MINUTES OF 264th MEETING OF CENTRAL LICENSING BOARD HELD ON 9thJULY, 2018

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264th meeting of the Central Licensing Board (CLB) was held on 9thJuly, 2018 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Ghulam Rasool Dutani, Director Drug Licensing, Drug Regulatory Authority of Pakistan, Islamabad.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1	Dr.Ikram-ul-Haque, Expert inQC/QA of drugs.	Member
2	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
3	Prof. Dr. Mohammad Usman, Expert in manufacturing of drugs	Member
4	Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar.	Member
5	Mr. Munawar Hayat, Chief Drug Controller, Primary and Secondary Health Care Department, Govt. of Punjab, Lahore	Member
6	Mr. Zakir Shah, Drug Inspector Representative, Chief Drug Inspector, Health Department, KPK.	Member
7	Syed Saleem Shah, Chief Drug Inspector, Department of Health, Govt. of Balochistan, Quetta.	Member
8	Mr. Muhammad Israr Additional Draftsman/Joint Secretary (Ex-officio), Ministry of Law and Justice, Islamabad.	Member
9	Dr. Hafsa Karam Ellahi Representative Director (QA/LT), DRAP, Islamabad	Member
10	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
11	Mr. Nadeem Alamgir, Representative of Pharma Bureau	Observer
12	Mr. Kamran Anwar, Representative of PCDA.	Observer
13	Mr.Iftikhar Ahmed, Representative of PPMA.	Observer

The meeting started with the recitation of verses from the Holy Qura'an. The Chairman Central Licensing Board welcomed the honorable members and participants of the meeting. 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. Mr. Abdul Sattar Sohrani, Deputy Director (QC), Mr. Zeeshan Nazir, Deputy Director (QA), Mr. Ayyaz Ahmad, Deputy Director (Lic), Dr. Muhammad Yaqoob AD (Lic.), Dr. Muhammad Usman, AD (Lic) and Dr. Zunaira Farayad, Assistant Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 263rd MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 263rd meeting held on 11th June, 2018.

A. DRUG LICENSING DIVISION

Item-I: **GRANT OF ADDITIONAL SECTIONS/EXPANSION/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	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Intervac (Pvt) Ltd, 18-Km, Sheikhupura Road, Sheikhupura. DML No. 000623(Formulation) **Section (02)** 1. iquid Injectable(Penicillin)(Veterinary) 2. ry Powder injection (Penicillin)(Veterinary)	16-05-2018	**Good**	1. Dr.Ikram-ul-Haq, Member Central Licensing Board. 2. Dr. Qurban Ali, Director NVL, Islamabad. 3. Mrs. MajidaMujahidFederal Inspector of Drugs, DRAP, Lahore. 4. Ms. Nusrat, Drug Inspector Industries, Health Department Government of Punjab, Lahore

Recommendations of the panel: -

Firm has done considerable improvement in microbiological Lab which are appreciated by panel.Keeping in view the above observations, the members of the panel are of the opinion to recommend the grant of the above mentioned new additional sections to M/s Intervac (Pvt) Ltd, 18-Km, Sheikhupura Road, Sheikhupura as per approved layout plan approved by DRAP.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered and approved grant of additional Sections to M/s Intervac (Pvt) Ltd, 18-Km, Sheikhupura Road, Sheikhupura under Drug Manufacturing Licence No. 000623 (Formulation) for the following two additional Sections:

Section (02)

1. Liquid Injectable(Penicillin)(Veterinary)
2. Dry Powder injection (Penicillin)(Veterinary)

2.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission centre Hyderabad Road, Landhi, Karachi. DML No. 000001(Formulation) **<u>Section 02</u>** 1. ablet (General) Section First Floor(Amendments) 2. mall Volume Parental Ground Floor(Amendments)	06-06-2018	**Good**	1. Mr. Syed Muid Ahmed, Member Central Licensing Board. 2. Director, Drug Testing Laboratory, Govt of Sindh, Karachi. 3. Ms. MehwishTanveerFederal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel: -

The premises of above mentioned sections were visited and related documents were reviewed. Some SOP's required upgradation and necessary revision. However, firm's management is committed for continuous improvements and has assured prompt compliance.

Keeping in view the above observations, panel recommends the grant of additional/amendments in sections.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered and approved amendments of M/s M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission centre Hyderabad Road, Landhi, Karachi under the Drug Manufacturing Licence No. 000001 (Formulation) for the following two sections:

<u>Section 02</u>

1. Tablet (General) Section First Floor(Amendments)
2. Small Volume Parental Ground Floor (Amendments)

3.	M/s Martin Dow Ltd, Plot No 37, Sector 19, Korangi Industrial Area, Karachi. DML No. 000267(Formulation) **<u>Section 06</u>** 1. ablet (General) Section (Regularized) 2. iquid Syrup (General) Section (Regularized) 3. apsule (General) Section (Amendments) 4. arehouse (Amendments) 5. ablet (Psychotropic) (Amendments) 6. ew Packing Area(Primary & Secondary Packaging)	07-06-2018	**Good**	1. Mr. Syed Muid Ahmed, Member Central Licensing Board. 2. Chief Drugs Inspector, Karachi/ Member Central Licensing Board. 3. Ms. Muneeza Khan, Federal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel: -

During the visit, panel visited all storage, manufacturing and Quality Control, areas, documents reviewed and observed that all the sections are constructed as per approved layout plan and GMP compliance. The panel recommends the grant of regularization /amendments in sections.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered and approved amendments/ regularization of M/s Martin Dow Ltd, Plot No 37, Sector 19, Korangi Industrial Area, Karachi under the Drug Manufacturing Licence No. 000267 (Formulation) for the following six sections:

<u>Section 06</u>

1.	Tablet (General) Section (Regularized)
2.	Liquid Syrup (General) Section (Regularized)

	3. Capsule (General) Section (Amendments) 4. Warehouse (Amendments) 5. Tablet (Psychotropic) (Amendments) 6. New Packing Area(Primary& Secondary Packaging)			
4.	M/s Saakh Pharma (Pvt) Ltd, C-7/1, N.W.I.Z, Port Qasim , Karachi. DML No. 000588 (Formulation) **<u>Section 02</u>** 1. Building No. 3 (Taste masking &Pelletization) 2. Building No. 4 (General)	4-7-2018	**Good**	1. Mr. Ghulam Sarwar, Member DRB, DRAP, Islamabad. 2. Dr. Najam-us-Saqib, Additional Director(E&M), DRAP, Karachi. 3. Ms. MehwishTanveerFederal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel: -

M/s Saakh Pharma (Pvt) Ltd, C-7/1, N.W.I.Z, Port Qasim , Karachi was inspected on 04th July, 2018 by the panel constituted as per DRAP letter for the purpose of grant of following additional section:

3. Building No. 3 (Taste masking &Pelletization)
4. Building No. 4(General)

The firm has constructed two new buildings (Names as above) for the purpose of Taste masking & palletization, and semi basic manufacturing of API's. Keeping in view , people met, documents reviewed, finding of inspection and management intentions towards export of API's from Pakistan, Panel recommends the grant of above mentioned additional sections. The panel also recommended following Molecules/APIs to be manufactured by way of semi basic manufacture in above mentioned sections/ facilities.

S#NO.	Name of Drugs (s) **Pelletization and Taste Masking**	S#NO.	Name of Drugs (s) **General Section**
1	Esomeprazole (Ph.Eur)	**1**	Montelukast Sodium (BP/USP)
2	Omeprazole (Ph.Eur / USP)	**2**	Sitagliptin (in house specs)
3	Clarithromysin (Ph.Eur)	**3**	Clarithromycin (Ph.Eur)

4	Orislistat (In house specs)	**4**	Azithromycin (Ph.Eur)
5	Tamsosulin (Ph.Eur)	**5**	Sofosbuvir (In-House Specs)
6	Azithromycin (Ph.Eur)	**6**	Paracetamol (BP/USP)
7	Cefexime (USP)	**7**	Sulfamethozazole (USP)
8	Paracetamol (BP/USP)	**8**	Mefenamic Acid (Ph.Eur)
9	Ciprofloxacin (Ph.Eur)	**9**	Ciprofloxcin (USP)
10	Dexlansoprazole (In-House Specs)	**10**	Levoflaxacin (BP)
11	Lansoprazole (In-House Specs)	**11**	DaclatasvirDihydchloride (In-House Specs)
		12	Glimepride (Ph.Eur) + USP
		13	Omeprazole (Ph.Eur) + USP
		14	Dexlansoprazole (In-House Specs)
		15	Lansoprazole (In-House Specs)

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered and approved additional facilities for manufacture of Active Pharmaceutical Ingredients (APIs) and Pelletization/ Taste Masking by way of semi basic manufacture of M/s Saakh Pharma (Pvt) Ltd, C-7/1, N.W.I.Z, Port Qasim , Karachi under Drug Manufacturing Licence No. 000588 (Semi Basic Manufacture) for the following additional section:

1. Building No. 3 (Taste Masking & Pelletization)
2. Building No. 4 (General)

The Central Licensing Bard also considered and approved following Active Pharmaceutical Ingredients (APIs) and Pelletization/Taste masking of APIs:

S#NO.	Name of Drugs (s) **Pelletization and Test Masking**	S#NO.	Name of Drugs (s) **General Section**
1	Esomeprazole (Ph.Eur)	**1**	Montelukast Sodium (BP/USP)
2	Omeprazole (Ph.Eur / USP)	**2**	Sitagliptin (in house specs)
3	Clarithromysin (Ph.Eur)	**3**	Clarithromycin (Ph.Eur)
4	Orislistat (In house specs)	**4**	Azithromycin (Ph.Eur)
5	Tamsosulin (Ph.Eur)	**5**	Sofosbuvir (In-House Specs)
6	Azithromycin (Ph.Eur)	**6**	Paracetamol (BP/USP)

	7	Cefexime (USP)	**7**	Sulfamethozazole (USP)
	8	Paracetamol (BP/USP)	**8**	Mefenamic Acid (Ph.Eur)
	9	Ciprofloxacin (Ph.Eur)	**9**	Ciprofloxcin (USP)
	10	Dexlansoprazole (In-House Specs)	**10**	Levoflaxacin (BP)
	11	Lansoprazole (In-House Specs)	**11**	DaclatasvirDihydchloride (In-House Specs)
			12	Glimepride (Ph.Eur) + USP
			13	Omeprazole (Ph.Eur) + USP
			14	Dexlansoprazole (In-House Specs)
			15	Lansoprazole (In-House Specs)

While considering the case of M/s Saakh Pharma (Pvt) Ltd, C-7/1, N.W.I.Z, Port Qasim , Karachi observed that there is need of uniformity in testing protocols/release pattern for pelletization and In House Specification. The Board therefore, decided to constitute a Committee of following to make recommendations of the subject matter for the consideration of the Board.

1. **Dr. Ikram ul Haq, Member Central Licensing Board**
2. **Mr. Syed Muied Ahmad, Member Central Licensing Board**
3. **Dr. Abdul Manan, Manufacturing Expert, M/s Pharmagen Ltd, Lahore**
4. **Mr. Abdul Aziz, Manufacturing Expert, M/s Vision Pharmaceuticals (Pvt) Ltd, Islamabad**
5. **Mr. Ayyaz Ahmad, deputy Director (Lic) Member/ Coordinator**
6. **The Committee may co-opt any expert as member.**

TORs of the Committee

1. The Committee shall frame its recommendations preferably within 90 days.
2. The Committee stands dissolved after submission of its recommendations.
3. The Central Licensing Board shall consider and deliberate on the report for uniformity in working of the pharmaceutical manufacturers involved in Semi Basic manufacture.

Item-II: **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 GlaxoSmithKline Pakistan Ltd,35, Dockyard Road, West Wharf, Karachi DML No. 000017 (Formulation) **Period**: Commencing on 31-03-2015 ending on 30-03-2020.	**20-03-2018**	**Good**	1. Mr. Syed Muid Ahmed, Member Central Licensing Board. 2. D. Abdullah Dayo, Member Central Licensing Board. 3. DR. Saifur Rehman Khattak, Director CDL, DRAP, Karachi. 4. Syed Hakim Masood, Federal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel: -

1. It is an old factory, however, maintained very well by the management. The infrastructure, human resource and other manufacturing and Quality Control facility are well established. The panel recommends the renewal of DML No. 000017 (Formulation) for the approved sections.
2. **The renewal of section for manufacturing Aerosol (HFA based MDI's) may not be considered as per request of the firm.**
3. The transfer of registrations of Liquid Injectable products from West Wharf side to Korangi Site be expedited.
4. The firm may also be directed to establish dedicated section for Eye Ointment manufacturing as per revised layout plan.
5. **Authentication/regularization of the master layout plan may kindly be made after successful changes in the layout as proposed by the panel and completion by the same.**

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered and deferred the case for personal hearing in next meeting of the Board for seeking clarification on the observations of the members of the panel

	of experts.

Item-IV: **MISCELLANEOUS CASES**

Case No. 1 **CHANGE OF TITLE/LEGAL STAUS OF M/S NOVARTANA PHARMACEUTICALS, LAHORE.**

M/s Novartana Pharmaceuticals, 87-B Sunder Industrial Estate, Raiwind Road, Lahore under DML No. 000738 by way of formulation has submitted request for change of title of the firm as per Certificate of incorporation Form S.E.C.P with prescribed Fee Challan of Rs.50,000/-. The detail is as under:

Previous Name as per Form I and Form-2	**Proposed Name/Title/Legal Status as per Certificate of Incorporation from S.E.C.P**
M/s Novartana Pharmaceuticals, 87-B Sunder Industrial Estate, Raiwind Road, Lahore	M/s Novartana Pharmaceuticals (Private) Limited, 87-B Sunder Industrial Estate, Raiwind Road, Lahore

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered and approved change of title / name of the firm / company M/s Novartana Pharmaceuticals, 87-B Sunder Industrial Estate, Raiwind Road, Lahoreunder DML No. 000738 by way of formulation as under:

Previous Name as per Form I and Form-2	**New Name/Title as per Certificate of Incorporation from S.E.C.P**
M/s Novartana Pharmaceuticals, 87-B Sunder Industrial Estate, Raiwind Road, Lahore	M/s Novartana Pharmaceuticals (Private) Limited, 87-B Sunder Industrial Estate, Raiwind Road, Lahore

Case No. 2. **CHANGE OF MANAGEMENT OF M/S NOVARTANA PHARMACEUTICALS, LAHORE.**

M/s NovartanaPharmaceuticals,87-B Sunder Industrial Estate, Raiwind Road, Lahore under DML No. 000738 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 partnership deed	Interim Management as per Form-29	Proposed Management / Directors on Form-29
1. Mr.Badar-uz-Zaman Khan S/o MuahmmadYousaf Khan CNIC No. 35201-1588493-3. 2. Mr. Basir Ahmad Azhar S/o Ch. Rehmat Ali CNIC No. 36502-1283110-5.	1. Mr.Muhammad Ishtiaq Khan S/o Muhammad Aslam Khan CNIC No. 35201-1685474-9. 2. Mr.Badar-uz-Zaman Khan S/o MuahmmadYousaf Khan CNIC No. 35201-1588493-3. 3. Mr. Saad Ali Khan S/o Muhammad Yousaf CNIC No. 35201-7814025-3.	1. Mr. Ch. ShamasMujahid S/o Ch. Ashgar CNIC No. 34202-3873681-3. 2. Mr.Muhammad Irfan S/o Muhammad Aslam CNIC No. 33302-2214891-9.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered and endorsed change of management of the firm / company M/s Novartana Pharmaceuticals, 87-B Sunder Industrial Estate, Raiwind Road, Lahore under DML No. 000738 by way of formulation as under:

Previous Management / as per partnership deed	Interim Management as per Form-29	NewManagement / Directors on Form-29
1. Mr.Badar-uz-Zaman Khan S/o MuahmmadYousaf Khan CNIC No. 35201-1588493-3. 2. Mr. Basir Ahmad Azhar S/o Ch. Rehmat Ali CNIC No. 36502-1283110-5.	1. Mr. Muhammad Ishtiaq Khan S/o Muhammad Aslam Khan CNIC No. 35201-1685474-9. 2. Mr. Badar-uz-Zaman Khan S/o MuahmmadYousaf Khan CNIC No. 35201-1588493-3. 3. Mr. Saad Ali Khan S/o Muhammad Yousaf CNIC No. 35201-7814025-3.	1. Mr. Ch. ShamasMujahid S/o Ch. Ashgar CNIC No. 34202-3873681-3. 2. Mr. Muhammad Irfan S/o Muhammad Aslam CNIC No. 33302-2214891-9.

Case No.3. CHANGE OF MANAGEMENT OF M/S RADIANT PHARMA (PVT) LTD, LAHORE.

M/s Radiant Pharma (Pvt) Ltd,43-E Sunder Industrial Estate, Sunder Raiwind Road, Lahore under DML No. 000776 by way of formulation has submitted request for change in management of the firm as per Form 29& Form-A along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-A	**Interim Management as per Form-29**	**Proposed Management as per Form-29 & Form-A**
1. Mr. Ali Ahmad CNIC No. 35202-2616223-7 2. Ms. HumairaZahid CNIC No. 35202-2311443-0. 3. Mr. Ch. Imran Javed CNIC No. 35202-5889976-9. 4. Mr. Sabir Ali CNIC No. 35202-5595688-3. 5. Mr. Muhammad Latif CNIC No. 36302-3948027-1.	1. Mr. Hamid Raza S/o Abdul Jabbar CNIC No. 35202-9569392-7. 2. Mr. Amjad Iqbal S/o Muhammad Bashir CNIC No. 31105-0302345-5.	1. Mr. Zahid Iqbal S/o Ch. Muhammad Yousaf CNIC No. 35202-2695641-1. 2. Mr. Amjad Iqbal S/o Muhammad Bashir CNIC No. 31105-0302345-5.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered and endorsed change of management of the firm / company M/sRadiant Pharma (Pvt) Ltd,43-E Sunder Industrial Estate, Sunder Raiwind Road, Lahore under DML No. 000776 by way of formulation as under:

Previous Management as per Form-A	**Interim Management as per Form-29**	**New Management as per Form-29 & Form-A**
1. Mr. Ali Ahmad CNIC No. 35202-2616223-7 2. Ms. HumairaZahid CNIC No. 35202-2311443-0. 3. Mr. Ch. Imran Javed CNIC No. 35202-5889976-9. 4. Mr. Sabir Ali CNIC No. 35202-5595688-3. 5. Mr. Muhammad Latif CNIC No. 36302-3948027-1.	1. Mr. Hamid Raza S/o Abdul Jabbar CNIC No. 35202-9569392-7. 2. Mr. Amjad Iqbal S/o Muhammad Bashir CNIC No. 31105-0302345-5.	1. Mr. Zahid Iqbal S/o Ch. Muhammad Yousaf CNIC No. 35202-2695641-1. 2. Mr. Amjad Iqbal S/o Muhammad Bashir CNIC No. 31105-0302345-5.

Case No.4 **M/S BF BIOSCIENCES LIMITED, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000655 (FORMULATION) FOR COMPAIGN MANUFACTURING OF NON BIOLOGICAL PRODUCTS IN BILOLOGICAL MANUFACTURING FACILITY**

Case Background

The Central Licensing Board in its 235th meeting held on 15th May, 2014 considered the case of M/sBF Biosciences Limited, Lahore and decided is as under:-

"Approved the Grant of Renewal of DML

The Board was further apprised by Licensing Division that the firm in its renewal application has mentioned that they have registration of Omeprazole at Biotech facility where as panel in the inspection report has mentioned that the firm has dedicated biotech manufacturing facility only.

The Board in this regard advised to refer the case of registration of Omera Injection (Omeprazole) with Reg. No. 067967 to Drug Registration Board for its consideration and further necessary action accordingly."

This decision was conveyed to Drug Registration Board vide letter issued on 27th August, 2014. The Drug Registration Board in its 277th meeting held on 27-29th December, 2017 considered the case of the firm and proceedings of the case are as under:

"Followingapplicationnowhavebeensubmittedon Form5alongwithenclosureson CTDformat,details of which are presented here for consideration of Registration Board.

845.	*Name and address of manufacturer /Applicant*	*M/s BFBiosciencesLtd.,5-Km,Sundar Raiwind Road, Raiwind.*
	Brand Name+Dosage Form+Strength	*Omera40mg Infusion (Lyophilized Powder For Solution For Injection) Intra*
	Composition	*Each vial contains: Omeprazole (as sodium)…40mg*
	Diary No. Date of R&I & fee	*Dy.No.16942;04-10-2017;Rs.20,000/-(03-10-2017)*
	Pharmacological Group	*Proton pump inhibitors*
	Type of Form	*Form-5*
	Finished product Specification	*Manufacturer specifications*
	Pack size & Demanded Price	*1's;AsperSRO*

	Approval status of product in Reference Regulatory Authorities.	*Approved by MHRA of UK*
	Me-too status	*RisekInjection40mgof M/s Getz Pharma(Reg.#024170)*
	GMP status	*Lastinspectionreport08-09-2017PanelconcludesgoodlevelofGMPcompli*
	Remarks of the Evaluator.	• *FirmhassectionapprovalforBiologicalparenteralonlywhereasappliedformulation does not fall in this category.* • *FirmhassubmittedEnclosuresalongwithform5asperCTDformatapproved in 264thmeeting of registration Board.* • *Firmhassubmittedreportsofaccelerated&real timestabilitystudiesforthreebatches.*
	Decision:RegistrationBoarddeferredthecaseforpersonalhearingforclarificationoffirm'srequest to manufacture applied formulation in Biological parenteral section.	
846.	*Name and address of manufacturer /Applicant*	*M/s BFBiosciencesLtd.,5-Km,Sundar Raiwind Road, Raiwind.*
	Brand Name+ Dosage Form+ Strength	*Esomega 40mg Infusion (Lyophilized Powder For Solution For Intravenous Injection)*
	Composition	*Each vial contains:* *Esomeprazole (as sodium)…40mg*
	Diary No. Date of R&I & fee	*Dy.No.16941;04-10-2017;Rs.20,000/-(03-10-2017)*
	Pharmacological Group	*Proton pump inhibitors*
	Type of Form	*Form-5*
	Finished product Specification	*Manufacturer specifications*
	Pack size & Demanded Price	*As per SRO*
	Approval status of product in Reference Regulatory Authorities.	*Approved by MHRA of UK*
	Me-too status	*X-Prazole40mgInfusionofM/sMediatePharmaceuticals Karachi(Reg #057925)*
	GMP status	*Lastinspectionreport08-09-2017PanelconcludesgoodlevelofGMPcompliance.*

	Remarks of the Evaluator.	• *Firm has section approval for Biological parenteral only where as applied formulation does not fall in this category.* • *Firm has submitted Enclosures alongwith form 5 as per CTD format approved in 264th meeting of registration Board.* • *Firm has submitted reports of accelerated & real time stability studies for three batches.*
	Decision: Registration Board deferred the case for personal hearing for clarification of firm's request to manufacture applied formulation in Biological parenteral section.	

The Proceedings Of 278th Meeting Of Drug Registration Board

Following cases were presented in 277th meeting of Registration Board, submitted on Form 5 alongwith enclosures on CTD format. The details of cases & decisions of Board are reproduced as under:

846.	*Name and address of manufacturer/Applicant*	*M/sBFBiosciencesLtd.,5-Km,SundarRaiwindRoad,Raiwind.*
	Brand Name+ Dosage Form+ Strength	*Omera 40mg Infusion (Lyophilized Powder Injection) For Solution For Intravenous*
	Composition	*Each vial contains:* *Omeprazole (as sodium)…40mg*
	Diary No. Date of R&I & fee	*Dy.No.16942; 04-10-2017; Rs.20,000/-(03-10-2017)*
	Pharmacological Group	*Proton pump inhibitors*
	Type of Form	*Form-5*
	Finished product Specification	*Manufacturer specifications*
	Pack size & Demanded Price	*1's; As per SRO*
	Approval status of production Reference Regulatory Authorities.	*Approved by MHRA of UK*
	Me-too status	*Risek Injection 40mg of M/s Getz Pharma(Reg.#024170)*
	GMP status	*Lastinspectionreport08-09-2017PanelconcludesgoodlevelofGMPcompliance.*

	Remarks of the Evaluator.	• *Firm has section approval for Biological parenteral only where as applied formulation does not fall in this category.* • *Firm has submitted Enclosures alongwith form 5 as per CTD format approved in 264th meeting of registration Board.* • *Firm has submitted reports of accelerated & real time stability studies for three batches.*
	Decision: Registration Board deferred the case for personal hearing for clarification of firm's request to manufacture applied formulation in Biological Parenteral section.	
847.	*Name and address of manufacturer/ Applicant*	*M/s BFBiosciencesLtd.,5-Km, Sundar Raiwind Road, Raiwind.*
	Brand Name+ Dosage Form+ Strength	*Esomega 40mg Infusion (Lyophilized Powder For Solution For Intravenous Injection)*
	Composition	*Each vial contains:* *Esomeprazole (assodium)…40mg*
	Diary No. Date of R&I & fee	*Dy.No.16941;04-10-2017;Rs.20,000/-(03-10-2017)*
	Pharmacological Group	*Proton pump inhibitors*
	Type of Form	*Form-5*
	Finished product Specification	*Manufacturer specifications*
	Pack size & Demanded Price	*As per SRO*
	Approval status of production Reference Regulatory Authorities.	*Approved by MHRA of UK*
	Me-too status	*X-Prazole 40mg Infusion of M/s Mediate Pharmaceuticals, Karachi(Reg.#057925)*
	GMP status	*Last inspection report 08-09-2017 Panel concludes good level of GMP compliance.*
	Remarks of the Evaluator.	• *Firm has section approval for Biological parenteral*
		Only where as applied formulation does not fall in this category. • *Firm has submitted Enclosures along with form 5 as per CTD format approved in 264th meeting of registration Board.* • *Firm has submitted reports of accelerated & real time stability studies fort here batches.*

	Decision: Registration Board deferred the case for personal hearing for clarification of firm's request to manufacture applied formulation in Biological parenteral section.

Following details have been submitted of Module 3 (Quality / CMC) for both above cited applications: Contents of Module:3 (Quality / CMC)

Module	***Section***	***Sub-section***	***Contents***	***Data submitted***
3	***3.2.S***		***DRUG SUBSTANCE***	
		3.2.S.1	***General Information***	*Detail submitted for* *i. Nomenclature* *ii. Structure* *iii. General properties*
		3.2.S.2	***Manufacture***	*Detail submitted for* *i. Manufacturer(s)* *ii. Description of Manufacturing Process and Process Controls*
		3.2.S.3	***Characterization***	*Detail submitted for* *i. Elucidation of Structure and other Characteristics* *ii. Impurities*
		3.2.S.4	***Control of Drug Substance***	*Detail submitted for* *i. Control of DrugSubstance* *ii. Specification* *iii. Analytical Procedures* *iv. Validation of Analytical Procedures* *v. Batch Analyses* *vi. Justification of Specification*
		3.2.S.5	***Reference Standards or Materials***	*Detail submitted for Reference Standards*
		3.2.S.6	***Container Closure System***	*Detail submitted for Container Closure System*
		3.2.S.7	***Stability***	*Detail submitted for Stability. (Protocol & reports have been submitted)*

	3.2.P		***DRUG PRODUCT***	
		3.2.P.1	***Description and Composition of Drug Product***	*Detail submitted for Composition of Drug Product*
		3.2.P.2	***Pharmaceutical Development***	*Detail submitted for Components of the Drug Product.*
		3.2.P.3	***Manufacture***	*Detail submitted for* *i. Manufacturer(s)* *ii. Batch Formula* *iii. Description of Manufacturing Process and Process Controls* *iv. Controls of Critical Steps and Intermediates* *Undertaking has been submitted for Process validation*
		3.2.P.4	***Control of Excipient***	*Detail submitted for* *i. Specifications* *ii. Analytical Procedures* *All excipients used are of Pharmacopoeal grades*
		3.2.P.5	***Control of Drug Product***	*Detail submitted for* *i. Specification(s)* *ii. Analytical Procedures* *iii. ValidationofAnalyticalProcedures(Protocol&reporthavebeensubmitted)*
		3.2.P.6	***Reference Standards or Materials***	*Detail submitted for Reference Standards or Materials*
		3.2.P.7	***Container Closure System***	*Detail submitted for Container Closure System*
		3.2.P.8	***Stability***	*Following have been submitted:* *i. Stability Summary and Conclusions* *ii. Post-approval Stability Protocol and Stability Commitment* *iii. Stability Data (Only reports have been submitted.)*

- *Now, the firm has requested for personal hearing before the Honourable Drug Registration Board to enable to them to present their case. The representatives of the firm now have been called upon for personal hearing.*

Proceedings: *Dr. Ajmal Nasir (DirectorTechnical) appeared before the Board and briefed regarding justification for the manufacturing of non-biologicals alongwith bio-pharmaceuticals at BF Biosciences Ltd as under:*

"BF Biosciences is manufacturing six products i.e. Interferon Alpha 2a ,Interferon Alpha 2b, Pegylated interferon alpha 2a, Erythropoietin, Filgrastim and Terlipressin acetate injections. Drug Substances manufactured using a Biological system using living organisms /cell lines through culturing or Recombinant DNA are termed as BIOLOGICALS, whereas Drug Products manufactured using already produced Biological Drug Substances (which no longer contain living organisms) are termed as Bio Pharmaceuticals. Dedicated facility is required for the manufacturing of BIOLOGICAL SUBSTANCES and certain other highly sensitizing compounds etc., but not for bio pharmaceuticals

All above-mentioned products manufactured at BF Biosciences are ***Bio-Pharmaceuticals****. These bio-pharmaceutical formulations are peptides that are easily denatured by temperature as well as pH changes, and thus can be eliminated from the facility through cleaning validation between production batches. These do not therefore bear contamination risks carried by penicillin-based antibiotics and other products requiring dedicated manufacturing facilities.*

Bio-Pharmaceuticals formulation and filling / Lyophilization (if required) is allowed as per WHO[1], Eudralex[2] and FDA[3] guide lines alongwith non-Bio pharmaceuticals on Campaign basis.

At BF Biosciences we intend to avail this allowance to manufacture non-Biologicals alongwith Bio-Pharmaceuticals on Campaign basis.

All required controls and systems are in place and are compliant to requirements for campaign-based manufacturing of bio- pharmaceuticals and non- biologicals."

REFERENCES

1) Annex 3 WHO good manufacturing practices for biological products Replacement of Annex 1 of WHO Technical Report Series, No. 822 Section 9, 13.

2) Eudra Lex The Rules Governing Medicinal Products in the European Union Volume 4EU guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Annex 2 Manufacture of Biological active substances and Medicinal Products for Human Use Section 8 g and 9

3) **FDA approves Bio Marin's manufacturing facility in Cork, Ireland** the FDA has approved Bio Marin Pharmaceutical's bulk biologics manufacturing plant, located in Cork, Ireland for production of the formulated bulk substance. Niamh Marriott (European Pharmaceutical Review)

1. It is pertinent to mention that M/s BF Biosciences Ltd. Lahore was previously granted registration for Omega injection (Omeprazole), Reg.No.067967, in same manufacturing facility vide letter no. F.15-7/2010-Reg-V (M-228) dated 10-12-2010.

   Later Central Licensing Board in 235th meeting while discussing the case of renewal of DML of M/s BF Bio Sciences, Lahore passed following orders in respect of Omega injection (Omeprazole), Reg.No.067967:-

"The Board was apprised by Licensing Division that the firm in its renewal application has mentioned that they have registration of omeprazole at biotech facility whereas panel in the inspection report has mentioned that the firm has dedicated biotech manufacturing facility only. The Board in this regard advised to refer the case of registration of Omega injection (Omeprazole),Reg.No.067967 to Drug Registration Board for its consideration and further necessary action accordingly".

Registration Board in its 245th meeting held on 29th & 30th September, 2014 decided to issue showcause for cancellation of registration of Omega injection (Omeprazole),Reg.No.067967, registered in the name of M/s BF Biosciences Ltd. Lahore.

Subsequently Omega injection (Omeprazole), Reg. No. 067967 of M/s BF Biosciences Ltd. Lahore, was de-registered vide letter no. F.15-2/2015-Reg-V(M-247)

Decision: Registration Board deliberated the matter in detail and decided to refer the case to Central Licensing Board for their comments on firm's request as CLB has granted for Biological parenteral section only".

Proceedings of Licensing Division

The firm has requested for grant of personal to present their case before the Central Licensing Board.

Proceedings and Decision of Central Licensing Board in 259th meeting

Dr. Ajmal Nasir, Director Technical and Mr. Baqar Hassan appeared before the Board on behalf of the firm and gave detailed presentation on subject matter of compaign manufacture. The Board considering the facts on the record and after thread bare deliberation decided to defer the case for detailed working before reaching a conclusive decision.

Proceedings and Decision of Central Licensing Board in 260th meeting

The Board deliberated on the subject matter and decided to constitute following Technical Evaluation Committee to submit its recommendations on subject matter within 30 days for consideration of the Board.

1.	Dr. Ikram-ul-Haque, Member Central Licensing Board.	Chairman
2.	Prof. Dr. Abdullah Dayo, Member Central Licensing Board.	Member
3.	Prof. Dr. Jamshaid Ali Khan, Member Central Licensing Board.	Member
4.	Syed Muied Ahmed, Member Central Licensing Board.	Member
5.	Director (PE&R), DRAP, Islamabad.	Member
6.	Director (Biologicals), DRAP, Islamabad.	Member
7.	Additional Director (Licensing), DRAP, Islamabad	Member/Coordinator

The Boardalso framed following TOR's for the purpose of working of Technical Evaluation Committee on the subject matter:

1. International Practices.
2. Process mechanism of Manufacturer.
3. Domestic Regulations.

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

Inspection of the firm was conducted on29-30th May, 2018 and letter for panel inspection was issued on 23rd May,2018. The panel has submitted its report as under;

Inspection Panel Members

1. Dr. Ikram-ul-Haque, Member Central Licensing Board.
2. Prof. Dr. Abdullah Dayo, Member Central Licensing Board.
3. Prof. Dr. Jamshaid Ali Khan, Member Central Licensing Board.
4. Syed Muied Ahmed, Member Central Licensing Board.
5. Additional Director (Licensing) DRAP, Isalmabad.
6. Director (PE&R), DRAP, Islamabad (could not participate due to urgent official assignments at office).
7. Director (Biologicals), DRAP, Islamabad (could not participate due to urgent official assignments at office).

Recommendations of the panel: -

The panel of experts discussed in detail all aspects of the subject matter in hand and recommended that:

1. Since WHO guidelines provide for campaign manufacture based on provisions as mentioned above and in compliance to National Regulation Authority (NRA) regulations. The local regulators are not comprehensive as required in WHO guidelines. Local regulation for campaign manufacture is as under:

   " In exceptional cases by emergency , the principle of campaign working in the same facility may be allowed by the Central Licensing Board provided that specific precautions are taken and the necessary validations are made."

   Since , no such circumstances/exceptional case of emergency exists , therefore the panel is of the view that campaign manufacture of non-biological products in existing biological facility may not be allowed.

2. BF Biosciences facility for manufacture of Biological products is purpose built in collaboration with Bago Group, Argentina and has god level of GMP compliance. The panel , therefore, recommends that BF Biosciences may be facilitated by processing pending applications for biological drugs on priority to overcome underutilization of the facility as country needs biological products as well. Moreover, BF Biosciences may be encouraged to bring more biological products to its portfolio.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered the report of the Technical Evaluation Committee and decided to regret the permission for manufacture of non-biological parental preparations at the facility of biological preparations at M/s BF Biosciences Limited, Lahore under Drug Manufacturing License no. 000655 (formulation) on campaign manufacture basis as no such circumstances /exceptional case of emergency exists as required under the rules. The same may be conveyed to Drug Registration Board as the case was referred by the said Board for comments. The Central Licensing Board however, considered the recommendations at Serial No. 2 of the Committee and also decided to forward the same to Drug Registration Board for consideration.

Case No.5 **M/S PHARMATEC PAKISTAN (PVT) LTD, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000024 (FORMULATION) FOR COMPAIGN MANUFACTURING OF HORMONES IN LIQUID AMPOULE (GENERAL) SECTION**

M/s Pharmatec Pakistan (Pvt) Ltd, Karachi has requested to run a manufacturing campaign for agreed quantity of hormonal range of products in Liquid Ampoule (General) Section for M/s OBS Pakistan (Pvt) Karachi on contract basis. The Drug Registration Board has also referred the request of M/s M/s OBS Pakistan (Pvt) Karachi for manufacture of hormonal products by M/s Pharmatec Pakistan (Pvt) Ltd, Karachi on contract basis in the facility of Parenteral Preparation (General).

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered the case and decided to regret the permission for manufacture of hormonal parenteral products at the facility of parenteral Preparations (General) at under Drug Manufacturing License no. 000024 (formulation)for M/s OBS Pakistan (Pvt) Karachi on campaign manufacture basis as no such circumstances /exceptional case of emergency exists as required under the rules. The same may be conveyed to Drug Registration Board as the case was referred by the said Board for comments.

Case No.6 **M/S MEDISURE LABORATORIES PAKISTAN (PVT) LTD, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000503 (FORMULATION) FOR COMPAIGN MANUFACTURING OF CIKABRIN POWDER IN DRY SYRUP (GENERAL) SECTION**

M/s Medisure Laboratories Pakistan (Pvt) Ltd, Karachi has requested for manufacturing of Cikabrin Powder an alternative brand of CicatrinPowder(which external preparation) in Dry Syrup (General) section on campaign manufacture basis.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered the case and decided to regret the permission for manufacture of Cikabrin Powder an external preparation in the Syrup Section (General) under Drug Manufacturing License no. 000503 (formulation) by M/s Medisure Laboratories Pakistan (Pvt) Ltd, Karachi on campaign manufacture basis as no such circumstances /exceptional case of emergency exists as required under the rules. The same may be conveyed to the applicant.

Case No.7 **M/S JINNAH PHARMACEUTICALS (PVT) LTD, MULTAN UNDER DRUG MANUFACTURING LICENSE NO. 000578 (FORMULATION) FOR COMPAIGN MANUFACTURING OF CLONAZEPAM IN EXISTING FACILITY**

M/s Jinnah Pharmaceuticals (Pvt) Ltd, Multan wherein the firm has stated that they have received quota allocation with import authorization on 21-10-2015. ADC cleared raw material Clonazepam 05 Kg and they have consumed 1.886 Kg. FID conducted inspection of the firm on 01-06-2016 and ordered to stop manufacturing of Psychotropic / Narcotic Drugs till dedicated section. According, to instruction of FID they got approval of layout plan of dedicated Psychotropic / Narcotic section from DRAP and the construction is in-progress. New Quota will applied only on completion of new dedicated Psychotropic / Narcotic section. Now the firm has requested for one time manufacturing of remaining quantity of allocated quota of Clonazepam 3.114 Kg in existing facility to complete market demand of their registered product Medyo (Clonazepam 0.5, 2mg) Tablets on campaign manufacturing basis in Tablet (General) area. They will insure cleaning validation of production machinery and will stop other manufacturing activity until consumption of stated raw material in minimum time period.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered the case and decided to regret the permission for manufacture of Psychotropic Tablets in Tablet (General) Section on campaign manufacture basis by M/s Jinnah

Pharmaceuticals (Pvt) Ltd, Multan as no such circumstances /exceptional case of emergency exists as required under the rules. The same may be conveyed to the applicant.

Item-V **CORRECTION IN THE MINUTES OF 254th MEETING**

Case No. 1 GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.

S. No	Name of the firm/ Type of License	Date of Inspection	Decision of CLB
1.	M/s City Pharmaceutical Laboratories, Plot No. 12-A, 1-5, Sector -5, New survey No. 276, Korangi Industrial Area, Karachi DML No. 000723 (Formulation)	**13-05-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.**15-06-2015 to 14-06-2020** While considering the case of M/s City Pharmaceutical Laboratories, Karachi for renewal of Drug Manufacturing Licence the Board observed that an other company in the name and style of "M/s Citi Pharma (Pvt) Ltd, Lahore " exists which resembles the name with each other with mere difference of one alphabet letter. The Board, therefore, suggested that legal opinion may be sought from Legal Affairs Division of Drug Regulatory Authority of Pakistan on the subject matter.

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

In the aforesaid minutes of Central Licensing Board, the tenure of the firm was inadvertently typed as15-06-2015 to 14-06-2020, License No. 000723by way of Formulation instead of 15-06-2016 to 14-06-2021.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered the case and decided to accede the correction in date of renewal of Drug Manufacture Licence No. 000723by way of Formulation in the name of M/s M/s City Pharmaceutical Laboratories, Plot No. 12-A, 1-5, Sector -5, New survey No. 276, Korangi Industrial Area, Karachi commencing on 15-06-2016 to and ending on 14-06-2021.

QUALITY ASSURANCE CASES (GMP NON-COMPLIANCE)

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

Case No. i: M/s Decent Pharma (Pvt) Ltd, Rawat, Rawalpindi

Background of the case:

Mr. Hassan Afzaal, Area FID, Islamabad conducted surprise inspection of the firm M/s Decent Pharma (Pvt) Ltd, Rawat, Rawalpindi on 30.01.2018 to verify GMP compliance / production activities of the firm.

2. The FID noticed critical observations, which may endanger the public health at large and need urgent attention and rectification. The observations include:-

Premises:-

i. Administration area requires improvement.

Documentation:-

ii. Important documents pertaining to the unit were not present including the inspection book.

Ware Houses:-

iii. Dispensing Hood installed in the raw material store, which requires further improvement.

iv. Packing material store and finished goods store provided; however the PMS has been shifted to the first floor without intimation and all the packaging material has been stored in an in appropriate manner.

v. Temperature/Humidity records require improvements.

Oral Liquid Syrup Section (Veterinary):-

vi. The firm was advised to strictly adhere to provisions of Schedule B-II. Improvement of Referencing of SOP was advised.

vii. The section is equipped with machines including; S.S Liquid Manufacturing Tank (500 L) the tank was not cleaned no labels were given.

viii. Storage Tank (500 L), Transfer pump was out of order, Liquid Filling Machine.

ix. The management is advised to improve the requisite machines.

x. The overall sanitation of the section was not up to mark. IPQ provided for Liquid Section has not been provided.

Oral Liquid (General) Veterinary:-

xi. Remaining portion of previous batch was present the tank was neither cleaned nor labeled.

xii. Storage Tanks, Transfer pump was out of order, Liquid Filling Machine but filling is performed manually.

xiii. Bottle Sealer (Manual), Bottle Blowing Machine, Filtration Assembly was not present; instead sieves were used for filtration.

xiv. The management is advised to improve machinery and compliance of GMP in true letter and spirit. General SOPs for routine working have been prepared.

xv. The walls, floor and roof found smooth require improved cleaning.

xvi. IPQ provided for Liquid Section has not been provided.

xvii. The management has installed HVAC of in the production area; however the validation of HVAC system is advised.

Oral Dry Powder Section (Veterinary):-

xviii. The walls, floor and roof require proper cleaning.
xix. The management is advised comply with GMP in true letter and spirit.

Powder (General) Veterinary:-

xx. The section has been equipped with the following machinery/ equipment i.e. Double Cone mixer, Sealing machine, Powder filling machine; however the filling is performed manually.
xxi. The walls, floor and roof require proper cleaning. Hygrometers and manometers are installed in the production area.
xxii. The management is advised comply with GMP in true letter and spirit.

Liquid Injection (General) Veterinary:-

xxiii. The air from HVAC of section has been controlled for particulate matter and microbial contamination by installation of HEPA filters; HEPA integrity tests were not found present.
xxiv. Epoxy floor and wall coating has been provided; improvement advised.
xxv. Double Distilled Water is not available as distillation assembly is not present.
xxvi. The management has been advised to further improve the Machinery for the section.
xxvii. The management is advised to perform media fill study after developing a rational schedule.

Penicillin (Powder) Veterinary:-

xxviii. FGS and QC are common.
xxix. Dispensing hood requires upgrading.
xxx. The section has been equipped with the following machinery/ equipment i.e. Double Cone mixer, Sealing machine, Powder filling is performed manually.
xxxi. The management is advised comply with GMP in true letter and spirit.

Quality Control Laboratory:-

xxxii. Overall assessment of quality control could not be made as the lab was under renovation/maintenance to treat the dampness of roof, however production activities were underway and the undersigned had no intimation of the same.
xxxiii. It is pertinent to mention that the microbiologist was also not present.
xxxiv. A record for BET was not found present as the test is not being performed.
xxxv. Particle Counter was not present.
xxxvi. No record for the classified production areas was found as tests have not been performed.
xxxvii. Computer connectivity of UV was not done so spectra could not be printed.
xxxviii. PAO/DOP test results for HEPA were not present.
xxxix. QC dead weights were present.
xl. Latest versions of official books are advised to be present in the lab.
xli. Record for method validation was not present.
xlii. Management is advised to switch to Compendial Methods wherever applicable.
xliii. LPC and TOC are not present.

Action taken by DRAP: Accordinglyshowcause notice / suspension of production activities was issued to the firm on 23.02.2018. The area FID was also directed to ensure the delivery of this order and compliance of orders in its true letter and spirit.

Reply by the firm: The firm vide letter Ref.# DP/QA-01 dated 06.03.2018 informed that they have suspended production activities in all sections and they are continuously working on the improvements advised by FID, Islamabad during the surprise visit on 30.01.2018. They will immediately inform the DRAP when the observations noted are rectified.

The firm vide letter Ref # DP/QA-02 dated 30.03.2018 informed that they have rectified the observations noted by FID. They requested to fix a schedule to visit the premises.

Proceedings of the 260th Meeting of CLB

Mr. Ghulam Jilani, CEO along with Mr. Sheraz Khan, production incharge of the firm M/s Decent Pharma, Rawat appeared before the board for personnel hearing. The Central Licensing Board decided as under:-

Decision of the 260th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and compliance report of the firm, CLB decided to:-

i. *Conduct GMP inspection of the firm* M/s Decent Pharma, Rawat*by the following panel of experts:-*

- *Prof. Dr. Muhammad Usman, member CLB.*
- *Mr. Abdul SattarSohrani, DD, QC.*
- *Area Federal Inspector of Drugs, Islamabad*

ii. *Production of the firm shall remain suspended till recommendation by panel and subsequent approval by CLB.*

iii. *The panel shall submit detail inspection report including rectification status of the observations noted by the FID in its report dated 30.01.2018, with clear and candid recommendations.*

Updated Status:

Decision of the 260th meeting of CLB was conveyed to the firm M/s Decent Pharma, Rawaton 11.05.2018 after approval of the minutes of the meeting.

In compliance to decision of 260th Meeting of CLB the panel conducted inspection of the firm on 31.05.2018 & 07.06.2018 and forward the report to Division of QA&LT on 11.06.2018. The panel submitted detailed inspection report as under:-

S#	Observations noticed on 29.01.2018	Panel inspection conducted on 31.05.2018 & 07.06.2018
1	**Premises:-** Administration area requires improvement.	Verified
2	**Documentation:-** Important documents pertaining to the unit were not present including the inspection book.	Verified
3	**Ware Houses:-** Dispensing Hood installed in the raw material store, which requires further improvement. Packing material store and finished goods store provided; however the PMS has been shifted to the first floor without intimation and all the packaging material has been stored in an in appropriate manner. Temperature/Humidity records require improvements.	Verified and further advice given to provide digital recording support.
4	**Oral Liquid Syrup Section (Veterinary):-** The firm was advised to strictly adhere to provisions of Schedule B-II. Improvement of Referencing of SOP was advised. The section is equipped with machines including; S.S Liquid Manufacturing Tank (500 L) the tank was not cleaned no labels were given. Storage Tank (500 L), Transfer pump was out of order, Liquid Filling Machine. The management is advised to improve the requisite machines. The overall sanitation of the section was not up to mark. IPQ provided for Liquid Section has not been provided.	Improvement in cGMP is a continues process; management has taken initiative for improvement
5	**Oral Liquid (General) Veterinary:-** Remaining portion of previous batch was present the tank was neither cleaned nor labeled. Storage Tanks, Transfer pump was out of order, Liquid Filling Machine but filling is performed manually. Bottle Sealer (Manual), Bottle Blowing Machine, Filtration Assembly was not present; instead sieves were used for filtration. The management is advised to improve machinery and compliance of GMP in true letter and spirit. General SOPs for routine working have been prepared. The walls, floor and roof found smooth require improved cleaning.	Verified

	IPQ provided for Liquid Section has not been provided. The management has installed HVAC of in the production area; however the validation of HVAC system is advised.	
6	**Oral Dry Powder Section (Veterinary):-** The walls, floor and roof require proper cleaning. The management is advised comply with GMP in true letter and spirit.	Verified
7	**Powder (General) Veterinary:-** The section has been equipped with the following machinery/ equipment i.e. Double Cone mixer, Sealing machine, Powder filling machine; however the filling is performed manually. The walls, floor and roof require proper cleaning. Hygrometers and manometers are installed in the production area. The management is advised comply with GMP in true letter and spirit.	Verified
8	**Liquid Injection (General) Veterinary:-** The air from HVAC of section has been controlled for particulate matter and microbial contamination by installation of HEPA filters; HEPA integrity tests were not found present. Epoxy floor and wall coating has been provided; improvement advised. Double Distilled Water is not available as distillation assembly is not present. The management has been advised to further improve the Machinery for the section. The management is advised to perform media fill study after developing a rational schedule.	Verified and documents have been reviewed.
9	**Penicillin (Powder) Veterinary:-** FGS and QC are common. Dispensing hood requires upgrading. The section has been equipped with the following machinery/ equipment i.e. Double Cone mixer, Sealing machine, Powder filling is performed manually. The management is advised comply with GMP in true letter and spirit.	Verified
10	**Quality Control Laboratory:-** Overall assessment of quality control could not be made as the lab was under renovation/maintenance to treat the dampness of roof, however production activities were underway and the undersigned had no intimation of the same.	Verified The management has agreed not to manufacture sterile products prior to the

	It is pertinent to mention that the microbiologist was also not present. A record for BET was not found present as the test is not being performed. Particle Counter was not present. No record for the classified production areas was found as tests have not been performed. Computer connectivity of UV was not done so spectra could not be printed. PAO/DOP test results for HEPA were not present. QC dead weights were present. Latest versions of official books are advised to be present in the lab. Record for method validation was not present. Management is advised to switch to Compendial Methods wherever applicable. LPC and TOC are not present.	installation of Distillation Assembly; during this tenure the management has been advised to conduct BET testing on market samples (post market surveillance) and retained samples.

Conclusion of the panel

"Keeping in view the above stated facts the panel is of the opinion that the approval for the resumption of production to M/s Decent Pharmaceuticals, Rawat, may be granted by the competent forum of Central Licensing Board subject to the following conditions:-

- The management has agreed not to manufacture sterile products prior to the installation of Distillation Assembly; during the tenure the management has been advised to conduct BET testing on market samples (post marketing surveillance) and regained samples.
- The management shall subject monthly progress report to the office of the concerned Federal Inspector of Drugs on the updated progress on all undertaking submitted by the firm.
- The management has also undertaken to purchase FTIR within 2 months.

The report is placed before the Board in compliance to the decision of the 260thmeeting of Central Licensing Board.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered the case and decided to allow resumption of production in oral dosage forms subject to verification of FTIR by Federal Inspector of Drugs, Islamabad, as per recommendations of the panel of experts constituted in 260th meeting of the Central Licensing Board. Production is sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production.

Case No. ii: - **M/S Hamaz Pharmaceuticals (Pvt) Ltd, Multan**

Background of the case

Syed Zia Husnain, FID, Lahore conducted inspection of company on 02.06.2016 to verify the GMP compliance and production activities. The FID noticed number of observations, which needs urgent attention and rectification. The observations include:-

- Store temperature is not satisfactory.
- Temperature of packaging material store is also not satisfactory.
- Segregated dispensing and storage not provided.
- De-dusting area not provided in R.M store.
- Color of quarantine strips is not yellow which should be rectified.

General / General Antibiotic Area

- Mixer is old and need to be re-placed.
- FB dryer is also rusted and need to be replaced.
- HVAC in packing room is required.
- Granulator and pour compression machines were also very old and required to be re-placed.

Cephalosporin Area

- Capsule filling machine needs to be changed.

Penicillin Area

- Sampling booth required to be installed.
- Dispensing also be done under HVAC system.
- Segregation of raw materials APIs and non-actives be done.
- Tablet penicillin area is not satisfactory.
- Only one single punch machine is place in same room where granulation was carried out.
- Revamp the tablet area before start of production in tablet Section.
- Double door hatch advised between bottle blowing area and production area.
- No working was going on.

Quality Assurance

- It needs further up-gradation.

Validation and Calibration

- Carry on the process validations and keep records.

Water Treatment

- Time to time check the quality of water and keep records in future as well.

The FID further concluded that:-

- Install air conditioners in raw material store and packing material store
- Develop de-dusting area for general raw material.
- Color of quarantine slips should be yellow rejected item area should be in lock and key.

- Install HVAC in paste preparation area of general tablet section.
- Change the old rusted granulators, compression machines and FB dryers.
- Change capsule filling and sealing machine in cephalosporin capsule section.
- Install digital polarimeter in QC laboratory.
- Make the FTIR operational on urgent basis.
- HVAC be installed in dispensing area of penicillin section.
- Re-vamp the tablet (penicillin) area immediately.
- Double door hatch be given in bottle blowing and production area of penicillin section.
- Give the supply of water in coating area of penicillin section.
- Production of steroidal must be stopped till segregated of dispensing / storage in line with current guidelines of DRAP.

Action Taken by DRAP:- Accordingly, a show cause notice was served to the firm for above mentioned violations on 24.06.2016.

Reply of the firm: - The firm vide letter No. Nil dated 09.07.2016 submitted detailed reply of showcause notice and requested for withdrawal of showcause notice.

Proceedings of the 249th Meeting of CLB

Mr. Adnan Zafar, Managing Director, Mr. Muhammad Ashraf, QCM and Mr. ShakeelAzhar, Director of the firm M/s Hamaz Pharmaceuticals (Pvt) Ltd, Multan appeared before the Board for personal hearing. Mr. Adnan Zafar informed to the Board that most of the observations has been rectified and purchase order for new equipments, as per direction, has been issued and will be installed within 2 weeks. Mr. Adnan Zafar further added that segregation for steriodal section has been completed, as per directions passed by the FID. Mr. Adnan Zafar informed to the Board that they are ready for inspection.

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, compliance report of the firm, the Board decided to:-

i. Conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members:-

   a. Dr. IkramulHaq, Member CLB.
   b. Director DTL, Multan.
   c. Syed Zia Husnain, Area FID, Lahore

ii. The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous observations and the current status, with clear and candid recommendations.

Get approval of change in layout plan, as advised by the FID, by the Licensing Division.

Decision

Decision of the 249th Meeting of CLB was conveyed to the firm and members of panel vide letter No.F.8-19/2016-QA (M-249-CLB)dated 03.10.2016.

Updated status

The panel constituted in 249th Meeting of CLB conducted inspection of the firm M/s Hamaz Pharma, Multan on 17.01.2018 and forwarded the detailed inspection report on 12.06.2018. The panel also submitted the report on approved Schedule B-II format and also submitted the detailed inspection report in tabulated form indicating the previous observations and current status. The panel concluded the report as under:-

"It is observed that the management has addressed most of the shortcomings, which were pointed out during the last inspection, which leads the panel of inspectors to the conclusions that the firm is presently operating at the satisfactory level of GMP compliance of M/s Hamaz Pharma, Multan hence it is advised to the management to continue their efforts to further upgrade their systems."

The case is placed before the Board in compliance to the 249th Meeting of CLB.

Decision of the Central Licensing Board in 264th meeting

The Central Licensing Board considered the case and decided to revoke the show cause notice in the light of the report of the panel of experts.

(Quality Control Cases)

Case No. 1: **Seizure of un registered Drugs under Section 18(1) of the Drug Act 1976. Raid on M/s. Mehmood Pharmacy, Metro habib Cash and Carry, Multan Road, Lahore.**

Proceeding of 259th Meeting of CLB

01. That Mr. AjmalSohail Asif, FID-Lahore, raided and inspected M/s. Mehmood Pharmacy, Metro habib Cash and Carry, Multan road, Lahore on 03.01.2017 at about 11:00 am along with FID Miss Ayesha Irfan, FID Mr. Zia Husnain and FID Mr. Abdul Rashid Sheikh.
02. That At the time of raid, Proprietor of the pharmacy namely Muhammad Zeeshan S/o Muhammad ArjumandMehmood and Qualified Person namely Ms. AmnaRiaz D/o Muhammad Riaz were absent. However, a person namely Haseeb Ahmed was present, who told to be the employee of the pharmacy.
03. That During inspection huge quantity of un-registered (smuggled/ unwarranted) drugs including different brands of sexual drugs and many other branded drugs were found at the pharmacy. Some of the quantities of these drugs were seized on form-2, under section 18 (1) (f) of the Drugs Act, 1976 as per following detail:

Sr.#	Names of therapeutic goods	Quantity
1.	Levitra 20mg tablets, Mfd. By Bayer AG Germany	06 packs × 04 tablets
2.	Viagra tablets 100mg, Mfd. By Pfizer France	01 pack × 04 tablets
3.	Cialis 20mg tablets, Mfd. By EliLilly UK	15 packs × 02 tablets
4.	Penegra tablets 100mg, Mfd. By Cadila Healthcare India	05 packs × 04 tablets
5.	Eltroxin tablets 50 mg, Mfd. By GSK Germany	18 packs
6.	Eltroxin tablets 100 mg, Mfd. By GSK Germany	06 packs
7.	Amaryl 03 mg tablets, Mfd. By Sanofi	07 packs × 30 tablets
8.	Amaryl 02 mg tablets, Mfd. By Sanofi	09 packs × 30 tablets
9.	Furolin tablets 30 mg, MFD. BY IASIS Pharma Cyprus	02 packs × 30 tablets
10.	Lipitor 20mg tablets, Mfd. By Pfizer, Istanbul, Turkey	02 packs × 30 tablets
11.	Lipitor 10mg tablets, Mfd. By Pfizer, Istanbul, Turkey	13 packs × 30 tablets
12.	Plaquenil 200 mg tablets, Mfd. By Sanofi Istanbul, Turkey	02 packs × 30 tablets
13.	Roaccutane capsule 20mg, Mfd. By Roche	01 pack × 30 tablets
14.	CellCept 500 mg capsule, Mfd. By Roche	01 pack × 50 capsules
15.	Emla Cream 5%, Mfd. By AstraZeneca UK	03 packs × 5 gm
16.	Centrum Silver tablets (Men), Mfd. By Pfizer Canada	05 packs
17.	Centrum Silver tablets (Adults), Mfd. By Pfizer USA	06 packs
18.	Centrum Silver tablets (Women), Mfd. By Pfizer USA	04 packs
19.	Centrum vlaue tablets (Adults), Mfd. By Pfizer USA	04 packs
20.	One A Day tablets (Men), Mfd. By Bayer USA	01 packs
21.	Infacol Oral Suspension, Mfd/Mktd. By Forest Labs UK	10 packs

04. That All of the above drugs were recovered and seized on Form-2 in the presence of Haseeb Ahmed, employee of the Pharmacy (Person present), Mr. Zia husnain FID, Mr. Abdul Rashid Sheikh FID and Mr. Faraz, Floor manager of Metro-Habib Cash & Carry. The witnesses were recorded on Form-2.

05. That After the seizure of above said drugs the premises comprising a room was sealed under section 18(1) (h) in front of above mentioned witnesses. The Copy of Form-2 along with sealed keys was handed over to Mr. Haseeb Ahmed S/o Tanvir Ahmed (Person present, employee of pharmacy).

06. That the Person present was asked to provide the invoices/warranties of above mentioned drugs or to explain their position by FID that why they were selling these drugs in violation of provisions of the DRAP Act, 2012.But he did not provide any document (invoices/ warranties) and said that owner may have the requisite documents.

07. That Accused persons were served a show cause notice vide office letter No. 6-9/2016-FID (F) dated 06-01-2017 and were directed to provide the invoices/ warranties of seized drugs if any and to explain their position that why they were stocking & selling un-registered drugs. They were also directed to attend the office of the FID for recording of statement regarding the case on 13-01-2017, but neither they did not submit any invoice / warranty regarding the seized drugs nor they attended the office of the undersigned. Two reminders were sent by FID dated 23-02-2017 and 28-03-2017 but no reply has been received.

08. That the FID requested to grant permission for safe custody of seized drugs and to keep the premises sealed till the decision of the case. Permission of safe custody of the stock and to keep the premises sealed till decision of the case was granted to the FID on 17th February, 2017. Meanwhile the accused filed a petition in the Honorable Drug Court for de-sealing of the premises. The Honorable Court ordered to de-seal the premises on 11-01-2017, which was accordingly de-sealed on 17-01-2017.`

09. Findings:

The FID Lahore requested that either the permission for prosecution of the accused person may be granted or if Honorable Board requires further investigation in the case permission for lodging FIR against the accused persons may be granted as the accused persons have nothing to say in their defense and were involved in the stocking and selling of unregistered/ unwarranted drugs. Since sale and storage of Un- registered/ Unwarranted drugs is prohibited under Section A(1) (a) & A (1) (i) of Schedule-II of the DRAP Act, 2012 read with Section 23 of the Drug Act, 1976 punishable under Schedule-III of the DRAP Act 2012 read with section 27 of the Drug Act, 1976 and is cognizable offence under Section (1)(a) of Schedule-IV of the DRAP Act, 2012 read with Section 30(1)(a) of the Drug Act, 1976 as to the action to be taken in respect of contraventions of the Act as mentioned above.

10. Permission For FIR against the following accused persons may be granted to the FID Lahore For selling un registered drugs in violation to the Drug Act 1976 and DRAP Act 2012:-

i M/s Mehmood Pharmacy, through Mr. Muhammad Zeeshan (Proprietor) S/o Muhammad Arjumand Mahmood, M/s. Mehmood Pharmacy, Inside Metro Habib Cash and Carry, ThokarNiazBaig, Multan road, Lahore. Resident of house No.92 army Housing Scheme Defence, Lahore.

ii. Mr. Muhammad Zeeshan (Proprietor) S/o Muhammad Arjumand Mahmood, M/s. Mehmood Pharmacy, Inside Metro Habib Cash and Carry, Thokar NiazBaig, Multan road, Lahore. Resident of house No.92 army Housing Scheme Defence, Lahore.

ii. Mr. Matee Ur Rehman (Salesman) S/o Tanvir Ahmed, Resident of House No. 254-C, SabzaZar Scheme, Lahore.

iii. Mr. Haseeb Ahmed (person present at the time of raid) S/o Tanvir Ahmed. Resident of House No. 254-C, SabzaZar Scheme, Lahore.

11. "Decision of the Case:-

The Central Licensing Board examined/evaluated the facts of the case in the light of investigations conducted by the FIDs and Quality Assurance Division and decided to grant permission for registration of FIR against the following accused persons:-

A. M/s Mehmood Pharmacy, through Mr. Muhammad Zeeshan (Proprietor) S/o Muhammad Arjumand Mahmood, M/s. Mehmood Pharmacy, Inside Metro Habib Cash and Carry, ThokarNiazBaig, Multan road, Lahore. Resident of house No.92 army Housing Scheme Defence, Lahore.

B. Mr. Muhammad Zeeshan (Proprietor) S/o Muhammad Arjumand Mahmood, M/s. Mehmood Pharmacy, Inside Metro Habib Cash and Carry, ThokarNiazBaig, Multan road, Lahore. Resident of house No.92 army Housing Scheme Defence, Lahore.

C. Mr. Matee Ur Rehman (Salesman) S/o Tanvir Ahmed, Resident of House No. 254-C, SabzaZar Scheme, Lahore.

D. Mr. Haseeb Ahmed (person present at the time of raid) S/o Tanvir Ahmed. Resident of House No. 254-C, SabzaZar Scheme, Lahore.

The accused persons are involved in contraventions of the provision of schedule-II and schedule-III of the DRAP Act 2012 as under:-

i. Sale of un registered drugs
ii. Sale of drugs without warranty.
iii. Manufacturing/import without authorization from the DRAP.

The offence is punishable under section 1 (a) and para (4) (contraventions of rules) of schedule-III of DRAP Act 2012.

12. The accused Mr. Muhammad Zeeshan (Proprietor)etc, filed a writ petition no. 211268 of 2018 in the Lahore High Court, Lahore.

13. The FID Lahore (L-VI) has submitted the Honorable Lahore High Court, Lahore orders dated 11.06.2018 passed in writ petitions 211268-18 + 211763-18 reproduced as under:

" This constitutional petition calls into question the letter dated 24-04-2018 whereby Secretary, Central Licensing Board Respondent No. 2 has requested the Federal Inspector of Drugs to file complaint for registration of FIR against the present petitioner.

2. The grouse of petitioner is that the said letter has been issued without affording opportunity of hearing to them. It is, therefore, requested that buy setting aside the letter dated 24-04-2018 Respondent No. 2 be directed to afford opportunity of hearing to the petitioner and thereafter pass a fresh order in accordance with law.

3. The above noted request is not opposed by the Assistant Director (Legal Affairs), DRAP

4. in view of above, letter dated 24-04-2018 is hereby set aside and consequently the matter shall be deemed to be pending before respondent no. 2, who shall decide the same afresh strictly in accordance with law, after affording opportunity of hearing to the petitioners; and through a well-reasoned speaking order.

5. Disposed of."

14. In compliance to the orders of the Honorable Court, the accused have called for personal hearing in the meeting.

Decision of the Central Licensing Board in 264th meeting

Mr. Waqar Ahmad Warraich, Authorized Attorney appeared before the CLB on behalf of the accused persons Mr. Arjumand Maqsood & Mr. Muhammad Zeeshan. He submitted request for adjournment of the cases because of the reason that his clients (Mr. Arjumand Maqsood & Mr. Muhammad Zeeshan) were abroad since 9 & 12th June, 2018, respectively. He also submitted photocopies of passports and tickets of the accused persons. He further stated that he has been telephonically informed that the accused will return on 21st & 28th July, 2018. The CLB after considering his request and evaluation of tickets & passports unanimously decided to adjourn the case till upcoming meeting of CLB after 28th July, 2018.

Case No. 2 Illegal/ Unauthorized Sale of Un-registered/ Alternative Medicine
Raid on M/s. Mehmood Pharmacy, Property No. S-36-R-2(D),/2, Chowk Mayo Hospital, Lahore.

Proceeding of 259th Meeting of CLB

FID Lahore-V, Mrs. Aisha Irfan visited the premises of M/s. Mehmood Pharmacy, Property No. S-36-R-2(D),/2,Chowk Mayo Hospital, Lahore on 30-01-2017 alongwith Mr. Abdul Rashid Sheikh, Federal Inspector Of Drugs, Lahore-I and Rana IhsanulHaq Athar, Assistant Drugs Controller, DRAP, Lahore and send the case vide letter No.1548/2017-DRAP (L-V) dated 31-01-2017.

02. FID informed that she seized the products at Sr. No. 01 being unregistered/ smuggled and the products at Sr. No. 02-05 are being sold without enlistment on Form-7 in violation to SRO 412(1)/2014, of Schedule-II of DRAP Act, 2012 and sections 23 and 27 of Drugs Act, 1976. Qualified person was also not present at the time of inspection. The Drugs were seized in the presence of Mr. SaqibMaqsood, (preson present)/ InchargeMehmood Pharmacy, chowk Mayo Hospital, Lahore.

Sr. No.	Name Of Products/ Batch No.	Date Of Mfg.	Date Of Exp.	Manufactured By	Quantity
01.	MyDacla 60 (DaclatasavirDihydrochloride) Tablets 60 mg/ MYDA 16020	09-2016	08-2018	M/s Natco Pharma Limited Kokjhar, Mirza Garru Bazar, District Kamrup Guwahati India.	28 Tablets
02.	Alopia 004	02-2016	03-2020	Nil	11 Packs
03.	Alopia Hair Food 004	02-2016	Use Within 03 Years	Nil	07 Packs
04.	Alopia Hair Food Plus 004	02-2016	Use Within 03 Years	Nil	02 Packs
05.	Alopia Hair Loss Solution 002	03-2016	Use Within 03 Years	M/s Primose 293 A-1, Gulberg-III, Lahore.	05 Packs

03. The FID requested to grant the permission to keep the seized stock in safe custody of drugs mentioned on Form-2 till decision of the case under Section 19(5) of the Drug Act, 1976. The permission for safe custody has been granted on 17th February, 2017.

04. FID Lahore-V, Mrs. Aisha Irfan forwarded the complete case vide reference letter No.5533/2017-DRAP (L-V) dated 26th April, 2017.

05. Findings:

FID recommended that the sale of Un-registered drugs prohibited under Section 23 of the Drugs Act, 1976 read with section A(1) (a) (vii) of Schedule-II of the DRAP Act, 2012 which is punishable under Section 27 of the Drugs Act, 1976 read with section (1) (a) of Schedule-III of the DRAP Act, 2012, therefore the case may be placed before the central Licensing Board.

06. 06. ***Permission For FIR against the following accused persons may be granted to the FID Lahore For selling un registered drugs in violation to the Drug Act 1976 and DRAP Act 2012***:-

i. M/s Mehmood Pharmacy through Mr. Arjumand maqsood.
ii. Mr. Saqib Maqsood, person present/ incharge Mehmood Pharmacy, R/O House No.07, street No.98, Kocha Mehar Faizan Main Bazar Mozang, Lahore.
ii. Muhammad Arjumand Maqsood R/o House No.92, Army Housing Society, Defense, Lahore.
iii. Ms. Anem Saeed Qualified person, R/o House No.92 Street No.117, Nisbat Road, Lahore.

06. "Decision of the Case:-

The Central Licensing Board examined/evaluated the facts of the case in the light of investigations conducted by the FIDs and Quality Assurance Division and decided to grant permission for registration of FIR against the following accused persons:-

i. M/s Mehmood Pharmacy through Mr. Arjumand Maqsood.
ii. Mr. SaqibMaqsood, person present/ incharge Mehmood Pharmacy, R/O House No.07, street No.98, Kocha Mehar Faizan Main Bazar Mozang, Lahore.
ii. Muhammad Arjumand Maqsood R/o House No.92, Army Housing Society, Defense, Lahore.
iii. Ms. Anem Saeed Qualified person, R/o House No.92 Street No.117, Nisbat Road, Lahore

The accused persons are involved in contraventions of the provision of schedule-II and schedule-III of the DRAP Act 2012 as under:-

i. Sale of un registered drugs/therapeutic goods
ii. Sale of drugs without warranty.
iii. Manufacturing/import without authorization from the DRAP.

The offence is punishable under section 1 (a) and para (4) (contraventions of rules) of schedule-III of DRAP Act 2012.

07. **The accused Mr. Muhammad Arjumand Maqsood etc, filed a writ petition no. 211763 of 2018 in the Lahore High Court, Lahore.**

08. **The FID Lahore (L-VI) has submitted the Honorable Lahore High Court, Lahore orders dated 11.06.2018 passed in writ petitions 211268-18 + 211763-18 reproduced as under:**

" This constitutional petition calls into question the letter dated 24-04-2018 whereby Secretary, Central Licensing Board Respondent No. 2 has requested the Federal Inspector of Drugs to file complaint for registration of FIR against the present petitioner.

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5. Disposed of."

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Decision of the Central Licensing Board in 264th meeting

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