikram ul Haq, Member CLB informed the Board that he along-with other members of the panel visited the firm, in compliance to decision of 245th Meeting of CLB, but the firm was found closed and the inspection could not be carried out.

Decision of the 250th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, non serious and non-professional attitude of the firm, , the Board decided to:-

i. Suspend the Drug Manufacturing License of the firm M/s Mediways International, Lahore for a period of six months under Section 41 of the Drugs Act, 1976 read with Rule 12 (1) of the Drugs (LR&A) Rules, 1976.
ii. Direct the area FID to visit the firm on alternate months to verify the suspension of production and submit report.
iii. Resumption of production shall only be allowed after completion of suspension of DML period, verification by the panel of experts and subsequent approval from the Competent Authority.

Updated status:-

The panel constituted by the Director QA&LT conducted inspection of the firm on 26.12.2017 (received on 17.04.2018). The panel submitted detailed inspection report including previous observations and updated status on Schedule B-II format and recommended as under:-

"Based on the areas inspected, the people met and the documents reviewed, and considering the finding of the inspection in comparison with the observations of the previous inspection, the panel of inspectors does not consider the firm to be at a satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under. The plot size is smaller than the prescribed requirement. However, CLB in its 241st meeting held on 15.5.2015 decide "to allow two years time for shifting of unit / enhancement of plot size according to rules"; and that two years period. Therefore, the panel of inspectors does not recommend M/s Mediways International, 16KM Multan Road, Lahore, for resumption of production. The report is forwarded herewith for further consideration and necessary action".

Proceedings of the 261st meeting of the CLB

The case was placed before the board for appraisal in the light of recommendations of the panel of experts in its report dated 26.12.2017.

Decision of the 261st Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendation of the panel of experts in its report dated 26.12.2017, the Central Licensing Board decided to:-

i. Further extend Suspension of DML period for next six months from the date of issuance of decision of 261st meeting of CLB.
ii. The Licensing Division Shall place the case in forthcoming meeting of CLB in the light of decision of 241st meeting of CLB.

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

The Central Licensing Board in its 241st meeting held on 15th May, 2015 has considered the case of M/S Mediways International, Lahore and decided as under:

- *"To allow two years time for shifting of unit / enhancement of plot size according to the rules.*
- *To scrutinize the application of the renewal of DML of the firm for the period 09-02-2015 to 09-02-2020 and inform the applicant the status of the application according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976 and conduct inspection of the firm after completion of application of renewal of DML."*

The same decision was conveyed to the firm vide letter issued on 24th August, 2015 but till date no application is received from the firm for shifting of their existing facility and

application for renewal of DML No. 000468 (Formulation) for period of 09-02-2015 to 08-02-2020 is incomplete with following documents being deficient:

i. Nothing due certificate regarding CRF (Updated).
ii. Approval letters of Production Incharge and Quality Control Incharge, if not approved, complete set of duly attested documents (as per checklist) of qualified staff alongwith prescribed fee of Rs.10,000/-
iii. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs.50, 000/- for change in management.
iv. CNIC copies of owner/partners.
v. Proof of CLB approved sections.
vi. Legal status of the firm.

Proceedings and Decision of Central Licensing Board in 265th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19,Schedule B-II and Rule 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/sMediways International, Multan Road, Lahore, under Drug Manufacturing Licence No. 000468 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 27thSeptember, 2018 was issued to the M/sMediways International, Multan Road, Lahore which was returned back. Then The Additional Director (E&M),DRAP, Lahore requested to ensure delivery and receiving of show cause notice to the firm.

The firm replied to the show cause notice and the application for renewal of DML is incomplete till date with following short comings.

i. Nothing due certificate regarding CRF (Updated).
ii. Proof of CLB approved sections.
iii. Undertaking as sole proprietor on stamp paper.

Furthermore, the firm requested to allow three year for shifting unit after earning some revenue as the production has remained suspended for two years.

Proceedings and Decision of Central Licensing Board in 267th meeting

The Board considering the facts on the record and after thread bare deliberation decided to call the firm M/s Mediways International, Multan Road, Lahore for personal hearing in forthcoming meeting of the Central Licensing Board.

Proceedings and Decision of Central Licensing Board in 267th meeting

The Board considering the facts on the record and after thread bare deliberation decided to call the firm M/s Mediways International, Multan Road, Lahore for personal hearing in forthcoming meeting of the Central Licensing Board.

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

A letter of Personal hearing has been issued on 19-02-2019

Decision by the Central Licensing Board in 269th meeting

No person appeared on behalf of the firm. The Board after considering the facts decided to defer the case to give final opportunity to the firm to plead his case.

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

M/s Mediways International, Multan Road, Lahore had applied for renewal of DML No. 000468 by way of formulation on 07-02-2020.The application for the renewal of DML of the firm was evaluated and following documents still shortcomings / deficiencies:-

i. Proof of sections / Section approval letter approved by CLB.

ii. Duly attested CNIC copy of owner.

Now M/s Mediways International, Lahore has requested for exemption in area of 4-Kanal and stated as under:-

"It is stated that I, Jamil Ahrnad Proprietor of Mediways International Lahore being a Pharmacist belong to an honorable family, got Drug Manufacturing License in 2000 and fulfilled all the coda1 formalities prevailed at that time.

I have only one section (Oral Liquid) in an area of 1-kana1 3-marala duly approved by the competent authority as per existing law at that time. In August, 20 15 a notice was given for expansion in area to 4-kanal. The DRAP very kindly gave me exemption in 4-kana1 arca for 2 years with the directions to extend meanwhile up to 4-kana1 vide Letter No. F.1-42/92-Lic (Vol-1).

But Unfortunately the Federal Inspector of Drugs stopped the production before grant of exemption period by the Drug Regulatory Authority of Pakistan (DRAP), Therefore the factory remained closed up till now. I deposited the Renewal fee and relevant documents as per law,

Sir, in the above mentioned circumstances I was unable to purchase 4-kanal plot and build a new factory due to severe upset in my financial position. I have been damaged very badly even education of my children have to be suspended. There is no case pending in the court of law.

Respected Sir, kindly grant me exemption from area of 4-kanal for at least a period of 3 years on sympathetic grounds with the permission to start manufacturing simultaneously. I have only one liquid section for which 1-kanal 3-marala is sufficient to, meet out the requirements.

*I **assure** you sir, I will abide by the law **and** establish a new unit on 4-kana1 within 3 years. This act of kindness will save my family along with continuity in education of my children".*

A letter of Personal Hearing was issued to the firm on 28th August, 2020.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

Mr. Jameel Ahmed, Chief Executive of the firm appeared before the Board and requested to give further time of three years for shifting to industrial area as exisitingfacitility do not comply minimum area of plot under the Rules. He also contended that he wanted to generate resources from this unit to shift to new area which comply the provision of law. He also stated that it is also difficult to maintain the GMP compliance in existing building therefore, unit has remainnon operational for last three years. The Board also considered the previous GMP inspection report which noted number of serious observations noted by the Inspector. The Board also noted shortcomings in the application for renewal of Drug Manufacturing Licence.
The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19,Schedule B-II and Rule 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976, as to why their application for renewal of M/s Mediways International, Multan Road, Lahore, under Drug Manufacturing Licence No. 000468, by way of formulation, may not be rejected or Drug Manufacturing Licence may not be cancelled by Central Licensing Board.

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

The show CauseNotice dated 25th September, 2020 was issued to M/s Mediways International, Multan Road, Lahore.

A letter of Personal Hearing was issued to the firm on 8thOctober, 2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

Mr. Jameel Ahmed, Chief Executive of the firm appeared before the Board and reiterated his statement made before the Board in its 276th meeting held on 3rd September, 2020 for seeking three years time for shifting to new premises. The Board after hearing the representative observed that unit is non operational since last five years and owner is not taking serious and

sincere efforts to make it operational. The Boards also noted that at present premises legal and GMP compliance can not be made. The Board therefore, decided to cancel the Drug manufacturing Licence No. 000468 (formulation) in the name of M/s Mediways International, Multan Road, Lahore with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19,Schedule B-II and Rule 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No. 29 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDISAVE PHARMACEUTICALS, LAHORE.

M/s Medisave Pharmaceuticals. Plot No. 578,579 Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000681 by way of Formulation for the period of 26-01-2020 to 25-01-2025 on 17-01-2019.

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 18th February, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Duly attested CNIC Copies of all partners.
iii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm replied to this letter on 03rd March, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 27th April, 2020 to the firm for completion of application:

i. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm submitted documents on 04th June, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

ii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976

as to why their application for renewal of M/s Medisave Pharmaceuticals. Plot No. 578,579 Sunder Industrial Estate, Lahore Drug Manufacturing License No. 000681 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

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

The show Cause Notice dated 25th September, 2020 was issued to M/s Medisave Pharmaceuticals. Plot No. 578,579 Sunder Industrial Estate, Lahore.

The firm has not replied to show Cause Notice and application for renewal of DML is incomplete.

A letter of Personal Hearing was issued to the firm on 8thOctober, 2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

Mr. Imtiaz Ahmed, Chief Executive of the firm appeared before the Board and contended that he has submitted lay out plan for regularization a day before personal hearing. Therefore, all codal formalities has been complied. Hence, Show cause notice may be with drawn. The Board after hearing the representative of the firm decided to defer the case till next meeting of the Board.

Case No. 30 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S IRZA PHARMA (PVT) LTD, DISTRICT SHEIKHUPURA.

M/s Irza Pharma (Pvt) Ltd, 10/2-Km, Lahore Sheikhupura Road, P.O Kot Abdul Malik, District Sheikhupura had applied for renewal of DML No. 000108 by way of Formulation for the period of 12-07-2019 to 11-07-2024 on 15-07-2019.

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 23rd August, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Detail of management at the time of previous renewal and at present, if any change, apply for change of management.
iii. Duly attested job acceptance letter by Quality Control Incharge.
iv. Latest certified true copy of Form-29 mentioning all Directors (Attestation by SECP).
v. Duly attested CNIC copies of all Directors.

The firm replied to this letter on 18th September, 2019 and the deposited balance fee of Rs. 15,000/-for late submission of application on 14th February, 2020 but application was incomplete

with following shortcomings and reminder letter was issued on 27thApril, 2020 to the firm for completion of application:

i. Latest certified true copy of Form-29 duly attested by S.E.C.P without phrase that S.E.C.P does not take any responsibility of the correctness of the contents of Form.

The firm submitted documents on 12th May, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 duly attested by S.E.C.P without phrase that S.E.C.P does not take any responsibility of the correctness of the contents of Form.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Irza Pharma (Pvt) Ltd, 10/2-Km, Lahore Sheikhupura Road, P.O KotAbdul Malik, District Sheikhupura Drug Manufacturing Licence No. 000108 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The show CauseNotice dated 25th September, 2020 was issued to M/s Irza Pharma (Pvt) Ltd, Sheikhupura.
A letter of Personal Hearing was issued to the firm on 8thOctober, 2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

Mr. Imran Jawa, managing Director and dr. Iftikhar Masood, Plant Manager of the firm appeared before the Board and contended that all codal formalities has been complied, therefore, showcause notice may be withdrawn. The Board after hearing the representative of the case decided to cease the operation of show cause notice.

Case No. 31 **RENEWAL OF DRUG MANUFACTURING LICENCE AND CHANGE OF TECHNICAL STAFF APPLICATION OF M/S**

NEOMEDIX, PLOT NO. N/5, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD.

M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, had applied for renewal of DML 000539 by way of (Formulation) for the period of 02-04-2019 to 01-04-2024. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 11th September, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Form-1A duly signed & stamp by CEO.
ii. Classes of Drugs.
iii. Dosage forms of drugs.
iv. Name(s) of drugs registered / approved.
v. Detail of management at the time of previous and present renewal
vi. Partnership Deed alongwith CNIC's of all partners.
vii. Proof of Licensed Section from CLB.
viii. Up to date nothing due certificate regarding CRF from STO.
ix. All documents should be duly attested.

The firm submitted their reply on 15th October, 2019 after evaluation of the submitted documents, final reminder was issued on 15th October, 2019 to the firm with following shortcomings: -

For Quality Control Incharge.

1. Appointment letter.
2. Job acceptance letter by the appointee.
3. Copy of CNIC of appointee.
4. Copy of academic degrees.
5. Registration certificate from Pharmacy Council.
6. Experience Certificate.
7. Resignation of earlier Q.C Incharge.
8. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Attested).
9. Undertaking as whole time employee on stamp paper as per check list.

For Production Incharge.

i. Job acceptance letter by the appointee.
ii. Resignation / retirement of earlier approved Production Incharge.

iii. Undertaking as whole time employee on stamp paper as per check list.

Firm has submitted their reply in response to this Division's Final Reminder and following documents are still deficient /short and application for renewal of DML was incomplete:-

For Renewal of DML.

i. Name(s) of drugs registered / approved.
i. Detail of management at the time of previous and present renewal.
ii. Partnership Deed alongwith CNIC's of all partners.
iii. Detail of premises including layout plan.
iv. All documents should be duly attested.

For Prod. Incharge.

iv. Job acceptance letter by the appointee.
v. Resignation / retirement of earlier approved Production Incharge.
vi. Undertaking as whole time employee on stamp paper as per check list.
vii. All documents should be duly attested

For Q.C. Incharge.

i. Job acceptance letter by the appointee.
ii. Copy of CNIC of appointee.
iii. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
iv. Registration certificate from Pharmacy Council (in case of Pharmacist).
v. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
vi. Resignation / retirement of earlier QC Incharge.
vii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
viii. Undertaking as whole time employee.

Proceedings and Decision by the Central Licensing Board in 276nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Drug Manufacturing License No 000539 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

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

The show cause notice dated 25th September, 2020 was issued to Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, and Islamabad.

The firm has replied to show cause notice & submitted all documents except undertaking for approval of Production & QC Incharge & proof of licensed sections from CLB.

A letter of Personal Hearing was issued to the firm on 8th October, 2020

Proceedings and Decision by the Central Licensing Board in 277th meeting:

Mr. Shahid Hussain, General manager and Mr. Ghulam Ghous Quality control manager appeared before the Board. and contended that all codal formalities has been complied, therefore, showcause notice may be withdrawn. The Board after hearing the representative of the case decided to cease the operation of show cause notice.

Case No. 32 APPROVAL OF QUALITY CONTROL INCHARGE OF M/S CURE LABORATORIES (PVT) LTD, RAWAT, RAWALPINDI.

Mr. Ameer Hussain, approved Quality Control Incharge of M/s Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi, under Drug Manufacturing Licence No. 000897 by way of formulation had resigned w.e.f, 06-03-2019. The firm filed application for approval of new Quality Control Incharge on 13-11-2019.The application was evaluated and letter for following shortcomings / deficiencies was issued to the firm on 22nd January, 2020.

i. It has been noticed that there is duplication in dates of experience certificates of proposed Quality Control Inchargei.e Ambrosia Pharmaceutical, Islamabad 16th August, 2004 to 9th January, 2007 and Goodman Laboratories, Islamabad 1st December, 2006 to 12th February, 2014, the said person was working at two different organizations at the same time. Moreover, the previous Quality Control Incharge resigned on 6th March, 2019 from your firm and Quality Control testing has been continued without the supervision of approved Quality Control Incharge.

ii. You are therefore required to justify your position in writing regarding said experience and for violating the Rule 16 and 19 of Drugs (Licensing, Registering & Advertising) Rules 1976.

The firm submitted their reply on 6thFebruary, 2020. The application was complete and propose Quality Control Incharge was approved.

The firm carried production activity without approved Quality Control Incharge which is violation of Rule 16 of the Drugs (Licensing, Registering and Advertising) Rule, 1976.

Proceedings and Decision by the Central Licensing Board in 275th 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, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing Licence No. 000897by way of formulation in the name of M/s Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2, National Industrial Zone, Rawat may not be suspended or cancelled.

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

The show cause notice dated 6thJuly, 2020 was issued to M/s Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2, National Industrial Zone, Rawat.

The firm has replied to show cause notice on17-07-2020 and stated that they were in the process of hiring a Quality Control Incharge and during this period, no production activities were carried out because of the fact that the product registrations were in the process of approval in the DRAP and the registration certificates were issued on 22nd August and 25th September, 2019. The production activities at Cure Laboratories were started in the month of November 2019 after the hiring of Quality Control Incharge on 13th October, 2019.

A letter of Personal Hearing was issued to the firm on 28th August, 2020

Proceedings and Decision by the Central Licensing Board in 276th meeting:

No person appeared on behalf of the firm. The Board after considering the facts decided to defer the case to give final opportunity to the firm to plead his case. Moreover the Board decided to verify the start of production activities from Batch Manufacturing Record through Area Federal Inspector of Drugs.

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

A letter of Personal Hearing was issued to the firm on 8thOctober, 2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

Mr. Asif Humayun, Chief executive of the firm appeared before the Board and contended that Drug Manufacturing Licence was granted in March, 2019 and Registration letter of drugs were issued in late August and September, 2019 and production was commenced in November, 2019 and t that time they had approved Quality control Incharge. He, however, stated before the Board that he law abiding citizen and will take due diligence in compliance of law. The Board after hearing the representative of the case decided to cease the operation of show cause notice.

QUALITY CONTROL CASES

[F. No. 04-02/2019-QC]

Case No. 01 **MANUFACTURE AND SALE OF UN-REGISTERED DRUGS – M/S PRINCE MEDICOS, K.E 27, DOUBLE ROAD, BILAL COLONY, NEAR GUL AHMED CHOWRANGI. LANDHI KARACHI.**

That Miss. Mehwish Tanvir, FID-VII, Karachi vide letter no. DMK-01-14/2019-FID-VII-(K) dated 08.07.2019 received on 17.07.2019 forward the subject captioned case.

02. That the Miss. Mehwish Tanvir, FID-VII, Karachi informed that Dr. Muhammad Kashif, the-then Federal Inspector of Drugs-VII, Karachi alongwith the team of officers & Officials of DRAP Karachi & Mr. Sajid Ali, Provincial Drug Inspector visited/inspected the premises of M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi on 16th January 2019. During visit following unregistered drugs were recovered and seized on prescribed Form-2 under the Drugs Act 1976 and rules framed thereunder.

Detail of Drugs Seized			
Serial No.	**Name Of Drugs**	**Batch No.**	**Purported to Be Manufactured By:**
01	Tablet Diclocin Forte+	412	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Ur.) India.
02	Tablet Pinadol CF	PCF-195	.....Do .....
03	Tablet Dynalid-pt	7361	M/s Unmax Laboratories India.
04	Tab. Dynalid-pt	7360	.....Do .....
05	Neurobin Ampoules	240272	M/s. Merck kga A Darmstalt (Germany).
06	Dona Capsules	850	M/s. Faazli Homoeo Pharma Karachi
07	Dona Capsules	852	**.....**Do .....
08	Arfifen 50mg Tablets	ARF31	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Hr.) India
09	Pyricam-20 Capsules,	PC-141	……..Do……..
10	Citriz Tablets.	CZ 109	……..Do…….
11	Cezin Tablets	MT-17-710 MT-17-	M/s. Maiden Pharmaceutical Sonepat- India
12	Cofcal + Tablets	000822	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Hr.) India
13	Diclo Tablets 50mg	170842	M/s. Shanxi federal Pharmast Co China
14	Voven Capsules	MC 17-	M/s. Maiden Pharmaceutical Sonepat- India

15	Sulpiride Capsules 50mg	MC-I7-I57	..... Do .....
16	Ring Guard Cream	DG 267	M/s. Rackill Benckieser Health Care India
7	Aobama Tablets		..... Do .....
18	MMG		..... Do .....
19	Cobra-150 Tablet	Nil	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Hr.) India
20	Sildenafil Citrate Tablets New Panegra	Nil	..... Do .....
21	American Superman Tablets	Nil	M/s. Americal Ernoron medicine nation group.
22	Knight Rider Tablets	Nil	Made in UK
23	Duraza 100 tables	Nil	M/s. Torque Pharmaceutical
24	MM-3 Cream	Nil	U.S.A.
25	Viga 84000 Spray	Nil	Made in Germans.
26	Neherpa Tablets	Nil	M/s. Maiden Pharmaceutical Sonepat- India
27	Rega Tablets	Nil	M/s Indkus Biotech India
28	Dilkhush Tablets	Nil	Torque
29	Zinetac l50mg Tablets	Nil	G.S.K India
30	Grucid Capsules	Nil	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Hr.) India
31	Spasrid Injection	Nil	M/s Barrett Hodgson Pak Karachi

03. The FID-VII, Karachi informed that following samples of suspected un-registered drugs were taken for the purpose of test analysis on prescribed Form-3 under the Drugs Act 1976:

S. No.	**Name of Drug**	**Batch No.**	**Mfg. By**
DMK-01/19	Tab. Pinodol CF	PCF-195	M/s. Combitic Global Caplet. LTD. M-15. D-2.D-3. Industrial Area. Sonepat-13 1001 (Hr.) India
DMK-02/19	Tab. Diclocin Forte+	DTF-811	.....Do .....
DMK-03/19	Tab. Arfifen 50mg	ARF-31	.....Do .....
DMK-04/19	Cap, Pyricam-20	**PC-141**	.....Do .....
DMK-05/19	Tab. Citriz	CZ-109	.....Do .....
DMK-06/19	Cap. Voven 50mg	MC-17-195	.....Do .....
DMK-07/19	Tab. Cobra-1 50	-NIL-	.....Do .....
DMK-08/19	Tab Zinetac 1 50mg	N5211	.....Do .....

DMK-09/19	Cap. Grucid	GC1221	.....Do .....
DMK-10/19	Tab. Augmentin 375mg	HATB1	M/s. Glaxo SmithKline F-268. S.I.T.E. Karachi.
DMK-11/19	Iodex Ointment	EIADA	.....Do .....
DMK-12/19	Iodex Ointment	EIADA	.....Do .....
DMK-13/19	Iodex Ointment	D1AAS	.....Do .....
DMK-14/19	Iodex Ointment	EIADA	.....Do .....

04. FID-VII, Karachi also informed that the sealed sample of above drugs were sent to Federal Government Analyst. Central Drugs Laboratory, Karachi for the purpose of test/analysis vide memorandum No. DMK-0l to 15/2019-FID VII(K) dated 18th January 2019.

05. FID-VII, Karachi added that the-then FID vide their letter No.F.DMK.24-30/2019-FID-VII DRAP(K) dated 21stJanuary 2019 requested to DRAP Islamabad to grant permission for the safe custody of drugs seized on prescribed Form-2 under the Drugs Act l976.

06. FID-VII, Karachi also added that M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi was asked to provide bill warranty under section 23(1)(i) of the Drugs Act 1976 vide her office letter of No.F.DMK.24-30/2019-FID-VIl-DRAP(K) dated 21stJanuary 2O19.

07. FID-VII, Karachi reported that DRAP Islamabad vide their letter No.F.13-45 2019-(QC) dated 28thFebruary 2019 grant permission to continue the custody of the seized stocks till decision of the case.

08. FID-VII, Karachi informed that the Federal Government Analyst, Central Drugs Laboratory, Karachi declared the following sample of drugs as "**Unregistered Drug Products**". Detail are as under:-

S.NO.	**Name of Drug**	**Batch No.**	**Mnfd: by**	**Test Report No & Dale**	**Test Repo**

01	Pipadol CF Tablets	PCF-195	M/s Combiotic Global Caplet Ltd: India.	RKQ.51/2019 Dated 18-03-19	Un-Registered Drug Product
02	Diclocin Forte + Tablet	DTF-811	M/s Combiotic Global Caplet Ltd: India.	RKQ.52 2019 dated 18-03-19	Un-Registered Drug Product
03	Arfifen 50ntg Tablets	ARF-31	M/s Combiotic Global Caplet Ltd: India.	RKQ.53/2019 dated 18-03-19	Un-Registered Drug Product
04	Pyricam-20 Capsules	PC-141	M/s Combiotic Global Caplet Ltd: India.	RKQ.54 2019 dated 18-03-19	Un-Registered Drug Product
05	Citriz Tablets	CZ-109	M/s Combiotic Global Caplet Ltd: India.	RKQ.55 2019 Dated 18-03-19	Un-Registered Drug Product
06	Voven Capsules	MC-I7-195	M/s Maiden Pharmaceuticals Ltd: India.	RKQ.56 2019 dated 15-03-19	Un-Registered Drug Product
07	Cobra-150 Tablets	Nil	M/s Combiotic Global Caplet Ltd: India.	RKQ.57/2019 dated 28-02-19	Un-Registered Drug Product
08	Grucid Capsules	GC-1221	M/s Combiotic Global Caplet Ltd: India.	RKQ.59/2019 dated 15-03-19	Un-Registered Drug Product

09. FID-VII, Karachi in the light of above test report of Federal Government Analyst, Central Drug Laboratory, Karachi issued explanation letter to M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi, Landhi Karachi. Subsequent reminders were also issued vide her office letters of even number dated 24thApril & 13thMay 2019. No any reply was received from M/s Prince Medicos, Landhi Karachi till the case reporting day i.e. 08.07.2019.

10. FID-VII, Karachi reported that M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi and Mr. Ali Muhammad S/O Nazir Muhammad (owner) were found involved in storing \ selling of unregistered drug products and contravened the section 23(1)(a)(vii) of the Drugs Act 19'6. which is punishable under section 27 of the Drugs Act 1976 and rules framed thereunder.

FID-VII, Karachi stated that the names of responsible person of M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi are as under:

1. M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi.
2. Ali Muhammad S/O Nazir Muhammad (Proprietor).

RECOMMENDATIONS OF FID: -

M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi and Mr. Ali Muhammad S/O Nazir Muhammad (Owner) found involved in the storing & selling of unregistered drug products and violated the section 23(1)(a)(vii) of the Drugs Act,1976 and punishable under section 27 of the Drugs Act 1976. Therefore:-

1. Grant permission to registered FIR against above said accused responsible person.

OR

2. Permission for prosecution in the Drug Court of Sindh. Karachi may be issue against the accused/responsible person.

That the area FID-VII, Karachi submitted the complete case for information and directives action in the matter, as per section 19(7) of Drugs Act, 1976.

11. That the area FID, Karachi vide letter no. DMK-01-14/2019-FID-VII(K) dated 24th July, 2019 submitted her reply as under, in response to a clarificationletter No. 04-02/2019-QC dated 19th July, 2019:

1). As per available record provided by the-then FID, M/s Prine Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi, Landhi, Karachi have no drug sale license. They only provided the copy of paid challan for Rs. 5000 dated 15.10.2018.

2). No qualified person as they have no Drug Sale License.

3). As per CNIC complete address of Ali Muhammad is House No. 201. New Muslimabad Colony, Landhi, Malir, Karachi.

12. Keeping in view the request and recommendation of area FID-VII, Karachi, the Director, QA&LT, DRAP, Islamabad has acceded the requestof FID *"to grant the permission to lodge FIR"*being authorized by the Central Licensing Board in its 237th Meeting held on 01.10.2014 as required under DRAP Act, 2012/the Drugs Act, 1976 and rules framed thereunder. The approval was communicated to FID-IV, Islamabad vide letter **F. No.04-02/2019-(QC)** dated 28th August, 2019 against following persons:

1. M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi.
2. Ali Muhammad S/O Nazir Muhammad (Proprietor).

As per report of area FID, Karachi, the above mentioned accused persons have committed offence in contraventions of Schedule II of DRAP Act 2012 /Section 23 of Drug Act 1976, which is cognizable offence under Schedule-IV(2)(a) of DRAP Act 2012 / section 30(2)(a) and punishable under Schedule III/ Section 27 of Drug Act 1976.

13. That the case was placed before the CLB in its 271st meeting wherein the Board decided as under:

"The Board deliberated the matter in depth, considered the facts of the case and after perusal of record decided to allow recommendations of FIDs as under:

a. Board allowed the ratification of permission granted by the Director (QA&LT) for registration of FIR against following accused persons for contraventions of Schedule II of DRAP Act 2012 /Section 23 of Drug Act 1976, which is cognizable offence under Schedule-IV(2)(a) of DRAP Act 2012 / section 30(2)(a) and punishable under Schedule III/ Section 27 of Drug Act 1976 communicated vide letter no. 04-02/2019-QC dated 28th August, 2019; and

i. M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi.
ii. Ali Muhammad S/O Nazir Muhammad (Proprietor), House No. 201. New Muslimabad Colony, Landhi, Malir, Karachi.

b. Board allowed the ratification of permission granted by the Director (QA&LT) for safe custody of seized stock till decision of the case communicated vide letter no. 13-45/2019-QC dated 28th February, 2019 ; and

c. Board allowed to recommend for non-issuance of license/cacellation of license (if issued) of M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi."

14. The above-mentioned decision of the Board was communicated to the area FID Karachi, The Decretary Health, Government of Sind, Karachi and Chief Drug Inspector, Government of Sind, Karachi vide letter No. F. 03-44/2019-QC (271-CLB) (Pt-II) dated 11-09-2019.

15. FID VII Karachi vide letter No. DMT.10/6-2020-AD/FID-VII (DRAP) (K) dated 10-06-2020 provided the copy of Interim investigation report in the case FIR NO. 02/2020 of FIA ACC Karachi which was sent to her by Additional Director FIA Sindh, Karachi. Contentes of the interim investigation report are as under;

"ANTI CORRUPTION CIRCLE KARACHI
INTERIM INVESTIVATION REPORT

01.	***Case FIR No. & Date.***	*02/2020 dated 13-02-2020*
02.	***Under Section.***	*U/S 23 & 27 OF Drugs Act 1976.*
03.	***Name of Complainant.***	*Dr. Mehwish Tanveer, Assistant Director/ Federal Inspector of Drugs-VII, Karachi*
	Name of Accused Person.	*Ali Muhammad S/O Nazir Muhammad (CNIC No. 42501-7448033-7).*
05.	***Allegation***	*Sale of unregistered Drugs*
	Authority who permitted for Registration of Case.	*The Director FIA, Sindh, Karachi.*
07.	***Name of I.O.***	*Inspector Javed Ahmed Babbar*

BRIEF FACTS

Brief facts of the case are that the subject case was registered by the undersigned consequent upon receipt of complaint from the above named complainant. The contents of FIR are reproduced below:

"Brief facts of the case are that a complaint from the above named complainant addressed to the Director FIA Sindh, Karachi has been received in this circle. The complaint is reproduced as below:-

'The Director,
Federal Investigation Agency,
Karachi.

Subject: ***Sale of "un-registered Drug Products" by M/s Price Medicos, K.E. 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi, Landhi, Karachi.***

Dear Sir,

I am directed to refer to the subject mentioned above and to submit the complaint under Schedule IV of the DRAP Act, 2012 for registration of FIR.

Grounds/Facts of the case:

1. Undersigned is working in Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulations and Coordination, Karachi and due to I was on leave Dr. Muhammad Kashif the then Federal Inspector of Drugs-VII along with the team of officers and Officials of DRAP Karachi and Mr. Sajid Ali, Provincial Drug Inspector had been appointed as Federal Inspector of Drugs (BPS-18), Karachi (Annexure-A).

In compliance to the DRAP Islamabad letter No.F.04-02/2019-(QC) dated 28th August 2019, undersigned inspected M/s. Prince Medicos, situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi on 16th January 2019. During visit following un-registered drugs were recovered and seized on prescribed Form-2 under the Drugs Act 1976 and rules framed there under:

S. No.	***Name of Drugs***	***Batch No.***	***Purported to be Manufactured By***
01	*Tablet Diclocin Forte+*	*412*	*M/s Combitic Global Caplet, LTD, M-15, D*
02	*Tablet Pinadol CF*	*PCF-195*	*-do-*
03	*Tablet Dynalid-pt*	*7361*	*M/s. Unmax Laboratories India. '*
04.	*Tablet Dynalid-pt*	*7360*	*-do-*
05	*Neurobin Ampoules*	*240272*	*M/s. Merck kgaA, Darmstalt Germany.*
06.	*Dona Capsules*	*850*	*M/s. Faazil Homoeo Pharma Karachi.*
07	*Dona Capsules*	*852*	*-do-*
08	*Affifen 50mg Tablet*	*ARF31*	*M/s. Combitic Global Caplet, LTD,. M-*
09	*Pyricam-20*	*JC-141*	*-do-*
10	*Citriz Tablets*	*CZ 109*	*-do-*
11	*Cezin Tablets*	*MT-17-710*	*M/s. ,Maiden Pharmaceutical Sonepat-*
12	*Cofcal+Tablets*	*000822*	*M/s. Combitic Global Caplet, LTD. M-*
13	*Dielo Tablets 50mg*	*170842*	*M/s. Shanxi Federal Pharmast Co China.*

14	*Voven Capsules*	*MC17-195*	*M/s. Maiden Phannaceutical Sonepat-*
15	*Sulpiride Capsules*	*MC-17-157.*	*-do-*
16	*Ring Guard Cream*	*DG 267*	*M/s. Rackitt Benckieser Health Care*
17	*Aobama Tablets*		*-do-*
18	*MMC*		*-do--*
19	*Cobra-150 Tablet*	*Nil*	*M/s. Combitic Global Caplet, LTD. M-*
20	*Sildenafil Citrae*	*Nil*	*-do--*
21	*American superman*	*Nil*	*M/s. Americal Ernoron medicine nation*
22	*Knight Rider Tablet*	*Nil*	*Made in UK*
23	*DURAZA 100*	*Nil*	*M/s. Torque Pharmaceutical*
24	*MM-3 Cream*	*Nil*	*USA.*
25	*VIGA 84000*	*Spray*	*Made in Germaney.*
26	*Neherpa Tablets*	*Nil*	*M/s. Maiden Pharmaceutical Sonepat-*
27	*Rega Tablets*	*Nil*	*M/s. Indkus Biotech India*
28	*Dikhush Tablets*	*Nil*	*Torque*
29	*Zintetac 15mg Tblet*	*Nil*	*G.S.K India*
30	*Crucid Capsules*	*Nil*	*M/s. Combitic Global, LTD. M-15, D-2,*
31	*Spasrid Injection*	*Nil*	*| M/s. Barrett Hodgson Pak Karachi.*

Following samples of suspected un-registered drugs were taken for the purpose of test analysis on prescribed Form-3 under the Drugs Act 1976.

S.No.	***Name of Drug***	***Batch No.***	***Mfg.By***
DMK-01/19	*TAB, Pinodol CF*	*Pcf-195*	*M/s. Combitic Global Caplet, LTD. M-15, D-2, D-3, Industrial Area. Sonepat-13100(Hr.) India*
DMK-02/19	*Tab, Diclocin Forte+*	*DTF-811*	*-do-*
DMK-03/19	*Tab, Arfifen 50mg*	*ARF-31*	*-do-*
DMK-04/19	*Cap, Pyricam-20*	*OC-141*	*-do-*
DMK-05/19	*Tab, Critriz*	*CZ-109*	*-do-*
DMK-06/19	*Cap, Voen 50mg*	*MC-17-195*	*-do-*
DMK-07/19	*Tab, Cobra-150*	*Nil*	*-do-*
DMI 08/19	*Tab, Zinetac 15mg*	*N5211*	*-do-*
DMI 09/19	*Cap, Grucid*	*GC 1221*	*-do-*
DMK-10/19	*Tab, Augmentin 375mg*	*HATBI*	*M/s. Claxo Smith Kline F-268, S.I.T.E. Karachi*
DMK-11-	*Iodex Ointment*	*EIADA*	*—do-*
DMK-12/19	*Iodex Ointment.*	*EIADA*	*-do-*
DMK-	*Iodex Ointment*	*DIAAS*	*-do-*

KMK-14/19	*Iodex Ointment*	*EIADA*	*—do-*

2. *That the sealed sample of under reference drug was taken for the purposes of test/analysis on prescribed Form-3 and the same was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the purpose of test/analysis vide memorandum No. DMK-01 to 15/2019-FID-VII(K) dated 18™ January 2019.*
3. *That the then FID vide their letter No. F-DDMK.24-30/2019-FID-VII-DRAP(K) dated 21st January 2019 requested to DRAP Islamabad to grant permission for the safe custody of drugs seized on prescribed Form-2 under the Drugs Act 1976.*
4. *That M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi, Landhi Karachi was asked to provide bill warranty under section 23(I)(i) of the Drugs Act 1976 vide this office letter NO. F.DMK-24-30/2019-FID- VII-DRAP(K) dated 21st January 2019.*
5. *That the Federal Government vide their letter No F-13-45/2019-(QC) dated 28th January 2019 grant permission to continue the custody of the seized stocks till decision of the case.*
6. *That the Federal Government Analyst, Central Drugs Laboratory, Karachi declared the following sample of drugs as "un-registered Drug Products".*

Detail are as under:

S.NO.	***Name of Drug***	***Batch No***	***Mnfd: by***	***Test Report No & Date***	***Test Report Remarks***
01	*Pipadol CF Tab,*	*PCF-195*	*M/s Combiotic Global Caplet Ltd India*	*RKQ. 51/2019 dated*	*Un-Registered*
02	*Diclocin Forte+Tab,*	*DTF-811*	*M/s Combiotic Global Caplet Ltd India*	*RKQ. 52/2019 dated*	*Un-Registered*
03	*Arfifen 50mg Tab,*	*ARF-31*	*M/s Combiotic Global Caplet Ltd India.*	*RKQ.53/2019 dated*	*Un-Registered*
04	*Pyricam-20 Cap,*	*PC-141*	*M/s Combiotic Global Caplet Ltd India.*	*RKQ.54/2019 dated*	*Un-Registered*
05	*Citriz Tab,*	*CZ-109*	*M/s Combiotic Global Caplet Ltd India.*	*RKQ.55/2019 dated*	*Un-Registered*
06	*Voven Cap,*	*MC-17-195 .*	*M/s Maiden Pharmaceuticals*	*RKQ.56/2019 dated*	*Un-Registered*
07	*Cobra-150 Tab,*	*Nil*	*M/s. Combiotic Global Caplet Ltd.*	*RKQ.57/2019 dated*	*Un-Registered*
08	*Crucid Capsules*	*GC-1221*	*M/s. Combiotic Global Caplet Ltd.*	*RKQ.59/2019 dated*	*Un-Registered*

7. *That in the light of above test report of Federal Government Analyst, Central Drug Laboratory, Karachi explanation letters was accordingly issued to M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed,*

Chownagi Landhi Karachi. Subsequent reminders were also issued vide this office letters of even number dated 24th April & 13th May 2019. No any reply has been received from M/s. Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed, Chownagi Landhi Karachi till to date.

8. *That M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed, Chownagi Landhi Karachi and Ali Muhammad S/o Nazir Muhammad (owner) found involved in storing & selling of unregistered drug products and contravened the section 23(I)(a)(vii) of the Drug Act 1976 and rules framed there under.*

9. *The complete case was forwarded to Director (QA & LT),DRAP Islamabad vide this office letter of even number dated 08th July 2019 for further necessary action / direction into the matter.*

10. *That Assistant Director (QC-I) for Secretary, Central Licensing Board, DRAP, Islamabad vide their letter No. F.04-02/2019-(QC) dated 28th August 2019 communicated the decision of Central Licensing Board, DRAP Islamabad i.e. "Approval for lodging FIR" against the following accused persons.*

1. M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed, Chownagi Landhi Karachi (Paid Challan Slip.

2. Ali Muhammad S/O Nazir Muhammad (Proprietor), House No. 201, New Muslimabad Colony Landhi, Malir Karachi.

In view of the above explained circumstances the above said accused persons has found involved in selling unregistered drug and contravened the Section 23 (I) (a) (vii) of the Drugs Act, 1976 which is punishable under Section 27 (I) (a) of Drugs Act, 1976 and rules framed there under.

Sd/-
Dr. Mehvish Tanveer
Federal Drug Inspector-VII
DRAP"

DOCUMENTARY EVIDENCE:

The complainant produced the following attested photocopies of the relevant record.

1. Complaint dated 18-11-2019 of Dr. Mehwish Tanveer Assistant Director/Federal Inspector of Drugs-VII Karachi Drug Regulatory Authority of Pakistan (DRAP), 2nd Floor, US AID Building No. 4, Block-B, S.M.C.H.S, Karachi alongwith its enclosures.
2. The Gazet of Pakistan, Ministry of National Health Services Regulations and Coordination's.
3. Permission issued from Assistant Director (QC-I) for Secretary. Central Licensing Board Islamabad to lodged FIR against Ali Muhammad S/o Nazir Muhammad.
4. Requested for grant of permission for the safe custody of Drugs Seized.
5. Permission for keeping the seized Drugs under DRAP Act.

6. Form-II, Receipt for stock of drugs seized under section 8 (F) of the drugs act, 1976.
7. Form-Ill, Intimation to person from whom simple is taken.
8. Form-IV, Memorandum to Govt. Analyst.
9. Form-VI, Certificate of test or analysis by the central drugs laboratory/Govt. Analyst sample bearing No. (DMK-01/19) (DMK- 02/19) (DMK-03/19) (DMK-04/19) (DMK-05/19) (DMK-06/19) (DMK-07/19) (DMK-09/19).
10. Report of sale of unregistered Drug sent to the Director (QA&LT), Drugs Regularities Authorities of Pakistan Islamabad sent by Dr. Mehwish Tanveer Federal Inspector of Drugs-VII, Karachi.
11. Masheer Nama.

ORAL EVIDENCE

STATEMENT OF MR. ABDUL RASOOL SHAIKH S/O MUHAMMAD MURAD FEDERAL INSPECTOR OF DRUGS, R/O FLAT NO. 313, AHMED COMFORTS, BLOCK-17, GULISTAN-E-JOHAR, KARACHI CNIC NO. 42201-2547662-5, RECORDED STATEMENT UNDER SECTION 161 Cr. Pc. INTO CASE FIR NO. 02/2020 OF FIA, ACC, KARACHI.

It is state that he is residing at above address and working being Federal Inspector of Drugs posted at the office of Drug Regularity Authority, situated at Plot No.4, Block-B, SMCHS, Karachi.
On being ask he stated that he being a senior Inspector along with the other Federal Inspectors of Drugs & Mr. Sajid Ali, Provincial Drug Inspector visited/inspected the premises of M/s. Prince Medicos, K. E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi, Landhi Karachi on 16-01-2019.
During the Visit/Raid at above Medical Store he found and recovered and seized on prescribe Form-2 under the Drugs Act 1976 rules.
On asking the question he stated that since one year ago he was along with Khurshid Shaikh, Provincial Drug Inspector visited/raided at the same above Medical Store and recovered the illegal medicine in huge quantity, all the recovered illegal medicine was handed over on spot to Khurshid Shaikh, Provincial Drug Inspector to prepare the seizer memo as per the rule, unfortunately the said inspector misappropriated recovered illegal medicine and also did not reported the matter to the concerned authority of Provincial Drug Regularity Authority.
Due to this circumstances and previous criminal record of the said medical store he randomly visited at the said medical store and found the same illegal medicine selling at the said store.

STATEMENT OF MR. Dr. SHOAIB AHMED S/O AIJAZ ALI FEDERALDEPUTY DIRECTOR FEDERAL DRUGS REGULARITY AUTHORITY ISLAMABAD R/O APPARTMENT NO. 201, METRO RESIDENCY CIVIL LINE, KARACHI CNIC NO. 42503-3840934-3, RECORDED STATEMENT UNDER SECTION 161 Cr, Pc. INTO CASE FIR NO. 02/2020 OF FIA, ACC, KARACHI.

It is state that he is residing at above address and working being Federal Inspector of Drugs posted at the office of Drug Regularity Authority, situated at Plot No.4, Block-B, SMCHS, Karachi.
On being ask he stated that he being a Federal Inspector of Drugs along with the other Federal Inspectors of Drugs & Mr. Sajid Ali, Provincial Drug Inspector visited/inspected the premises of M/s. Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi, Landhi Karachi on 16-01-2019.
During the Visit/Raid at above Medical Store he found and recovered and seized on prescribe Form-2 under the Drugs Act 1976 rules.
On asking the question he stated that since one year ago he was along with Khurshid Shaikh, Provincial Drug Inspector visited/raided at the same above Medical Store and recovered the illegal medicine in huge quantity, all the recovered illegal medicine was handed over on spot to Khurshid Shaikh, Provincial Drug Inspector to prepare the seizer memo as per the rule, unfortunately the said inspector misappropriated recovered illegal medicine and also did not reported the matter to the concerned authority of Provincial Drug Regularity Authority.
Due to this circumstances and previous criminal record of the said medical store he randomly visited at the said medical store and found the same illegal medicine selling at the said store.

STATEMENT OF MR. Dr. FARMAN ALI BOZDAR S/O GHULAM AKBAR BOZDAR ASSISTANT DIRECTOR FEDERAL DRUGS REGULARITY AUTHORITY ISLAMABAD R/O MOHALLA WADA BOZDAR TEHSIL THARI MIRWAH DIST. KHAIRPUR. CNIC NO. 45206-3840052-3, RECORDED STATEMENT UNDER SECTION 161 Cr. Pc. INTO CASE FIR NO. 02/2020 OF FIA, ACC, KARACHI CELL No. 03337219044.

It is state that he is residing at above address and working being Federal Inspector of Drugs posted at the office of Drug Regularity Authority, situated at Plot No.4, Block-B, SMCHS, Karachi.

On being ask he stated that he being a Federal Inspector of Drugs along with the other Federal Inspectors of Drugs & Mr. Sajid Ali, Provincial Drug Inspector visited/inspected the premises of M/s. Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi, Landhi Karachi on 16-01-2019.

During the Visit/Raid at above Medical Store he found and recovered and seized on prescribe Form-2 under the Drugs Act 1976 rules.

On asking the question he stated that since one year ago he was along with Khurshid Shaikh, Provincial Drug Inspector visited/raided at the same above Medical Store and recovered the illegal medicine in huge quantity, all the recovered illegal medicine was handed over on spot to Khurshid Shaikh, Provincial Drug Inspector to prepare the seizer memo as per the rule, unfortunately the said inspector misappropriated recovered illegal medicine and

also did not reported the matter to the concerned authority of Provincial Drug Regularity Authority.

Due to this circumstances and previous criminal record of the said medical store he randomly visited at the said medical store and found the same illegal medicine selling at the said store.

PLEA OF ACCUSED PERSON

STATEMENT U/S 161CR.P.C OF ACCUSED ALI MUHAMMAD S/O NAZEER MUHAMMAD R/O HOUSE NO. 201, MUHALLA NEW MUSLIMABAD COLONY, LANDHI, MALIR, KARACHI. CNIC NO. 42501-7448033-7, CELL NO. 0311-2548153. RECORDED IN FIR NO. 02/2020 OF FIA, ANTI-CORRUPTION CELL, KARACHI.

It is stated that he is living at above mentioned address and doing his whole sell business of selling of medicine in the name & style Prince Medicos, situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi since 2014.

The owner of the Prince Medicos is Muhammad Kamran S/o Saleh Muhammad (his step brother) as mentioned on the Drug License No. 0154 issued vide DHSKDK(Drug) 1-129 dated 18.01.2016. The name of qualified person Saeed Ahmed s/o Abdul Rasool Solangi, B-Pharmacy from University of Sindh. It is further stated that the said Drug License has expired on 27-December-2017, we are running the said business without valid license.

On asking he stated that on 16th January, 2019, Federal Inspector of Drugs-VII along with the team of officers & officials of DRAP Karachi visited/inspected at the above medical store and un-registered medicine were recovered and seized in front of him, the said team was ask to him to provide bill of warranty of the above recovered medicine, which he could not provide.

Further he stated that we buy the said un-registered medicine from Saifullah Khan Afridi CNIC No. 14301-7623366-7 from Kohat & Yaseen Khan s/o Ali Anwar CNIC No. 17301-9134227-1, from Peshawar. The way of the purchase of the medicine is Ehtisham his brother place the order of the required medicine on cell phone, the seller of the said medicine booked some time into his name and sometime of his brother Ehtisham, through Truck and we the same received from the Truck Adda at Karachi. We sell this medicine onward to the following retailer medical stores.

1. *Bilal Medical Store cell No. 0348-1345128, situated at Sherpow Colony, Landhi.*
2. *Asif Medical Store cell No. 0345-1000040,*
3. *Umer Medical Store, Muzaffarabad Colony, Landhi, Karachi.*
4. *Noor Medical Store, cell No. 0344-2165743, old Muzafarabad Colony, Landhi, Karachi.*

5. *Akhtar Medical, cell No. 0314-3947495, Hospital Chowrangi, Landhi, Karachi.*
6. *Bhitai Medical, cell No. 0323-2122304, Rerhi Goth, Landhi, Karachi.*
7. *Aman Medical, Kala Pani, Muzafarabad, Landhi, Karachi.*
8. *Batool Medical,----------do----------*
9. *Amir Medical, cell No. 0301-2963065 --------do----------*
10. *Urooj Medical, cell No. 0312-2425517-------do----------*
11. *Danish Pharmacy, cell No. 0301-2602336, Dawood Chali, Landhi, Karachi.*
12. *Shah Rukh Medical, cell No. 0300-3995262,------do-------*
13. *Ali Medical----------do----------*
14. *Ahmed Medical cell No. 0346-3176915, Gul Ahmed Chowrangi, Landhi, Karachi.*
15. *Wajid Medical Store, Shah Latif Town, Landhi, Karachi.*
16. *Masha Allah, Medical Store, Shah Latif Town, Landhi, Karachi.*

Beside the above we sell the un-registered medicine in whole sell to various persons at Gulshan-e-Buneer, Muslimabad, Bilal Colony and Muzaffarabad, Landhi, Karachi:

He further stated that in the year 2018, combine team of Federal & Provincial Drug Inspectors were also raided at Prince Medicos and recovered the un¬registered medicine in huge quantity, Khursheed Shaikh, Provincial Drug Inspector of Landhi Area, kept all the recovered medicine in his custody and no any case was registered against the said Prince Medicos as well as what happened with the recovered medicine, he is un-aware about that.

CONCLUSION/RECOMMENDATION

The complainant Dr. Muhammad Kashif the then Fedral Drug Inspector of Drugs -VII, DRAP, Karachi, along with the team of officers of DRAAP, Karachi namely Abdul Rasool Shaikh, Federal Drug Inspector, Shoaib Ahmed, Federal Drug Inspector, Farman Ali Bozdar, Federal Drug Inspector & Mr. Sajid Ali, Provincial Drug Inspector, Karachi inspected M/s Prince Medicos situate at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi on 16.01.2019. During course of inspection, they found of un-registered drugs/medicines claimed to be manufactured by India. Available stocks were seized on prescribed Form-2 under Section 18 (1) (f) of the Drugs Act, 1976.

After receiving the request for registration of case against accused Ali Muhammad (Proprietor) of M/s. Prince Medicos, situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi. The undersigned registered the Case FIR No. 02/2020 of FIA, ACC, Karachi u/s. 23&27 (1) (a) (vii) of Drug Act 1976.

After registration of said case at this circle, the undersigned arrested of accused namely Ali Muhammad s/o Nazir Muhammad dated on 13.06.2020, Time 15:30 hrs and produced before the Session Judged Karachi South/Link Judge, Chairman Drugs Court Karachi and obtained the Physical Remand of the accused Ah Muhammad s/o Nazeer Muhammad for 07 days viz 14.02.2020 to 20.02.2020.

During the course of investigation into the remand period, the above named accused confirmed the Federal Drug Inspectors inspected his Medical Store on 16.01.2019 and recovered & seized the huge quantity of un-registered medicine from his medical store namely M/s. Prince Medicos situated at Landhi, Karachi, he also confirmed he was involve for selling the un-registered medicine and further the above, he also disclosed that he purchase the un-registered medicine from one Muhammad Yaseen s/o Ali Anwar CNIC No. 17301-9134227-1, from Karkhan Markeet Peshawar & Saifulla Afreedi s/o Fareed Khan Afreedi CNIC No. 14301-7623366-7 from Peshawar. Further he sells this unregistered medicine to the various retail medical stores in Karachi.

After completing the previous remand period the undersigned produce of the above accused before the Session Judged Karachi South/Link Judge, Chairman Drugs Court Karachi of accused Ali Muhammad s/o Nazir Muhammad dated on 21.02.2020 for further remand. Accordingly the above named accused was remanded to judicial custody.

An explanation letters was issued to the owners of M/s Noor Medical Store, Old Muzaffarabad Colony, Landhi, Karachi. M/s. Bilal Medical Store, Sher Paw Colony, Landhi Karachi, M/s. Akhtar Medical Store, Hospital Chowrangi, Landhi Karachi, M/s Asif Medical Store, Sher Paw Colony, Landhi Karachi, M/s Umer Medical Store, Muzafarabad Colony, Landhi Karachi, M/s. Aman Medical Store, Kalapani Muzafarabad Colony, Landhi Karachi & M/s. Bilal Medical Store, Rerhi Goth, Landhi Karachi, but all in vain nobody attended this office.

During the course of investigation accused Ali Muhammad s/o Nazir Muhammad Proprietor of M/s Prince Medicos did not able to provide required documents, i.e. Sale & Purchase Invoices, License for sell of Drugs and the ownership of the said Medical Store.

From the investigation conducted and evidences collected so far on record, it has been established that accused Ali Muhammad s/o Nazeer Muhammad CNIC No. 42501-7448033-7, Proprietor of M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi, committed the offences u/s 23&27 Drugs Act 1976 punishable ibid and rules framed there under, for which they are liable to be prosecuted before the Hon'ble Drug Court Sindh at Karachi by way of filing a complaint by the Federal Inspector of Drugs, by mentioning the names of accuse.

Since the investigation of the case has been completed, therefore, this Report is being submitted for favour of kind perusal and onward transmission to

the Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulations & Coordination, Karachi for submission of complaint under the relevant provision of Drugs Act-1976, before the Honourable Drug Court Sindh at Karachi through Federal Inspector of Drug."

16. In the light of above-mentioned interim report, it is evident that the accused Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7, Proprietor of M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi, committed the offences which are punishable under section 27(1)(a) of the Drugs Act 1976 and rules framed there under, for which they are liable to be prosecuted before the Hon'ble Drug Court Sindh at Karachi by way of filing a complaint by the Federal Inspector of Drugs, by mentioning the names of accused given as under;

i. M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi through its Owner/Proprietor Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7 R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi

ii. Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7, R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi, Proprietor of M/s Prince Medicos, Karachi.

Proceedings and Decision of the 277th meeting of the Board:

17. The Board after thorough delbrations and considering the facets of the case decided as under:

a. To issue Show Cause and Personal Hearing notice to the following accused persons for violations which are punishable under section 27(1)(a) of the Drugs Act, 1976:

i. **M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi through its Owner/Proprietor Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7 R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi**
ii. **Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7, R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi, Proprietor of M/s Prince Medicos, Karachi**

Case No. 02 **MANUFACTURE & SALE OF SUBSTANDARD BISOPROLOL 10MG TABLETS, BATCH NO. KD8598, REG. No. NIL, MANUFACTURED BY M/S LEK S.A. PODLIPIE, POLAND.**

1. That the Assistant Director-V, DRAP, Karachi visited the warehouse of M/s Novartis Pharma Pakistan Limited, west wharf, Karachi on 13th March, 2020, wherein the samples of subject cited imported finished drug (imported specifically for M/s Health Promotion Foundation under Novartis Access Program as donation) along with other drug products were taken on prescribed Form-3 for the purpose of test/analysis.
2. The sealed samples of said samples of drugs were sent to Federal Government Analyst, Central Drug Laboratory, Karachi for test/analysis vide office memorandum No. DK-03-10/2020-AD-V dated 16th March, 2020 and a sealed portion was also sent to the Chairman, CLB, DRAP, Islamabad vide letter of even number dated 16th March, 2020.
3. The Federal Government Analyst, (CDL), declared the sample of product named "Bisoprolol l0mg Tablets" B# KD8598 as of "Sub-Standard" quality vide Test Report No. DON.KQ. 159/2020 dated 11th June, 2020.
4. In the light of above referred test/analysis report, the explanation letter of even number dated 15th June, 2020, was issued to M/s Novartis Pharma Pakistan Limited, Karachi, for explaining their position in the matter of importing of above mentioned sub-standard finished product and submission of required information.
5. M/s. Novartis Pharma Pakistan Limited, Karachi has submitted their reply vide letter No. Nil dated 24th June, 2020 (which is self-explanatory and detailed with annexure) in which the firm being dissatisfied with the contents of report, method of testing and result thereof. Furthermore, the firm requests for review and retest as per the method of analysis provided by them.
6. Assistant Director-V, DRAP, Karachi was requested vide letter No.F.03-30/2020-QC dated 05-08-2020 to clarify whether the firm has applied for retesting of the said product form Appellate laboratory, NIH, Islamabad or otherwise and submit clear & candid recommendations for further processing of the case.
7. FID-IV, DRAP, Karachi vide reference No.F.SHM/NTF-24/2020-FID-(K-IV) dated 27-07-2020 regarding the subject of "order made not to dispose of on Form-I under section 18(1) of

the Drugs Act, 1976" received to the undersigned on 25-08-2020 wherein he has referred DRAP, Islamabad letter NoF.03-30/2020/QC dated 25-06-2020 and as per directions of the Additional Director he visited the premises of M/s Novartis Pharma situated at 15 west Wharf, Karachi on 23rd July, 2020 and order were made not to dispose of on prescribed Form-I under section 18 (1) of the Drugs Act, 1976 for 28 days initially. Details are as under;

Name of Drugs	Qty	Batch No.	Mfg. Date	Exp. Date	Manufactur by
Bisoprolol AB 100mg FCT FSA (Declared Substandard vide CDL test report NoDON.KQ.159/2020 dated 11-06-2020)	3072 Table	KD8598	07/2019	07/2021	M/s LEK S.A, 16, Podlipic STR, Poland. For: M/s Novartis Access Pharma, situated at Novartis Pharma Pakistan, Limited.

8. He further requested that extension in the period not to dispose of may kindly be extended as per rules.
9. Assistant Director-V, DRAP, Karachi vide reference No.DK-03-10/2020-AD-V (K) dated 26-08-2020 regarding the subject cited wherein he has submitted that M/s Novartis Pharma Pakistan, submitted their reply in which they have requested to initiate retesting as per method of analysis provided by the firm.
10. Since the post of Director QA&LT is vacant, therefore following actions are requested from Central Licensing Board;
    i. Grant of extension in the period of ordered not to dispose of.
    ii. Approval of sending Board's portion of the subject cited drug for retesting from Appellate Laboratory, NIH, Islamabad Under section 22(5) of the Drugs Act, 1976.

11. <u>Proceedings and Decision of the 277th meeting of the Board:</u>

The Board after thorough deliberations and considering the facts of the case decided to acceded the request of Assistant Director V Karachi to grant the extension in the period of order "not to dispose of" till the decision of the case and sending the Board's portion of the subject cited drug for retesting from Appellate Laboratory, NIH, Islamabad under Section 22(5) of the Drugs Act, 1976.

Case No. 03: **INSPECTION OF M/S NUTRASOURCE INTERNATIONAL, PLOT NO. E-70, SITE, SUPER HIGHWAY, KARACHI.**

Mr. Abdul Rasool Shaikh, FID-VI, DRAP, Karachi vide letter No. F. 24-09/2020-FID-VI(K) dated 24th September, 2020 informed that he paid a surprise visit to M/s Nutrasource International, Plot No. E-70, SITE, Super Highway, Karachi, an enlisted H&OTC firm, on 23-09-2020. During the inspection, it was observed that certain products were illegally repacked by the firm that are listed in Schedule-D of Drugs (Licensing, Registering & Advertising) Rules, 1976 which require Drug Manufacturing License by way of Re-packing. The following stock was ordered "Not to dispose of" under section 18(1)(i) of the Drugs Act, 1976;

S. No.	Product Name	Batch No.	Quantity	Mfg. Date	Exp. Date	Mfg. by
1.	Gentian Violet 25ml	20I34	3396 Bottles	Sep-20	Aug-22	M/s Nutrasource International, Karachi
2.	Calamin Lotion 120ml	20F31	09 Bottles	June-20	May-22	-do-

02. **The Area FID has requested to grant extension in period of order made "Not to dispose of"** in respect of above-mentioned stocks. In this regard, the Director QA&LT is empowered to grant extension in period not to dispose of by the Central Licensing Board in its 273rd meeting held on 15th January, 2020. Since the post of Director QA&LT is vacant, the case is presented before the Central Licensing Board for grant of extension in order not to dispose of to FID VI Karachi for further processing of the case

03. **Proceedings and Decision of the 277th meeting of the Board:**

The Board after thorough deliberations and considering the facts of the case decided to acceded the request of FID VI Karachi to grant the extension in the period of order "not to dispose of" till the decision of the case. Moreover, the Board further decided to direct the FID VI Karachi to complete the investigation and submit the report within 60 days of communication of the decision.

QUALITY ASSUARNCE CASES

Item No. I GMP Non-Compliance Cases (New)

Case No. I:- M/s Servier Research & Pharmaceutical (Pakistan) Pvt Ltd. Lahore.

Background:-

Mr. Abdul Rashid Shaikh, FID, Lahore conducted routine GMP inspection of M/s Servier Research & Pharmaceutical (Pakistan), 9 KM Sheikhupura Road, Lahore (DML No. 000472) on 25-11-2019 and 26-11-2019.

2. **OBSERVATION:**

i. Most of the JDs were found without confirmed communication to the person concerned.
ii. Most of the responsibilities were overlapping.
iii. In organogram it was advised to review and upgrade their responsibilities by keeping in view conflict of interest.
iv. Batch release was only by quality control manager and plant head.
v. It was advised to review and upgrade the SOPs accordingly.
vi. Develop separate and independent quality assurance department under. The senior technical person without fail.
vii. It was observed the plant head is also approved technical person as incharge production however, practically Mr. Muhammad Rizwan Akhter was looking after the responsibilities of production.
viii. It was advised to ensure segregation in storage of APIs as the space constraint was also observed.
ix. Ensure the metal detector with tablet compression machines, old ZP 25 tablet compression machine also need to replace with new machine.
x. It was observed that many batches were kept in in-process store so it is advised to avoid such practice by removing bottle neck problem in packing of their products.
xi. The equipment in Quality Control Laboratory needs active upgradation.
xii. Upgrade dissolution test apparatus.
xiii. Ensure Double beam spectrophotometer
xiv. Ensure installation of printer with analytical balance.
xv. Upgrade the karl-Fischer
xvi. Replace the Polarimeter with the new one.
xvii. To ensure availability of additional HPLC

xviii. Remove wooden fixture and furniture from the premises.
xix. Make the microbiology lab functional and appoint a microbiologist as early as possible.
xx. The change rooms need to improve, like proper lockers for placement of workers belongings and ensure the ventilation in the worker change rooms.
xxi. In raw material/ packing material store, active improvements are needed;
xxii. Improve the false ceiling.
xxiii. Ensure vacuum cleaner in the receiving area for de-dusting.
xxiv. Upgrade the dispensing hood and also install printer with the dispensing balances.
xxv. Ensure close trolleys for the transportation of dispensed batches from dispensing area to production floor.
xxvi. Install safety grill around the cone mixers.
xxvii. During visit it was observed that the rejected/ de-blistered tablet and other waste powder and drugs were found placed in the outer area of factory without any control so, it is directed;
xxviii. Upgrade their SOPs for handling of waste/rejected materials properly and also SOPs for health and safety system and needs their strict compliance.
xxix. Ensure SS containers for the storage of in-process materials

CONCLUSION OF THE PANEL: -

"It is advised to overcome their shortcomings and the compliance report submit to the authorities, so re-inspection will be conducted accordingly."

Action Taken by DRAP:

3. Accordingly, the firm was issued explanation letter vide letter dated 06.05.2020.

4. The firm vide letter dated 11.06.2020 submitted CAPA and requested for verification of the observations noted by the panel.

Updated Status:

5. The CLB in its 273rd meeting delegated the power to constitute panel of experts to Director (QA&LT). At present post of Director QA&LT is vacant.

Proceedings of 277th Meeting of CLB

Division of QA&LT presented the case before the CLB. The Board go discuss the CAPA submitted by the firm M/s Servier Research & Pharmaceutical (Pakistan) Pvt LTd, Lahore.

Decision of 277th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view CAPA submitted by the firm, the Central Licensing Board decided to: -

iv. Constitute following panel of experts for verification of rectification status of the observations noted by the FID in its report dated 25.11.2019 & 26.11.2020: -

   d) Dr. Ikram Ul Haq, Member, CLB.
   e) Ch. Zeeshan Nazir, Deputy Director, DRAP, Islamabad
   f) Area FID, DRAP, Lahore

v. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 25.11.2019 & 26.11.2020, with clear and candid recommendations.

Case No. II:- M/s ATCO LABORATORIES LIMITED KARACHI

Mr. Awais Ahmed FID DRAP Karachi conducted GMP inspection of M/s Atco laboratories Limited Karachi on 21.08.2020 and 02.09.2020.

2. **OBSERVATION:**

i. Ware House:

a. Firm is advised to adopt appropriate controls including PVC curtains, insectocuter in ware house.

ii. Quality Control:

a. During inspection it was observed that rain water was leaking from roof top of change room. Colour of walls was faded as mentioned earlier, it could be due to leakage of the roof which needs immediate attention.

iii. Sterile Area (Injectable, Ear/Eye/Nasal Drops)

a. Firm is involved in manufacturing of aseptic filling and terminally sterilize products. No separate material entrance is provided for the dispensed material, Personal and material entrance is through the same area which is dedicated for optical checking without any appropriate control system including interlocking.
b. General corridor is unclassified area, area monitoring also not conducted by the firm, which leads to main entrance to sterile area and Lotion area and epoxy also not provided.
c. Dispensing room is situated at ground floor and sterile area is situated at first floor. Interlocking is also not provided in Dispensing room.
d. Outside corridor to Dispensing room is general unclassified corridor.
e. Dispensed Material, which is supposed to be used in sterile manufacturing is sent to cargo lift through general unclassified corridor and then to first floor, then carried away to lobby via general unclassified corridor and optical room. Optical area leads to uncontrolled buffer area from where man and material enter into Lobby area which is unclassified area.
f. From Lobby Man and material is entered through Air lock, which is classified as Class C and no change room provided for secondary gowning entering into manufacturing area. Man, and Material flow should immediately be controlled, and firm should immediately rectify this on top priority basis to avoid contamination and cross contamination, as firm is also involved in aseptic manufacturing, which is critical process.
g. Air sampling reports were also not available for Lobby Area, as it is immediately outside Airlock.

h. No Magnehelic gauges installed at the entrance of the sterile manufacturing area, which is clear evidence of uncontrolled area classification and monitoring.
i. No interlocking and Air shower provided before entrance into the sterile area.
j. Packing area walls were also faded and needs immediate attention.
k. Air sampling reports and area monitoring reports were evaluated, firm is also violating its own SOP regarding classification of area. After evaluating area monitoring reports, area classification drawing, it is evident that Area classification of the sterile area is not justified and is also contradictory to their own SOP Doc No: MIC/PP/EMSA/010.

iv. Ointment, Sachet and Lotion Area: -

a. During inspection it was observed that firm was involved in manufacturing of Lotion and Enema in ointment section which is clear violation of Approved layout, that area is also very congested.
b. Walls of the area were also faded due to leaking of the water.
c. Firm was issued suspension of production of lotion manufacturing immediately vide letter No. F.03-03/2019-AD/FID-IX (K) dated 09.09.2020, which was received by firm representative on same date. However, to check compliance of the directions passed vide above letter, surprise visit was conducted along with Mr. Abdur Rehman Jamro, Assistant DRAP, Karachi, on 12.09.2020 at 04:30 p.m.

v. Brief of the Surprise Visit: -

"During surprise visit, warehouse and old unit was visited, it was observed that, manufacturing of Lotion, Cream and Enema was being carried out under unorganized and haphazard manner, as too much dumping of empty and filled plastic drums, Liquid bulk tanks, packaging material including printed packaging material, shipper cartons, was placed one over another in general corridor which has entrance into sterile area, in storage areas, in Sachet Staging room, Raw Material transfer Lock. It was further observed that Empty drums, baskets and liquid tanks were also dumped in secondary packing hall. It was further observed that firm manufactured Lotion in unauthorized area after passing of suspension of production orders which was evident from Lotion Filling Machine Log Book. Lotion and Enema manufactured in unauthorized area from 10.09.2020 to 12.09.2020 was ordered Not to dispose of on Form- I. Keeping in view above mentioned major and critical observations, firm was immediately directed to halt the production in Sterile Area i.e. (Liquid Injectable, Ear/Eye/Nasal Drops), Lotion and Enema and submit compliance report & CAPA, which was pasted on the inspection report."

3. **CONCLUSION OF THE PANEL: -**

"Keeping in view above mentioned major and critical observations, violation of Schedule B-II of LRA rules 1976 and approved Layout, non-compliance of the directions issued for suspension of production area for lotion manufacturing in unauthorized area, firm was considered to be operating at unsatisfactory compliance level of GMP in Old unit, and firm has already been ***directed to suspend their production activities in Sterile Area (Liquid Injectable Ear/Eye/Nasal Drops), Lotion and Enema*** *vide letter No.NO.F.03-03 /2 019 AD / FID-I X (K) dated 09.10.2020 and submit compliance letter and CAPA to QA&L T division for above mentioned observations for onward consideration at earliest."*

4. Suspension of Production activities in Sterile area and for lotion manufacturing was issued by the FID on his own. The FID as per Section 18(h) of the Drugs Act 1976 can lock or seal the premises or any part of it.

Updated Status:

5. The CLB in its 273rd meeting delegated the power for suspension of production activities and to constitute panel of experts to Director (QA&LT). At present post of Director QA&LT is vacant.

Proceedings of 277th meeting of CLB:

Division of QA&LT presented the case before the Board. The Board considered Inspection report of FID 21.08.2020 and 02.09.2020, CAPA of the firm dated 22.09.2020 and reply of the firm M/s Atco Laboratories Limited, Karachi dated 30.09.2020. The report of FID dated 01.10.2020 was also presented before the board wherein FID had stated that production activities in Lotion and Enema Section has already been resumed by him. As per same report of FID, production activities in sterile area (Liquid Injectable, Ear/Eye/Nasal Drops) shall remain suspended.

Decision of 277th meeting of CLB:

After thorough discussion/deliberations, considering all the pros and cons of the case and recommendations of FID in his reports dated 21.08.2020, 02.09.2020 & 01.10.2020 and CAPA submitted by the firm, the Central Licensing Board decided as follows;

i. In order to verify CAPA submitted by the firm following panel has been constituted by the board;
    a. Dr. Abdullah Dayo, Member Central Licensing Board.

b. Mr. Sajjad Ahmed Abbasi, FID DRAP Karachi.
c. Area FID, DRAP Karachi

ii. The board authorized Chairman CLB/Additional Director QA&LT to pass orders on the recommendations of the panel of experts, accordingly.

Case No. III:- M/s Epoch Pharmaceutical (Pvt.) Ltd. Karachi.

Background:-

Mr. Abdul Rasool Shaikh, FID DRAP Karachi inspected M/s Epoch Pharmaceuticals (Pvt.) Ltd. Karachi on 02-12-2019 and recovered *Fenacold Injections, Batch No. 039* with apparent discoloration of half of ampoule. The Product was ordered not to dispose off on Form-I. The Director QA&LT constituted following panel of experts for Product Specific Inspection (PSI).The inspection was conducted on 07-05-2020 & 11-05-2020 by following panel;

i. Mr. Awais Ahmed, Assistant Director/ Federal Inspector of Drugs DRAP Karachi.
ii. Mrs. Hira Bhutto, Assistant Director DRAP Karachi.

2. The observations reported by the panel are mentioned below;

i. **Meeting / Discussion with technical Staff:**

a. The single batch was being autoclaved in 4 lots and last lot of 3125 ampoules was mistakenly exposed for prolonged time in autoclave after completion of autoclave cycle. The same lot showed discoloration.

b. No CAPA was available with the firm regarding this matter.

ii. **Raw Material Store:**

a. The RMS was uncontrolled having HVAC system instead fresh air system was installed, which was not working at the time of inspection. Temperature was observed 27°C and RH 60% and the material with storage condition of below 25°C were placed.

b. Cleaning condition of RMS was unsatisfactory and powder on drums and floor was seen, looks like material might be sampled in same area.

c. Job description of dispensing pharmacist was not available, when inquired they informed that Dispensing Pharmacist is directly reporting to CEO

d. Dispensing of material was being done without QA officer. Weight of raw material was not noted on dispensing slips.

e. Dispensing booth calibration is due by 30-12-2019, no further correspondence available.

f. Sampling booth used for raw material sampling is not adequate to perform sampling operations due to space constraints.

g. Raw material was not assigned unique identity code at the time of arrival. Raw material details could not be traced from material issuance note as no unique code assigned.

iii. **Quality Control Department:**

a. The record showed that product was tested as per in-house specifications, however no record of product retesting after complaint of apparent discoloration was shown to the panel.

b. COA of diclofenac sodium from manufacturer and testing record of raw material used in batch was checked. Reference standard and batch testing record was verified.

c. Calibration of most of the equipment in quality control lab was due for which no update schedule was available.

d. Document record/ log sheets and record of relevant raw calculation was found to be un-satisfactory and non-traceable.

iv. **Production Section:**

a. Chart of autoclave could not be interpreted as the graph was not clear and no reference scale was mentioned in SOP, however temperature was noted in hand writing as 117.6 °C and taken as equivalent to 121°C by firm. For which firm informed that, autoclave is placed in production and display of autoclave in Quality Control lab, that's why the difference in actual temperature of Autoclave is shown, which seems unjustifiable.

v. **Documentation:**

a. During document verification, it was observed that firm does not have standard validated Batch Size. Batch manufacturing record for 150 liter was available which is used for manufacturing of 275 liter batch.

b. Batch scale up studies was not available.

c. Most part of the Bach Document of Fenaclod injection B# 039 was not signed.

d. Batch validation documents were not available. Apparently no batch validation was performed as there is no standard batch size followed.

e. Batch size is dependent on availability of pre-printed (Batch No.: and Expiry Date printed) ampoules. B#038 has not been manufactured because of unavailability of pre-printed ampoules for which quality assurance finding report was raised, but no deviation form was and CAPA performed.

f. Autoclave qualification documents not available.

g. Autoclave batch lot validation documents were not provided.

h. Production steps time was not recorded in Batch documents, therefore autoclave cycle time and other step of manufacturing could not be traced from batch documents.

i. Incident report, deviation form and CAPA were not raised for this incident.

j. SOP of CAPA SOP# EP/QA/SOP-010/002 was implemented on 11-11-2019 having no description of CAPA investigation committee; firm is advised to review the SOP.

k. SOP of deviation available SOP# EP/QA/SOP-015/02 effective date 02-08-2018. However, not being implemented as no deviation of incident was raised.

l. Fenaclod injection B# 039 manufactured on 17-10-2019 and released by QA on 09-11-2019 with a note that 3125 quantity of ampoules are hold. However, QA release certificate is issued for complete release of batch without description of partial release and reason of hold quantity as per their written SOP of Product release. Firm did not follow the SOP of product.

m. Reconciliation on batch packaging record of fenaclod injection B#039 shows that batch is under process however Batch is released by QA on 09-11-2019 without investigation the reason of hold quantity and performing its destruction.

n. Destruction certificate of batch documents have description "damage ampoules for Destruction / Reprocessing" apparently it shows that reprocessing of ampoules couldn't be performed which is very critical looking into sterile products.

o. On investigating the subsequent batches it's been observed that firm is continuously facing the yield loss in batches more than their prescribed limit of loss (92-108% as per approved batch documents), but so far no investigation for increased loss performed in any of the batches.

3. The conclusion of panel PSI is reproduced below;

"In the light f the meeting with staff, area visited, documents review including manufacturing, testing and ware-house record and findings of the inspection, the firm is found non-compliant in manufacturing of the Fenaclod Injection in sterile area. It is further recommended that the said product may be suspended till rectification of above noted observations or any appropriate decision by the Director Registration Board."

Action Taken by DRAP:

4. Keeping in view recommendations of the panel in its report dated 11.05.2020, it was proposed to suspend production activities in Liquid Injectable/Sterile area till rectification of all observations, verification of rectification of all observations by a panel of experts and subsequent approval by the competent authority.

5. The CLB in its 273rd meeting has delegated following powers to the Director QA<

i. *Advisory letters, explanation letters or any other action as deems fit for the purpose of improvement (in case of GMP matters)*
ii. *Suspensions of Production (in case of GMP and Quality Control matters)*

Updated Status:

6. At present post of Director QA&LT is vacant. The matter is of the urgent nature and need immediate action for suspension of production in the Liquid Injectable/Sterile area, as recommended by the panel in its report dated 11.05.2020.

7. The case was placed before the 276th meeting of CLB, Wherein the Board decided as under:-

Decision of 276th Meeting of CLB.

After thorough discussion and deliberation, the Board decided to serve show cause notice to the firm M/s Epoch Pharmaceuticals, Plot No.83-85, Sector 15, Korangi Industrial Area, Karachi under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (L, R&A) Rules 1976 for GMP violations as envisaged in Schedule "B" Rule 16 (a) of the Drugs (L,R&A) Rules, 1976 in ***Liquid Injectable/Sterile area***.

8. The firm was issued show cause notice vide letter dated 28.09.2020 in compliance to decision of 276th meeting of CLB.

Reply of the firm:-

Reply of the firm is awaited.

Proceedings of 277th meeting: -

Quality Assurance Division presented the case before the Board. Mr. Salman Saleem (Owner) and Mrs. Zeenat Azhar (Head of Quality) of the firm M/s Epoch Pharma, Karachi appeared before the Board. They submitted that inspection was carried out for PSI. They also submitted CAPA before the Board during personal hearing.

Decision of the 277th Meeting of CLB: -

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view recommendation of panel in its report dated 07.05.2020 & 11.05.2020, the Central Licensing Board decided to: -

i. Constitute following panel of experts for detailed GMP inspection: -

   a) Dr. Abdullah Dayo, Member, CLB.
   b) Director, CDL, Karachi
   c) Area FID, DRAP, Karachi

ii. Production in ***Sterile Area (Liquid Injectable)*** of the firm M/s Epoch Pharma, Karachi shall remain suspended, till inspection by the panel of experts and subsequent approval by the competent authority.

Case No. IV: -M/s Epoch Pharmaceutical (Pvt.) Ltd. Karachi.

A. INSPECTION REPORT IN COMPLIANCE TO DECISION OF 296TH MEETING OF DRB:

Ms. Hira Bhutto, Assistant Director, CDL, Karachi, wherein she has enclosed *Product Specific Inspection* (PSI) report of M/s Epoch Pharmaceuticals (Pvt.) Ltd. Plot No. 83-85, Sector 15 Korangi Industrial Area, Karachi. The PSI of caps Epoclox 500mg was conducted by following panel in compliance to decision of 293rd meeting of Registration Board.

i. Dr. Rafeeq Alam Khan, Member Registration Board.
ii. Mr. Abdul Rasool Sheikh, area FID DRAP Islamabad.
iii. Mrs. Hira Bhutto, Assistant Director CDL Karachi.

OBSERVATIONS OF THE PANEL:

i. Quality Control Department:

a. No dedicated facility for testing of penicillin product available. The penicillin products were tested in general quality control Lab.
b. The record showed that product was tested as per In-House specifications, however, no record of product testing of Epoclox 500mg Capsule B # 5A00l available.
c. Calibration of most of the equipment in quality control lab was due for which no updated schedule for calibration available.
d. the documents record / log sheets and record of relevant raw calculation was found to be un-satisfactory and non-traceable.
e. Analytical method validation or verification of raw material and finished pharmaceutical product not available

ii. Raw Material Store:

a. The raw material store, storage conditions and relevant supporting documents / log sheets were reviewed.
b. Uncontrolled material storage area was provided within segregated facility of Penicillin
c. Cleaning condition of raw material store was unsatisfactory.
d. Job description of dispensing pharmacist was not available. Dispensing pharmacist is directly reporting to CEO.
e. No dedicated staff for penicillin production facility. The firm have only one dispensing pharmacist who perform the dispensing operation of penicillin and non-penicillin products
f. Raw material was not assigned unique identity code at the time of arrival. Raw material details could not be traced from material issuance note as no unique code assigned.
g. Dispensing booth is not of adequate size to perfmon dispensing operations

iii. Production Section: Technically the penicillin manufacturing areas were not dedicated on the following grounds.

a. The entrance to the area was provided through a common entrance from general area.
b. Area Classification and qualification was not justified.

c. HVAC of area was unfunctional, return ducts were provided on roof.
d. HVAC qualification record not available.
e. Current status of penicillin area is not as per provided lay out plan.
f. No area for in process checks control available.
g. Machine parts of penicillin were placed in tool room of general area.
h. Primary packaging of capsule in jar performed in uncontrolled area.
i. Batch manufacturing formula, production equipment, log books, equipment and relevant SOPs were checked and found at satisfactory level of compliance.

iv. Documentation

a. Batch manufacturing record of Epoclox 500mg capsule B# 010 manufactured in August, 2019 was reviewed by panel. Bach was manufactured as per standard BMR. The product testing record of that batch was also reviewed. The batch was tested as per In House specifications.
b. Equipment calibration und dispensing booth calibration records were reviewed.
c. No cleaning validation record available
d. Log books were uncontrolled without specification code and page numbering.

v. Findings of inspection.

a. Product validation of Epoclox 500mg capsule were not performed.
b. The firm change the primary packaging or epoclox 500mg from strip to jar without performing stability studies and without necessary regulatory approval.
c. The Material issuance note of Epoclox 500mg capsule B# 010 shows that cloxacillin sodium USP grade was used however COA of manufacturer shows that the raw material tested us per BP grade. The firms representative said it is a documentation error,
d. Batch documents have no recording of time of production steps.
e. Incident report, deviation form and CAPA not raised for this incident
f. SOP or CAPA SOP # EP/QA/SOP-010/002 were implemented on 1l-11-2019 have no description of CAPA investigation committee firm advised to review this SOP.
g. SOP of documentation control not available.
h. No CAPA and incident report or Epoclox 500mg capsule B#5A001 was available.
i. As per material issuance record of raw material (Bin card) no standard batch size of Epoclox 500mg capsule is followed batches are manufactured as per market demand.
j. The batch manufacturing record of Epoclox 500mg capsule B # 009 and 010 were available and reviewed. As per the record of batch # 0 l 0 weight variation in capsule were observed most of the capsule were filled below lower limit (limit 670mg to 700mg)
k. Batch # 009 weight variation limit is 656mg to 725mg. no standard limit is followed.
l. Change control mechanism and documents were not available.

RECOMMENDATIONS AND CONCLUSION OF PANEL:-

"In the light of the meeting with staff, documents review including manufacturing, testing and ware -house record and findings of the inspection, the firm has been found non-compliant in so called dedicated manufacturing facilities of Penicillin. Based on the stated observations the panel unanimously recommends as follows.

Suspension of manufacturing activities in Penicillin areas till the rectifications of all critical observations stated in the report.

The Panel also recommends suspension of subject product till the submission of product development data and reverification of the same by a panel

All the findings raised during inspection were discussed in detail with the representatives of the firm and they agreed to overcome those findings within four month time. Further they agreed to suspend their production activities in penicillin department till the rectification of observations raised by the panel."

B. INSPECTION REPORT DATED 17.08.2020

Mr. Abdul Rasool Shaikh, FID, DRAP, Karachi has enclosed panel GMP inspection report of M/s Epoch Pharmaceuticals (Pvt.) Ltd Plot No. 83-85, Sector No. 15, Korangi Industrial Area, Karachi conducted by following panel on 17.08.2020;

i. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi.
ii. Mr. Abdul Rasool Sheikh, area FID DRAP Islamabad.
iii. Dr. Affan Ali Qureshi, Assistant Director CDL Karachi.

PANEL OBSERVATIONS:

i. Pharmaceutical Quality System

a. During targeted inspection the panel found compromised quality management system starting from procurement of production materials from un-approved sources, inappropriate and un-controlled storage conditions, sub-optimal production conditions and more than that lack of necessary quality documents,
b. Overall resulting in un-safer products. However certain instant working SOPs and controlling documents were shown during inspection, which were found deficient of key quality elements.

ii. Premises & Equipment:

a. The flow of men & material and poor sanitation level might amplify the chances of cross-contamination among the products.
b. there were no proper buffers/air-locks and proper written plan to minimize the risks of cross-contamination was not available.
c. The processes were found un-validated and almost all equipment were seen without proper written qualification documents.
d. Certain key production machines like FB Dryers and bag filters used in drying were found key sources of cross-contamination, as cleaning procedures were not validated.

e. Certain walls of tablet sections were peeling off and floor was cracked resulting in bad maintenance and accumulation of dust and pathogens in claimed controlled areas.
f. The panel was not shown any preventive or emergency maintenance plan available with the management of the firm.
g. Warehouses were not maintained properly, materials were seen exposed to un-controlled and un-wanted environmental conditions.
h. The storage areas were provided with low lighting, the merely ducts provided there were open and no false ceiling was provided.

iii. Documentation:

a. During inspection the firm was advised to provide key quality documents like site master file, validation and calibration plan, HVAC design with qualification documents, certain key working SOPs, preventive maintenance plan, stability studies program, self-audit documents, training program, change control management, controlling the deviations, OOS and OOT etc. Among those only a few incomplete and insufficient documents were provided.
b. The panel found a very poor documentation control, which may badly affect the quality and safety of product the firm manufactures.

iv. Production:

a. The tablet section has been provided with un-qualified HVAC System which was found incapable of reducing the chances of contamination and cross-contamination and can provide better safety to working personnel.
b. Most of the bags of active materials were seen without necessary initial sampling and testing as required under GMP guidelines, instead seen tagged with released labels.
c. In-appropriate sampling plan and procedures were seen in place.
d. In-appropriate and irregular quality checks were noted in one of the BMR wherein apparent OOS were neglected and product was released for marketing.
e. Overall a feeble production system noted in place.

v. Quality Control:

a. The stability program of the firm needs to be improved with proper implementation.

CONCLUSION OF PANEL REPORT:

Keeping in view the above-mentioned facts and observations, the panel found the firm operating at sub-optimal GMP conditions particularly in tablet section and might not be allowed to carryout it's manufacturing under those conditions. All the major observations pointed out during the inspection were discussed in detail with the management of the firm and they showed interest to halt voluntarily their manufacturing operations and in addition to that the firm has submitted in written improvement plan to the panel for further consideration of the Board.

Proceedings of 277th meeting: -

The Board also considered panel inspection report of the firm M/s Epoch Pharma, Karachi dated 17.08.2020 regarding Penicillin Section and Tablet Section. Mr. Salman Saleem (Owner) and Mrs. Zeenat Azhar (Head of Quality) of the firm M/s Epoch Pharma, Karachi

appeared before the Board. They also submitted CAPA before the Board during personal hearing.

Decision of the 277th Meeting of CLB: -

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view recommendation of panel in its report dated 17.08.2020, the Central Licensing Board decided to: -

i. Constitute following panel of experts for detailed GMP inspection: -

   a) Dr. Abdullah Dayo, Member, CLB.
   b) Director, CDL, Karachi
   c) Area FID, DRAP, Karachi

ii. Production in Penicillin Section and Tablet Section of the firm M/s Epoch Pharma, Karachi shall remain suspended, till inspection by the panel of experts and subsequent approval by the competent authority.

Case No. V:- M/s Welwink Pharmaceutical. Gujranwala.

Background

The GMP inspection of the firm M/s. Welwink Pharmaceuticals, G.T. Road, Industrial Estate, Gujranwala Cantt, Gujranwala was conducted by following panel on 11.10.2019 to check the GMP compliance.

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

2. 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."

3. However the firm M/s. Welwink Pharmaceuticals, G.T. Road, Industrial Estate, Gujranwala Cantt, Gujranwala disagreed with the above report vide Letter No. Nil dated 06.01.2020. Management of the firm requested for re-inspection with other panel of inspectors.

4. Subsequently panel re-inspection report conducted on 25-02-2020 of M/s Welwink Pharmaceuticals, G.T. Road Industrial Estate Gujranwala Cantt, Gujranwala; by the following panel:-

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

5. The panel reported following observations:-

i. Change Rooms

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

ii. Storage Area:

a. Provide exterior solvent storage area to store solvents/liquids.
b. Provide HVAC ducting in dispensing room.
c. Ensure availability of sampling booth.
d. Provide separate rejected area.

e. Monitor temperature humidity of store because capsule shells were found stored inside Raw Material Store where humidity was 92% at the time of visit.
f. Provide separate recalled / returned area.
g. Improve labels.

iii. <u>Tablet Section:</u>

a. 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.

iv. <u>Capsule Section:</u>

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

v. <u>Sachet Section:</u>

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

vi. <u>Injectable Section:</u>

a. 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.
b. 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).
c. 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.
d. Firm was advised to validate HVAC system as differential pressures were not proper in many areas.
e. 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.
f. Firm was advised to make doors and windows smooth/flushed with proper door closures.
g. 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.
h. 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.
i. It was advised to provide cooling trolley with HEPA filter in the cooling zone.
j. It was advised to provide supply of RO water in solution preparation room.
k. It was advised to arrange separate autoclave for sterilization of uniform and utensils.

l. It was advised to calibrate temperature and pressure gauges of the solution preparation tanks and install heat exchanger in solution preparation room.
m. It was advised to replace screens of optical checking and ensure availability of Lux meter.
n. It was advised to perform media fill trial.

vii. Quality Control

a. HVAC ducting was not appropriate in microbiology laboratory and its buffers.
b. Improve LFC in sterility room as it was not working properly at the time of inspection.
c. Ensure the availability of air sampler and improve area monitoring reports as advised.
d. Purchase reference standards
e. Perform media fill trial.
f. Ensure the availability of FTIR, Karl Fischer and Digital Polarimeter.
g. Upgrade Dissolution and Disintegration apparatus.
h. Ensure the availability of cultures in microbiological laboratory.
i. Perform growth promotion test for media.

viii. Personnel:

a. 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.

ix. Water Purification System:

a. 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.
b. Provide proper storage tank for WFI with a proper loop system.
c. Validate water purification system.
d. Develop procedure for sanitization of water purification system.

x. HVAC System:

a. 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.
b. 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.

6. 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."*

7. Since the panel had reported critical points yet concluded that the firm was operating at satisfactory level of GMP compliance, the competent authority advised to ask the panel for clarification on the critical points.

8. Consequently, the panel submitted the following reply;

> *"As GMP is ongoing improvement process, where as 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."*

9. In light of above the firm was advised to rectify the observations of liquid injectable section and submit compliance report. It was communicated vide letter No.F.4-169/2016-QA dated 07.09.2020 that the ***production in liquid injectable section shall remain suspended till submission of compliance report****;* it was further informed that the verification shall be done by the panel and subsequent approval from competent authority as panel did not recommend the liquid injectable section.

10. In response to the above the firm submitted letter with the subject title **"Challenging GMP Inspection Report"**. Wherein the firm M/s. Welwink Pharmaceuticals, Gujranwala challenged this office letter of even No. dated 07.09.2020, recommending not to resume the production activities in Liquid Injectable Section. Furthermore, they have stated that *"they disagree with the recommendation in the report regarding* ***Liquid Injectable Section*** *and overall recommendations."* and they have requested to reconstitute new panel for inspection of their premises.

Proceedings of 277th meeting of CLB:

Division of QA&LT presented the case before the Board. The Board considered panel Inspection reports dated 11.10.2019 & 25.02.2020. The board also considered reply of the firm M/s Welwink Pharmaceuticals, GT Road, Gujranwala dated 06.01.2020 & 22.09.2020, wherein management of the firm disagree with the reports of the panel.

Decision of 277th meeting of CLB:

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendation of panel in its report dated 11.10.2019 & 25.02.2020 and reply of the firm dated 06.01.2020 & 22.09.2020, the Central Licensing Board decided to: -

i. 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, GT Road, Gujranwala shall remain suspended.

Item No. II **PERSONAL HEARING IN COMPLIANCE TO DECISION OF 275TH MEETING OF CLB**

Case No. I:- **M/s Helix Pharma (Pvt.) Ltd. Karachi (DML No. 000030)**

Background:-

Mr. Awais Ahmed, area FID DRAP Karachi conducted inspection of the firm M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E., Karachi (DML. No. 000030) on 16-01-2020 & 17-01-2020 to check GMP compliance.

2. The observations reported by FID are reproduced below;

i. Quality Assurance

i. QMS is not well established.
ii. Advised to prepare and improve SOPs and arrange trainings for the staff.

ii. Ware House

i. RMS is congested
ii. Floor of warehouse was broken from many points, needs immediate renovation.
iii. Advised to provide gowning for 2-8 C store.
iv. Some doors of dispensing area were out of order.
v. Magnehelic gauge was also not working at time of inspection.
vi. Interlocking is advised in dispensing area to maintain pressure differential.
vii. Firm is also advised to ensure cleanliness and improve hygiene.
viii. Firm has not provided proper emergency exists, fire alarms and smoke detectors in warehouse.
ix. Training to the staff also advised to ensure personal safety.

iii. Dry Powder Suspension (General & Ceph)

i. Door fixtures of blistering area were out of order.
ii. Material entry is not provided by buffer and interlock. Same entry is also used for over printing room.
iii. Compression room 1 has opening into compression room 2, which has no use, and door was temporarily fixed with tape.
iv. The firm found in violation of DRB decision on segregated section for Psychotropic substances, as firm has no segregated section for Psychotropic Products. Psychotropic product “Estazolim” was being manufactured in general OSD section.
v. HVAC is not provided in blistering area. Air conditioner was installed in blistering room, as product is exposed in blistering room, there are chances of contamination.

vi. Emergency exits not properly assigned and over occupied at some exits.
vii. In granulation section, firm found in violation of approved layout plan, as 2 Compression machines were installed in 2 different cubicles, one assigned for “utensils washing” and other is “assigned for C.M Store” as per approved layout plan.
viii. HVAC inlet of the compression room was closed and looks like it is closed since long.
ix. No dust collector is provided in compression room.
x. No HVAC/ Air Condition is installed in “In-process staging area” and temp & humidity record was also not available.

iv. Oral Liquid/ Syrup

i. No magnehelic gauges provided in Liquid manufacturing area.
ii. Door fixtures of blowing area were out of order at time of inspection.
iii. No temperature and humidity record was available in liquid packaging area at the time of inspection.

v. Liquid Sterile Ampoules/ Infusion/ Ophthalmic/Otic.

i. Primary change room is congested; in secondary change room no interlock is provided.
ii. Corridor is clean, NO HVAC is provided.
iii. No air shower is provided to enter into classified sterile area.
iv. Entrance door from buffer to class B has no interlocking and door fixture was also out of order. Hence it can be established as area is not maintained.
v. In injectable filling area, secondary gowning was not available for visitors even for In-charge, glass view in filling/ manufacturing section was also not provided and therefore manufacturing / filling could not be inspected in detail.
vi. In Injectable Quarantine area no HVAC is installed, Split air conditioner is installed.
vii. In quarantine area ball milling machine was placed.
viii. Firm has 2 autoclaves, one was out of order.

3. The FID concluded the report as under;

*“Based on the area visited, the documents reviewed and findings of the inspection, firm is considered to be operating at **Poor level of Compliance.** Under section 19(7) of the Drugs Act 1976, inspection report is placed before the competent authority for further necessary action into the matter.”*

Action Taken by DRAP:

4. Keeping in view the observations and conclusion of report of FID dated 16 & 17-01-2020, the firm was issued an Explanation letter and Suspension of Production orders vide letter No. 4-7/2006-QA dated 12-02-2020.

Non-compliance of the firm:

5. Mr. Awais Ahmed, area FID DRAP Karachi vide letter dated 06-03-2020 stated that he visit premises of M/s Helix Pharma (Pvt) Ltd S.I.T.E. Karachi on 06-03-2020 to check compliance of this office suspension of production orders dated 12-02-2020.

6. The FID reported that the firm had suspended production activities in sterile area and ***production was underway in other sections.***

7. The FID was directed vide letter dated 08-04-2020 & 29-04-2020 to submit detailed investigation report along with details of violations and clear & candid recommendations on observed violations.

Reply of the firm to Explanation letter:

8. The firm meanwhile submitted reply to this office explanation letter dated 12-02-2020 and stated that they have rectified the observations and are ready for inspection.

Panel Constituted:

Request of the firm was placed before the Director QA&LT. the Director QA&LT constituted following panel of experts to conduct inspection of firm M/s Helix Pharma Karachi.

i. Dr. Najam us Saqib Additional Director DRAP Karachi.
ii. Mr. Awais Ahmed, area FID, DRAP Karachi.
iii. Ms. Mehwish Tanveer, Assistant Director, DRAP Karachi.

Panel Report:

9. The panel inspected the firm M/s Helix Pharma (Pvt.) Ltd. A-56. S.I.T.E., Karachi (DML No. 000030 on 06-05-2020 and concluded the report as under;

> *"Keeping in view above mentioned rectification status in OSD and Oral Liquid section of the firm and positive intention towards improvements, panel unanimously recommends the resumption of production in OSD and Oral Liquid section only, However, construction work including HVAC ducting, installation of Air Showers etc. was in process in Liquid Sterile Ampoules/Infusion/Ophthalmic/Otic section, which need some time to be completed. Firm is also advised to provide segregated section for Psychotropic products and submit compliance report to QA&LT, Islamabad."*

10. Based on recommendations of panel, the Director QA&LT granted permission for resumption of production activities in Oral Solid Dosage Form Section and Oral Liquid Section only. The production activities in Liquid Sterile Ampoules/ Infusion/Ophthalmic/Otic section are still suspended.

11. Same panel has been asked to verify firm's compliance and give clear & candid recommendations whether resumption of production activities in remaining sections of M/s Helix Pharma (Pvt.) Ltd, A-56, S.I.T.E, Karachi (DML No. 000030) shall be granted or otherwise based on condition and facilities of the firm. The report from the panel is still awaited.

Detailed investigation report from FID on illegal manufacturing by M/s Helix Pharma Karachi.

Reply of FID:

12. Mr. Awais Ahmed, area FID DRAP Karachi in compliance to this office letter dated 29-04-2020 submitted detailed report which is reproduced below;

> *"With reference to the subject cited above and in compliance to letter No. F.4-7/2006-QA received on 11th May, 2020, undersigned visited M/s Helix Pharma (Pvt) Ltd, SITE, Karachi on 14th May, 2020 to investigate the matter. During inspection, it was revealed that suspension of production order issued on 12.02.2020, received by firm on 17.02.2020, however firm continued production till 16th May, 2020. Manufactured stock of all the batches manufactured after suspension of production order s were made "Not to dispose of" on prescribed Form-I for the period of initially 28 days. After detailed investigation, it was concluded that the firm was involved in unauthorized manufacturing in all sections and firm has violated the decision of the competent authority i.e. The Director QA&LT, for suspension of production orders communicated to the firm vide DRAP letter No. even dated 12.02.2020, which is violation of Section 23 (i)(a)(x) and section 23(i)(b) of the Drugs Act 1976, read with Schedule II(A)(1)(x) and Schedule (A)(1)(b) of the DRAP Act 2012.*

13. The FID further requested that;

i. The necessary permission for extension in the time period of the stock made ordered not to dispose of on prescribed Form-1 may kindly be granted.
ii. Case may be placed in upcoming CLB meeting for discussion and necessary directions.
iii. Any other action as per the law.

14. The case was placed before the 275th meeting of CLB, Wherein the Board decided as under:-

Decision of the 275thMeeting of CLB:-

After thorough discussion/deliberations, the Central Licensing Board decided to direct the area FID to investigate the matter of production activities till 06.03.2020, in non-compliance to the orders of QA&LT Division dated 12.02.2020 and fix the responsibility. The FID shall submit detailed investigation report with clear and candid recommendation for consideration of the CLB under the law.

15. Decision of 275th meeting of CLB was conveyed to FID vide letter dated 02.07.2020.

Reply of FID:-

The FID in compliance to decision of 275th meeting of CLB vide letter dated 18.08.2020 submitted reply as under:-

"Keeping in view the above stated facts and brief summary of the case, the firm has violated the section 23(i) (a) (x) and section 23(i) (b) of the Drugs Act, 1976 read with Schedule II (A) (I) (x) and Schedule II (A)(I) (b) of the DRAP Act, 2012, and rules made there under. However keeping in view repeated inspections of the firm, rectifications of the observations, overall improvements and resumption of productions in all sections after recommendation by the panel members, it is to be proposed that:

i. Show Cause Notice / Personal hearing may be issued to the following responsible persons for violations of the directions as passed by the QA & LT Division along with violation of above mentioned sections of the Drug Act, 1976 and DRAP Act, 2012.

- *Mr. Tahir Nabi Mirza, Director Quality Assurance & Regulatory Affairs.*
- *Mr. Abu Sagheer, General Manager Production.*

ii. Any other directions as may be passed by the Central Licensing Board."

16. Reply of the FID was placed before the 275th meeting of CLB, Wherein the Board decided as under: -

Decision of 276th Meeting of CLB.

The board decided to refer the case back to QA & LT Division to provide names of Management and Responsible persons of the firm M/s Helix Pharma (Pvt.) Ltd. Karachi (DML No. 000030).

17. The Area FID and Secretary CLB were requested vide letter dated 28.09.2020 to provide requisite information.

18. The Licensing Division vide letter dated 13.10.2020 provided names of management and qualified persons as below:-

i.	Mr. Naveed Nawazish Hakim	Director
ii.	Mrs. Nayyar Jahan Hakim	Director
iii.	Mr. Nawazish Ali Hakim	Director
iv.	Mr. Muhammad Tariq	Production Incharge
v.	Mr. Shakeel Ahmed	Quality Control Incharge

Proceedings of 277th meeting of CLB:

Division of QA&LT presented the case before the Board. The Board considered the names of the management and qualified persons provided by the Licensing Division.

Decision of 277th meeting of CLB:

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to issue show cause notice to following accused person on *violation of section 23(1) (a) (x) and section 23(1) (b) of the Drugs Act, 1976 read with Schedule II (A) (I) (x) and Schedule II (A)(I) (b) of the DRAP Act 2012* : -

i. Mr. Naveed Nawazish Hakim S/o Nawazish Ali Hakim Director
CNIC. No. 42201-9743780-3

ii. Mrs. Nayyar Jahan Hakim W/o Nawazish Ali Hakim Director
CNIC No. 42201-6458636-4

iii. Mr. Nawazish Ali Hakim S/o Fasihuddin Hakim Director
CNIC No. 42201-8483279-3

iv. Mr. Muhammad Tariq Production Incharge

v. Mr. Shakeel Ahmed S/o Abdul Mateen Quality Control Incharge
CNIC No. 42401-1829863-5

Item No. III RESUMPTION OF PRODUCTION

Case No. I: - M/S. MALLARD PHARMACEUTICALS, MULTAN

Background: -

Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore conducted inspection of the firm M/s. Mallard Pharmaceuticals (Pvt) Ltd, Multan on 14.11.2018 to check GMP compliance and production activities.

2. The FID during inspection noticed number of critical observations.

Action taken by DRAP:

The firm M/s. Mallard Pharmaceutical, Multan was issued Show Cause Notice and suspension of production orders in sterile area on 15.01.2019.

Reply of the firm:

The firm vide letter No. Nil date 24.01.2019 submitted reply of show cause notice and inform that they have arrange all missing points, request for inspection and allow production.

3. The case was placed in 269th meeting of CLB, wherein the Board decided as under: -

Decision of the 269th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and compliance by the Director of the firm, the Central Licensing Board decided to: -

i. Constitute following panel of experts for verification of the observations before resumption of production: -

    a) The Additional Director, DRAP, Lahore
    b) Mr. Munawar Hayat, Chief Drug Controller, Punjab
    c) Area Federal Inspector of Drugs, Lahore

ii. Production in the Injectable Section shall remain suspended till recommendation by panel and subsequent approval by the CLB.

iii. The panel shall submit detailed inspection report to CLB including rectification status of the observations noted by the FID in its report dated 14.11.2018, with clear and candid recommendations.

Inspection report in compliance to decision of 269th meeting: -

4. The following panel conducted inspection of M/s Mallard Pharmaceuticals (Pvt.) Ltd., 23-KM Lahore Road Qadir Pur, Multan on 08.05.2020 instead of panel constituted by CLB in its 269th meeting of CLB: -

a) Dr. Farzana Chaudhry,
b) Mr. Azhar Jamal Saleemi, Chief Drugs Controller Punjab
c) Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP Lahore.

Conclusion of panel: -

"As the firm has rectified most of the shortcomings and improved the conditions of the GMP, panel of inspectors is of the opinion to recommend the resumption of the production in Liquid Injectable Section (General Veterinary) of the firm M/s Mallard Pharmaceuticals (Pvt.) Ltd., 23-KM, Lahore Road, Qadir Pur, Multan."

Proceeding of 277th meeting of CLB

The Division of QA&LT presented the case before the Board. QA Division presented the panel inspection report and its recommendation dated 13.08.2020.

Decision of 277th Meeting of CLB

Keeping in view the recommendations of panel in its inspection conducted on 13.08.2020, in compliance to decision of 269th meeting the Board decided to;

i. Allow resumption of production in *Liquid Injectable Section (General Veterinary)*

ii. Seize the enforcement of Show Cause Notice dated 15.01.2019 from the date of issuance of decision of 277th meeting of CLB.

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